THE DEVELOPMENT, VALIDATION AND TESTING OF A VITAL SIGNS MONITORING TOOL FOR EARLY IDENTIFICATION OF DETERIORATION IN ADULT SURGICAL PATIENTS

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ABSTRACT

Background: Patients often exhibit premonitory abnormalities in vital signs before an adverse clinical outcome. Patient survival may depend on the decisions of nurses to call for assistance. There is a paucity of published early warning scores (EWS) literature for general ward use from South Africa.

Methods: The 3-part single centre study was undertaken in six adult surgical wards in a 867-bed academic public hospital in Cape Town between 1 May and 31 July 2009 and between the same months in 2010. The study employed 1), consensus methods (survey by questionnaire N=52; nominal group and Delphi techniques N=14 participants) to design and validate a modified EWS observation chart for improving vital signs recordings; 2), retrospective record review (2009: estimated 600 records); and 3), a pragmatic parallel group cluster randomised controlled trial (2010: estimated review of 114 records; knowledge tests of estimated 122 nurses) for the recognition and management of the deteriorating patient.

Results: - ***Study One*** - The consensus derived and validated Cape Town MEWS observation chart comprised clinical indicators and seven physiological parameters. ***Study Two*** – Eleven (1.9%) of 585 patients who met inclusion criteria had died. Consecutive sampling of four records for each death (SAE) gave a control sample of 44 records (total N=55). Patients had few postoperative vital sign recordings (SAE: median=2; control: median=1). Nurses did not call for assistance for most (recoded) MEWS that should have triggered the callout algorithm (SAE: 81.2%; control: 92.4%). Factors significantly associated with death in the first 8 postoperative hours: age - 61 years or older (OR 14.2, CI 3.0 - 68.0); having two or more pre-existing comorbid conditions (OR 75.3, CI 3.7 – 1527.4); high or low systolic BP on admission (OR 7.2, CI 1.5 – 34.2); fast heart rate (OR 6.6, CI 1.4 – 30.0) and low systolic BP (OR 8.0, CI 1.9 – 33.1). The sensitivity and specificity of the MEWS for predicting death: heart rate, a cut point of 2 was 45.5% (95% CI 16.8–76.6) sensitive and 81.4% (66.6-91.6) specific; for systolic BP, the cut point of 1 showed 72.7% (95% CI 39.0–94.0) sensitivity and 77.3% (62.2-88.5) specificity. ***Study Three****:* There was a significant difference (Mann-Whitney U 178.00, Z=-2.62, p=0.01) between post-intervention knowledge test scores of nurses in the

intervention wards (n=25) who had training (median 60.8%, mean rank 30.88, IQR 50.0 (13 to 100)) and those in the control arm (n=25) (median 34.8%, mean rank 20.12, IQR 28.3 (13 to 65)) who had no training.

Significantly more patients in the intervention arm had recordings of respiratory rate (OR 62.5, CI 12.9-303.2, p<0.001), oxygen saturation (OR 5.5, CI 1.05-28.96, p=0.05), conscious level (OR 5.9 CI 1.62-21.84, p=0.004) and of all parameters (OR 20.1, CI 1.08-375.09, p=0.003) than those in the control arm. Despite training, there was a 93.5% non-response in the intervention arm and in the control arm this was 97.9%.

Conclusion and recommendations: Advancing age, an upper MEWS of 1 for heart rate and/or a low MEWS of 2 for blood pressure and the presence of co-morbid conditions significantly increased the risk of SAEs. Such patients need careful monitoring.

Training and the MEWS chart resulted in improved knowledge and patient monitoring but not in summoning assistance. Further research is needed to establish how this can best be achieved.

The sample of SAEs was too small to detect any influence of the programme on reduction of SAEs and a large multi-centre trial is recommended for this purpose.

EXECUTIVE SUMMARY

Background: There were 1,502 deaths over a 12 month period (2007/8) among 25,546 in-patient admissions in a 867-bed academic referral public hospital in Cape Town (the Hospital), an incidence rate of 6%. In-hospital deaths are defined as serious adverse events (SAEs). In this study SAEs refer to unplanned admission to ICU, cardiac arrest without a pre-existing not-for-resuscitation (NFR) order and unexpected death. Adverse events can also be classified by degree of preventability. Preventability pertinent to this study is related to omission of systematized and regular vital signs' monitoring or appropriate response to patients' unstable vital signs' records.

Aim: In a public hospital in South Africa, to develop, validate and test the impact of implementation of a modified early warning scoring (MEWS) system vital signs chart and training programme designed to improve hospital nurses' performance in early identification of postoperative clinical and physiological deterioration in adult patients.

Rationale: Patient safety, and in particular avoidable in-hospital morbidity and mortality, is an unexplored research area in developing countries that demands attention at this time in South Africa's history, a period characterized by an increased public awareness of patients' rights and escalating litigation within a transforming health care system.

Research questions:

1. What published MEWS is most appropriate for the South African context (Study One: section 3.5.3)?
2. How was the existing vital signs chart operationalised by nurses for the identification of postoperative early warning signs of clinical and physiological deterioration in patients at risk of serious adverse events (SAEs) in adult surgical wards in one public hospital in Cape Town (Study Two: Objective 1, section 4.6.2.1, 4.6.2.2)?
3. What was the association between the number of recorded vital signs on the current observation chart and patient outcomes in those at risk of a SAE (Study Two: Objective Two, section 4.6.3)?

4. What was the association between the clinical responses of nurses to recordings on the current chart and patient outcomes in those at risk of a SAE (Study Two: Objective One, section 4.6.2.3)?
5. Would the introduction of an early warning vital signs chart and a training programme make a difference to the monitoring, recording and clinical responses of nurses (Study Three, Objective 2a, section 5.6.3)?
6. Would the introduction of an early warning vital signs chart and a training programme make a difference to patient outcomes (Study Three, Objective 2b, section 5.6.4)?

A three-part study was designed to develop, validate and test the impact of implementation of a modified early warning scoring (MEWS) observation chart and training programme designed to improve hospital nurses' performance in early identification of postoperative clinical and physiological deterioration in adult ward patients.

Summary of Study One

Background: Existing vital signs charts in use at the research setting (The Hospital) have not been validated and do not incorporate a track and trigger system for detecting early signs of physiological deterioration.

Aim: To develop and validate an observation chart for nurses incorporating a modified early warning scoring (MEWS) system for physiological parameters for bedside monitoring on general wards from available published evidence and local criteria, to meet the needs of a public hospital in South Africa.

Objectives for developing and validating the MEWS system and the observation chart incorporating the MEWS for general wards:

- To identify best practice vital signs 'track' and 'trigger' interventions (MEWS cut points (thresholds), weighted trigger points and callout algorithms, pen-and-paper observation charts with clinical indicators and calling criteria) aimed at improved recording and consistent interpretation of vital sign recordings and early clinical responses, for use in the South African context, from available published evidence.

- To construct a preliminary prototype MEWS range of cut points (thresholds) for physiological parameters with corresponding weighted trigger points (0, upper and lower 1 to 3) from published evidence.
- To design a preliminary prototype observation chart incorporating the preliminary cut points for physiological parameters with corresponding weighted trigger points (0, upper and lower 1 to 3), callout algorithm and clinical indicators.
- To use the preliminary prototype MEWS observation chart to establish local criteria for, and to determine the construct and content validity of a final MEWS observation chart, callout algorithm and 'calling criteria', through expert opinion and to modify the preliminary instrument based on the outcome.
- To pilot test the chart to establish accuracy of recording vital signs on the MEWS observation chart.

Design: Descriptive analytical study for developing and validating the MEWS chart.

Setting: Six purposively sampled adult surgical wards in an 867-bed academic referral public hospital (The Hospital) in Cape Town.

Participants: Experts in clinical physiology (specialist nurses and doctors) and health sciences research, 'head' nurses from the 6 research wards; surgical nurse operational managers.

Methods and procedures: Survey by questionnaire of opinions on local criteria for a MEWS. Consensus methods (modified nominal group and Delphi) for agreement on baseline MEWS from questionnaire data. Pilot testing the MEWS observation chart using fictional scenarios and prospective datasets.

Main outcome measure: Development, validation and testing the accuracy of charting on the modified early warning scoring (MEWS) observation chart.

Results: Poor questionnaire response rate (28.8%, 15/52). Consensus derived validation of the Cape Town MEWS system and observation chart comprising clinical indicators and seven physiological parameters with partitioned cut points (thresholds) and corresponding weighted

trigger points (0, upper and lower 1 to 3) to guide clinical intervention. Consensus derived MEWS for respiratory rate, pulse rate, oxygen saturation, systolic blood pressure and urine output differed to some extent from existing MEWS, temperature ranges differed entirely and the 'alert, responds to voice, responds to pain and unresponsive' (AVPU) system for conscious level was incorporated unchanged. The small sample size (17 to 21 vital sign recordings on five patients) for testing accuracy of charting resulted in wide confidence intervals, which in one case was as low as 58.1% for Observer A and 69.6% for Observer B. Nevertheless, the proportion correct was satisfactory and met the *a priori* cut point of 90% with the exception of respiratory rate at 81.0% for Observer A (measured subjectively without instrumentation).

Implications: Consensus methods were effective in deriving and validating a standardised scoring system (MEWS) for interpreting signs of clinical deterioration and an observation chart incorporating the MEWS. In a resource constrained setting such as The Hospital the nominal group technique is recommended over a Delphi by electronic means. The effectiveness of the MEWS in recoding vital signs data on the existing chart into a MEWS format was tested in Study Two. A standardised scoring system for vital signs is of great importance in practice as this informs clinical decision-making when summoning assistance. The feasibility of using the MEWS as a single parameter system, aggregate weighted system or combined system was explored in Study Three when it was left to nurses on the intervention wards to use clinical judgement when calling for assistance for a single parameter or for an aggregate MEWS or for both.

Summary of Study Two

Background: Record review is one of the main methods for establishing the extent of adverse events (AEs) and is not disruptive to health services. AEs affect nearly one out of seven in-hospital patients in the USA and cause the death of more people annually than death from breast cancer or AIDS. It is therefore not surprising that the world's largest provider of health care (Medicare) routinely reviews case-notes to improve quality of care, particularly since record review has become the mainstay of quality assurance measures following the publication of the leading

Harvard Medical Practice Study of New York hospitals, the Colorado-Utah Study and the Quality in Australian Health Care Study.

Aim: To establish a baseline prior to the intervention described in the following chapters, the aim of this study was to examine records of patients who did or did not have a SAE (unexpected death, admission to ICU or cardiac arrest) to investigate the quality and quantity of nurses' recordings of postoperative vital signs data and responses to signs of deterioration. To interpret the appropriateness of responses, vital signs recordings were recoded into a score. A secondary aim was to explore the efficacy of these scores (the MEWS) in identifying clinical deterioration in preparation for evaluating the intervention in the next study.

Objectives:

Objective 1 – Examination of nurses' current practice of vital signs recording through retrospective record review

- To describe the number of physiological variables, range and proportion of times that ward nurses recorded these on existing observation charts as prescribed by medical doctors over an 8 hour period where 100% completeness will be rated Good; 95-99% Fair and <94% Poor.
- To describe the proportion of MEWS weighted trigger points (1 to 3) that were associated with a response by converting the recorded values of the patients' single parameter vital signs into a MEWS.

Objective 2 – Analysis of SAEs

- To assess the incidence of SAEs in postoperative patients on six purposively selected surgical wards;
- To explore any associations between SAEs and the parameters included in the Cape Town MEWS observation chart.

Objective 3 – Sensitivity and specificity of the MEWS

- To establish the sensitivity and specificity of the Cape Town MEWS weighted trigger points (0 and upper and lower 1 to 3) of each physiological parameter where sensitivity refers to the ability of the MEWS chart to identify patients with established

critical illness (SAEs) who trigger predetermined physiological thresholds and specificity means the ability of the MEWS chart not to trigger a response for inappropriate patients (without established critical illness who did not trigger).

- To establish the cut point of each parameter associated with SAEs.

Design: Descriptive, analytical study using a retrospective dataset.

Setting: Six surgical wards in an 867-bed academic referral public hospital in Cape Town.

Population: The sampling frame comprised all records of inpatients over the age of 14 years having had a general anaesthetic between 1 May and 31 July 2009 who were admitted to six wards purposively selected for inclusion in the study from the 13 specialist surgical wards at the Hospital. The six wards comprised two for general surgery, three for orthopaedic surgery and one combined ward for vascular and general abdominal surgery. Records were excluded from areas where patients are monitored closely such as trauma, high dependency and ICU wards. For each estimated SAE the control group consisted of the next four records drawn of a patient who did not have an SAE, until a sample of 60 (60/6 = 10 from each ward) was reached. In summary, the number of records to be screened was estimated to be 600 and the number of records to be analysed in depth was estimated to be 15 of patients with SAEs and 60 of control patients who did not experience an SAE.

Methods: Retrospective patient record review.

Main outcome measure: Assessment of the quality and quantity of vital signs recording in patients who did or did not have a SAE. A secondary outcome measure was to explore the efficacy of recoding recordings into a MEWS.

Results: *Sampling for SAEs*: In total, 585 records met inclusion criteria. Eleven patients had died in the six wards. Four deaths were preceded by cardio-respiratory arrest. No other SAE was recorded.

Objective 1: Differences in median recordings, total recordings and nurses' responses to MEWS that should have triggered, between the patients who died (SAE) (n=11) and who did not die (n=44) are reported:

Respiratory Rate: SAE group – n=0/11 patients; no SAE (control) group – n=1/44 (2%) and one recording, median[i]=0 recordings.

Heart rate: SAE group n=11 (100%) patients, median=7 recordings, 14/80 recordings should have triggered on the MEWS: nurses responded to four; Control: n=43/44 (98%) patients, median=6 recordings, 23/272 recordings should have triggered: no responses.

Oxygen saturation: SAE group n=6 (54.4%) patients, median=1 recording, 5/13 recordings should have triggered: nurses responded to three; Control: n=3 (6.8%) patients, median=0 recordings. Differences in the number of patients with recordings between the groups reached statistical significance (Chi-Square p=0.001) as did differences in the number of recordings (Mann-Whitney U p<0.001).

Systolic BP: 100% coverage for both groups (N=55). SAE group: median=9 recordings, 8/92 recordings should have triggered a callout: four responses which included one for a critical score of 3; Control: median=7 recordings, 27/305 recordings should have triggered a callout: five responses including 4/6 callouts for a critical score of 3.

Temperature: SAE group - n=11 (100%) patients, median=2 recordings, 1/19 should have triggered a callout: no responses; Control: n=42 (96%) patients, median=2 recordings, 21/94 recordings should have triggered a callout: three responses.

Conscious level: SAE group – n=4 (36%), median=0 recordings and 2/5 recordings should have triggered a callout and nurses responded to both; Control: n=30 (68%), median=1 recording and 14/30 recordings should have triggered a callout: no responses. Differences in the number of patients with recordings between the groups reached statistical significance (Chi-Square p=0.05).

Urine output: SAE group - n=9 (82%), median=2 recordings and 18/25 recordings should have triggered callouts: no responses; Control group: n=42 (96%), median=1 recording and 21/72 recordings should have triggered callouts: no responses.

Doctors prescribed monitoring of nonspecific 'regular' observations for 64% (7/11) of patients who died and for 59% (26/44) of patients who did not die. Not one patient in either group had recordings for all (7) parameters. Median recordings for seven parameters: SAE group n=2; No SAE group n=1. No patient had recordings for all seven parameters. Nurses appeared to respond to few recordings for scores that should have triggered (SAE group: 9/48, 18.8% = 81.2% non-response; control group 8/106, 7.6% = 92.4% non-response).

Objective 2: Being 61 years of age and older (OR 14.2, CI 3.0 - 68.0), having two or more pre-existing comorbid conditions (OR 75.3) and either a high or low systolic BP on admission (OR 7.2),

[i] Due to asymmetry of data the median was calculated as nurses performed a variable number of observations on patients in an 8-hour period.

a fast heart rate (OR 6.6), low systolic BP (OR 8.0) and oliguria (OR 4.1) in the first 8 hours following surgery were significantly associated with death.

Objective 3: At a cut-off point of 2, the sensitivity of the MEWS for heart rate was 45.5% (95% CI 16.8–76.6) and the specificity was 81.4% (66.6-91.6). At a cut-off point of 1, the sensitivity of the MEWS for systolic BP was 72.7% (95% CI, 39.0–94.0) and the specificity was 77.3% (62.2-88.5). No further interpretation of parameters was useful.

Implications: The MEWS was effective for recoding parameters and for interpreting severity of illness. The record review procedure was effective in establishing poor recording of parameters during the first eight postoperative hours and inappropriate responses of nurses to MEWS that should have triggered callouts. Poor recording and low responses also meant that the training programme in Study Three would have to include measures to ensure more effective recording of parameters and improved clinical decision-making in terms of summoning assistance. The significant association between mortality and patients having surgery at the age of 61 years and older, with two or more pre-existing comorbid conditions, a high or low systolic BP on admission, a fast pulse and low systolic BP following surgery meant that nurses in Study Three would have to monitor such patients carefully. A known sensitivity and specificity for MEWS cut points for heart rate and systolic BP would have to be included in the training in Study Three to limit SAEs.

Summary of Study Three

Background: MEWS systems have been incorporated into observation charts in the developed countries but not in developing countries to any great extent. The consensus derived Cape Town MEWS observation chart incorporated a predetermined range of cut points (thresholds) for physiological parameters with corresponding weighted trigger points (0, upper and lower 1 to 3). Aiken and colleagues' (1994) Mortality Model predictors and a revised model provided a framing construct for a discussion of study results. The study was evaluated using the official extension of the 2001 CONSORT statement for cluster trials and pragmatic approaches to trials.

Aim: To implement and explore the effectiveness of a local MEWS training programme and consensus derived MEWS observation chart through a cluster randomised parallel group clinical trial of intervention versus standard care and patient record review.

Objectives: Effectiveness of the interventions.

Objective 1 - To establish whether the MEWS training programme resulted in a significant difference in knowledge test scores:

- at individual and cluster level between pre- and post-intervention test scores of nurses in the intervention arm who received training;
- at individual and cluster level between pre- and post-intervention knowledge test scores of nurses in the control arm who received no training; and
- at group level between post-intervention knowledge test scores of nurses in the intervention and control arms.

Objective 2 - To establish whether the MEWS training programme and observation chart resulted in a change in practice by a significant difference in:

- the number of physiological variables, range and proportion of times that ward nurses recorded these on the MEWS chart and existing observation charts in patient records respectively as prescribed by medical doctors over an 8 hour period at cluster level between the intervention and control wards;
- nurses' responses to high and low threshold vital sign recordings on the existing charts and MEWS observation chart between intervention and control wards respectively using the MEWS as a benchmark at cluster level; and
- the proportion of postoperative patients developing in-hospital SAEs in control and intervention wards respectively . As the number of SAEs (deaths) was so small (section 5.6.1.2, Figure 5-5), this study was under-powered to detect any difference in SAE outcome. However, this information was gathered to inform sample size determination in possible larger future multi-site trials.

Design: Pragmatic cluster randomised parallel group clinical trial of intervention versus standard care.

Setting: Three cluster randomized intervention wards and three control wards in an 867-bed academic referral public hospital (The Hospital) in Cape Town.

Population: All nurses in full-time employment and patient case-notes meeting inclusion criteria in three intervention surgical wards and three control surgical wards.

Methods: Cluster sampling size estimation did not take design effect into consideration; analysis was by intention to treat; and clusters were randomised in unmatched batches.

Main outcome measures: to explore the effects of the MEWS training programme at cluster level and between intervention and control arms on:

1. pre- and post-intervention knowledge test scores of nurses who received training and those who received no training and enhancing the quality of measurement by independent marking;
2. the number of physiological variables recorded on the MEWS chart in intervention wards and on existing vital signs charts in control wards and enhancing the quality of recording in intervention wards by appointing MEWS project leaders from amongst the nurses.

Results: *Objective 1*: Analysis by intention-to-treat showed a significant difference (Mann-Whitney U 178.00, Z=-2.62, p=0.01) between post-intervention knowledge test scores of nurses in the intervention wards (n=25) who had training (median 60.8%, mean rank 30.88, IQR 50.0 (13 to 100)) and those in the control arm (n=25) (median 34.8%, mean rank 20.12, IQR 28.3 (13 to 65)) who had no training. Overall, registered professional nurses (RPNs) performed the best in the post-test (59.0%, mean rank=30.85), followed by registered staff nurses (RSNs) (49.3%, mean rank=24.17) and registered nursing auxiliaries (RNAs) (39.1%, mean rank=17.03) and this was statistically significant (Kruskal-Wallis Chi-square 8.691, p=0.013, df=2).

Objective 2: Analysis by intention-to-treat of recordings of parameters (recoded for MEWS) and nurses' responses to signs of deterioration:

Respiratory Rate: Intervention arm – n=27 (47%) patients had recordings and 21/73 should have triggered a MEWS callout algorithm: nurses did not respond to any; Control: n=2 (3.5%) patients. Differences in the number of patients with recordings between the groups reached statistical

significance (Chi-square p<0.001) as did differences in the number of recordings (Mann-Whitney U 893.00, Z=-5.42, p<0.001).

Heart rate: All patients in both trial arms had recordings. Intervention arm: 19/285 recordings should have triggered and nurses responded to one of seven with scores of 2 but not to a critical score of 3; Control: 19/346 recordings should have triggered a callout: nurses did not respond to any. Differences in the number of recordings between the groups reached statistical significance (Mann-Whitney U 1258.50, Z=-2.09, p=0.036).

Oxygen saturation: Intervention arm - n=7 (12.3%) patients and 1/10 recordings should have triggered a callout for a score of 2: nurses did not respond; Control: n=2 (3.5%) patients and one had a MEWS of 1: nurses did not respond.

Systolic BP: 100% coverage for both groups (N=114). Intervention arm: 25/325 recordings should have triggered a callout - nurses responded to three which included two responses to seven critical MEWS of 3; Control arm: 27/414 recordings should have triggered a callout: nurses responded to one of three critical MEWS of 3. Differences in the number of recordings between the groups reached statistical significance (Mann-Whitney U 1096.50, Z=-3.03, p=0.002).

Temperature: Intervention arm - n=55 (96.5%) patients and 29/134 recordings should have triggered a callout: nurses responded to two; Control arm: n=54 (94.7%) patients and 23/113 recordings should have triggered a callout - nurses did not respond to any which included a critical score of 3. Differences in the number of recordings between the groups reached statistical significance (Mann-Whitney U 1157.50, Z=2.742, p=0.006).

Conscious level: Intervention arm – n=45 (78.9%) patients and 9/134 recordings should have triggered a callout for a MEWS of 1 (reacting to voice/drowsy): nurses did not respond to any; Control arm – n=37 (64.9%) patients and 7/38 recordings should have triggered a callout for a MEWS of 1: nurses did not respond. Differences in the number of recordings between the groups reached statistical significance (Mann-Whitney U 890.00, Z=-4.44, p<0.001).

Urine output: Intervention arm – n=49 (86%) patients and 24/93 recordings for should have triggered a callout: nurses responded to one for a critical MEWS of 3; Control – n=51 (90%) patients and 16/87 recordings should have triggered a callout: nurses responded to one for a critical MEWS of 3.

Five (13.9%) patients in the intervention arm and none in the control arm had recordings for all parameters and this did not reach statistical significance. Median recordings for seven parameters: intervention arm n=2; control arm n=1. Doctors prescribed observations for four (7.0%) patients in the intervention arm and for 11 (19.3%) patients in the control arm but these did not reach statistical significance. Cut points for vital signs were prescribed for 1.8% of patients (2/114, one in each arm), meaning that for the majority of patients nurses were required to use clinical judgement in deciding to call for more skilled assistance.

Per protocol analysis indicated significantly more patients with the MEWS chart in the intervention arm having recordings for respiratory rate (OR 62.5, CI 12.9-303.2, p<0.001), oxygen saturation (OR 5.5, CI 1.05-28.96, p=0.05), conscious level (OR 5.9 CI 1.62-21.84, p=0.004) and for all parameters (OR 20.1, CI 1.08-375.09, p=0.003) than for those with the existing observation chart in the control arm.

Implications: A training programme for nurses for the detection of early signs of clinical deterioration and a MEWS chart can make a significant difference to knowledge, and to the practice of recording certain vital signs and also the recording of all seven parameters. Although Registered Professional Nurses achieved the highest test scores, the monitoring of vital signs was undertaken by Registered Nursing Auxiliaries, the least qualified category who achieved the lowest scores. This has serious implications for patient safety. Further research is needed to establish the effectiveness of a MEWS training programme and MEWS observation chart on nurses' responses to scores that trigger the callout algorithm.

DECLARATION

I declare that this thesis, entitled: **The development, validation and testing of a vital signs monitoring tool for early identification of deterioration in adult surgical patients**, which I hereby submit for the degree of Doctor of Philosophy (Nursing) at the University of Cape Town, is my own work and has not previously been submitted by me for a degree at another university.

Name (Printed): UNA KYRIACOS

Researcher's Signature: Signed by candidate

Date: 25 August 2011

Key Terms

Adverse events, patient safety, deterioration, early warning scoring systems, track and trigger systems, early warning sign training programmes.

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DEDICATION

To Fotios

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Rosie and Marvin for reminding me that this study is not about me – it is for all patients… and so,

To all our patients, thank you.

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ABBREVIATIONS

AE – adverse event

AVPU – alert, responding to voice, responding to pain, unresponsive

AWTTS – aggregated weighted track and trigger system

CVI - index of content validity

CCOT/S – critical care outreach team/service

ED – emergency department

EWS – early warning score

EWSS – early warning scoring system

GCS – Glasgow coma scale

HDU – high dependency unit

ICU – intensive care unit

MET – medical emergency team

MEWS – modified early warning score

MEWSS – modified early warning scoring system

MPTTS – multiple-parameter track and trigger system

NGT – nominal group technique

NFR – not for resuscitation

PART – patient at risk team

PDA – personal digital assistant

RAND – not for profit research organization in the USA

RNA - Registered Nursing Auxiliary

RPN – Registered Professional Nurse

RRS/T – rapid response system/team

RSN - Registered Staff Nurse

SAE – serious adverse event

SEWS – standardized early warning scoring system

SPTTS – single-parameter track and trigger system

TEWS- triage early warning score

TTS – track and trigger system

OPERATIONAL DEFINITIONS

Accuracy of charting: refers to ascribing and recording (transcribing) physiological parameters in the correct partition (serving as the 'gold standard') on the MEWS observation chart. It is threatened by systematic error (bias) contributed by the observer, the subject (patient) and the instrument.[1]

Accuracy of calculating a modified early warning score (MEWS): refers to correct arithmetic addition of weighted trigger points (0, upper and lower 1 to 3) for each physiological parameter to arrive at a total (aggregated) score where there is a true MEWS (serving as the 'gold standard').

Adverse event: an injury or event that is due to health care management rather than to underlying disease that results in prolonged hospitalization or some disability.[1-5]

Aggregated MEWS: is the total score obtained by adding the weighted trigger points (0, upper and lower 1 to 3) for each physiological parameter.

Calling criteria: activate a rapid response system when one or more routinely measured physiological variables fall within an extremely abnormal range.[2, 3]

Cardiac/respiratory arrest: the complete cessation of a heart beat or breathing or both that may or may not respond to attempts at resuscitation.

Clinical deterioration: refers to subjective, subtle changes in a patients' colour or mood assessed by touching, observing, listening, feeling or sensing, and intuitive knowing.

Completeness of records refers to the quality of the following records:

- postoperative instructions by medical doctors concerning the frequency of monitoring specific vital signs for a specific period of time;
- the number of vital signs recorded by nurses on the observation chart;
- nursing progress notes that capture the patient's postoperative recovery to discharge or the development of a SAE and the outcome;

- operating room registers for tracing the administration of a general anaesthetic to patients, and
- hospital database for the number of days in hospital from admission to discharge or death.

Critical care outreach team/service: a team consisting of dedicated critical care trained and experienced nurses who respond to referrals from all areas of a hospital.[4]

Cut points: refer to the MEWS system characterized by a range of thresholds for each physiological parameter (for example respiratory rate range of 15-20).

Early warning scoring (EWS) system (EWSS): a simple scoring system (algorithm) used at general ward level based on careful routine physiological measurement of heart rate, blood pressure, respiratory rate, temperature and conscious level (AVPU scale); for recognition of clinical and physiological deterioration[5-8] based on the allocation of 'points' (0='normal', upper and lower score of 1-3), the calculation of a total 'score' and the designation of an agreed 'trigger' level"[9] first described by Morgan et al. (1997)[10] and later classified as aggregate weighted track and trigger systems (AWTTs), single- and multiple-parameter TTS and combination systems.[11]

Glasgow coma scale: a clinical tool used to assess the degree of consciousness and neurological functioning – and therefore severity of brain injury by testing motor responsiveness, verbal acuity, and eye opening.

Interobserver/interobserver reliability of the MEWS observation chart: a measurement of the level of agreement between two observers on the categorization of a recorded physiological parameter.

Medical emergency team: an Australian system first described in 1995 comprising a medical-led team summoned to hospital wards for deteriorating patients for example having a range of specific conditions (pulmonary oedema), physiological abnormalities (pulse rate <40 or >120 beats min^{-1}) and when urgent help is required at any time.[12]

Modified early warning scoring (MEWS) system: as for EWS but modified to include urine output and oxygen saturation (SPO_2).

Near miss/close call: "any patient safety incident that had the potential to cause harm but was prevented, resulting in no harm to patients …" (NHS NPSA, 2004:97).[13]

Observation set: recordings of one or more physiological parameters at one time.[14]

Patient safety: freedom from urgent and unanticipated admission to an intensive care unit (ICU), avoidable in-hospital cardiac arrest or death,[3] caused by human error of omission, that is, failure of cognitive function to synthesise, decide and/or act on available information (adapted from Wilson, Harrison, Gibberd & Hamilton, 1999).[15]

Physiological deterioration: changes in respiratory rate, heart rate, systolic blood pressure, temperature, conscious level, urine output and oxygen saturation.

Positive predictive value: the proportion of patients with established critical illness (serious adverse events) who correctly trigger[16] actions because predetermined physiological thresholds are reached.

Rapid response system/team: established in the UK, similar to the Australian MET, to respond to calls to patients at risk of acute deterioration on general wards by assessing patients and providing advice and support to ward staff to facilitate early ICU admission when appropriate or to prevent unnecessary ICU admissions.[2]

Reliability: refers to the degree of intra- and interobserver variability[17, 18] relative to the error[19] and in this context relates to an estimation[20] of consistency in both 'accuracy of charting' (see definition above) and consistency in repetition which is dealt with using inter-rater reliability (see definition above).

Reproducibility: relates to the agreement of test results with different operators.[21]

Sensitivity: the ability of the MEWS chart to identify patients who are deteriorating and require assessment (adapted from Cuthbertson, 2008)[22], that is, the proportion of patients with established critical illness (SAEs) who trigger[16] predetermined physiological thresholds.

Serious adverse event (SAE): an untoward occurrence that: (a) results in death; (b) is life-threatening; (c) requires prolongation of existing hospitalisation; (d) results in persistent or significant disability or incapacity;[23] results in avoidable in-hospital cardiac arrest without a pre-existing not-for-resuscitation (NFR) order ; and requires urgent and unanticipated admission to an intensive care unit (ICU).[3, 24] In the EWS literature SAE refers to deterioration in clinical status caused by human error, that is, failure to monitor patients' vital signs and/or failure of cognitive function to synthesise, decide and/or act on available information (adapted from Wilson, Harrison, Gibberd & Hamilton, 1999).[15]

Specificity: the ability of the MEWS chart not to trigger a response for inappropriate patients who are not deteriorating (adapted from Cuthbertson, 2008)[25]; the proportion of patients without established critical illness who did not trigger.[22]

Tracking: refers to periodic observation, monitoring and recording of selected basic vital signs.

Triggers: refer to predetermined criteria for basic vital signs that alert staff to request assistance from more experienced staff in the event that a patient presents with deranged clinical and physiological variables.

Track and trigger system: "a method of using physiological scoring to trigger action. Early warning scoring systems are based upon the allocation of 'points' to physiological observations, the calculation of a total 'score' and the designation of an agreed 'trigger' level".[9]

Unexpected deaths: all deaths without a pre-existing NFR order, including those with a preceding cardiac arrest[26] confirmed by the absence of a heart beat and breathing after attempts at resuscitation.

Unplanned ICU admission: any unscheduled admission to the ICU from a general ward.[26]

Validated MEWS: refers to published evidence of early warning signs of deterioration in a physiological parameter that is associated with in-hospital death.

Validity: Data tools have validity when they measure what they are intended to measure.[27] In this study validity refers to a unified view of validity comprising construct validity and two further aspects of construct validity, namely criterion and content validity,[18, 28-30] traditionally treated as compartmentalized aspects of validity.[28] For the sake of completeness each aspect of validity is defined:

- construct validity[28-30] means the *evidential* basis of test interpretation[28 18] that is, its ability to measure the variables or constructs that it proposes to measure;
- criterion validity refers to the degree to which a new instrument approximates the scores given by a previously developed one, which is regarded as a 'gold standard'.[18] The concept is associated with predictive validity.[1]
- content validity means that the assessment represents all aspects of the phenomenon under study.[1]

Vital signs monitoring tool: refers to a patient's observation chart used for monitoring physiological and clinical changes to alert clinicians to approaching deterioration.

Weighted trigger point: refers to the MEWS system characterized by points allocated to disturbed physiological values in a weighted manner (0, upper and lower 1 to 3) to guide intervention[3, 5, 8, 31, 32] and to monitor the effectiveness of medical interventions.

1. INTRODUCTION

Patients often exhibit premonitory abnormalities in vital signs before an adverse clinical outcome[33-36] or serious adverse event (SAE) which may include in-hospital deaths.[3] It is the nurses' professional responsibility to understand the significance of patient observations and patient survival often depends on the decisions of nurses to call for assistance. An example of a preventable adverse event is failure to assess a patient's clinical status by monitoring basic vital signs and/or failure to respond appropriately when vital signs are unstable, referred to in the literature as human error of omission. SAEs are common and over a 12 month period (2007/8) there were 1,502 deaths among 25,546 in-patients in a 867-bed academic referral public hospital in Cape Town (the Hospital), an incidence rate of 6%. Although not recorded, it is likely that a number of these deaths may have been avoidable.

Patients who have had a general or regional anaesthetic are only returned to a general ward after the patient has recovered sufficiently from the pharmacological effects of the anaesthetic and when the vital signs and clinical condition are stable in the recovery room. Postoperative patients require frequent, skilful monitoring of vital signs in general wards to avoid SAEs. However, there is particular concern about infrequent and incomplete monitoring and recording, misinterpretation of clinical data, delays in reporting and little convincing evidence of appropriate interventions being carried out.[37] In response to the need to facilitate early recognition of deterioration, vital signs charts that incorporate early warning scoring systems have been designed to 'track' signs of deterioration and 'trigger' a rapid response.

1.1 Background and significance

Studies have shown that abnormal physiology is common on general hospital wards[33] and that there is documented evidence of clinical and physiological deterioration for six[34] to eight hours[35] before cardiopulmonary arrest. In these cases, arrest often occurs after a period of slow and progressive physiological deterioration that was not recognized or when hypoxaemia and

hypotension were not treated adequately.[36] Many surgical deaths may occur several days after an operation.[38]

In addition, skin tone, sweating, nausea and other clinical signs such as 'looking unwell' or nurses' intuitive assessment of the patient being 'just not right'[39] are important signs which need to be monitored regularly in patients to reduce avoidable, serious adverse events (SAEs) such as cardiac arrest, urgent and unanticipated admission to an intensive care unit (ICU) or even death. Early interventions have been found to affect patient outcomes favourably.[40]

It is the right of each patient to receive the best health care possible, particularly when they are in danger of developing SAEs[41] or even death. In addition to obvious ethical considerations, authorities in the developed world are concerned at the increasing number of claims for malpractice associated with SAEs.[42] Unanticipated ICU admission and in-hospital death[43] have medico-legal consequences if found to be preventable. In well resourced settings, vital signs charts often incorporate early warning scoring (EWS) systems and in certain hospitals in the UK nurses use electronic devices such as handheld personal digital assistants (PDAs) for direct entry of vital signs data, linked via wi-fi to a central computer.[44]

1.1.1 Situation in South Africa

The situation with regard to EWS is less than ideal in South Africa. Vital signs charts used for monitoring adult patients in public hospital wards do not incorporate early warning 'tracking' systems, nor do they indicate normal values or physiological abnormalities or prompt a trigger if an abnormality is observed.[45] This means that early warning signs of physiological deterioration (changes in respiratory rate, heart rate, systolic blood pressure, temperature, conscious level and urine output) may not be identified. Non-recognition of deterioration in clinical status has implications for patient survival and seriously violates principles of professional practice as patient survival may depend on the decisions of nurses to call for assistance. Effective clinical decision-making is associated with knowledge and understanding[27] and in South Africa this is dependent on the level of nursing qualification.[46] Failure to adequately monitor a patient's condition also has legal implications. The South African Patients Charter,[47] Batho Pele Principles[48] and Bill of Rights[49] advocate public awareness of patients' rights and litigation.

1.1.2 Nursing structure

The mandate of the South African Nursing Council (SANC 2004:9) is to "create and maintain an environment that fosters safety, compassion and caring"[50] under the direct and indirect supervision and care of the registered professional nurse (RPN).

Currently in South Africa there is a dire shortage of RPNs[51] and as a result, patient monitoring responsibilities are delegated to registered staff nurses (RSNs) and registered nursing auxiliaries (RNAs), who may not have an appropriate level of scientific educational preparation to interpret the significance of signs of clinical and physiological deterioration. Patient safety is at stake when registered professional nurses (RPNs) are not in sufficient supply to provide the level of care required for safe practice and higher nurse-patient staffing ratios are associated with reduction in in-hospital cardiac arrest rates, shock and death.[36] The scope of practice of these categories of nurses, and therefore the level of educational preparation, is for basic nursing practice and elementary nursing practice respectively[50] and does not include the interpretation of data. It does, however, include reporting abnormal readings to the RPN. Only two studies concerning the nursing care of critically ill patients on South African general wards were located by the researcher.[52, 53]

1.1.3 Possible methods of addressing the South African problem

Education and training should be provided to ensure that nurses caring for the acutely ill patient on general wards have competence in measuring, interpreting, recording and responding promptly and appropriately to signs of deterioration, and these competencies should be assessed. A study undertaken by the researcher and others[54] explored the contribution of bioscience education programmes to nurses' clinical practice, their understanding of the rationale for practice, and their perceptions of their continuing professional development needs. Nurses reported that the key to teaching and learning in this area is bridging the theory-practice gap by relevant examples, particularly in pivotal areas such as observation of vital signs. An earlier study has shown that using bioscience knowledge improved practice in 45 nurses and directly saved seven lives.[55]

In this study SAEs refer to unplanned admission to ICU, cardiac arrest without a pre-existing not-for-resuscitation (NFR) order and unexpected death.[3, 56] It is intended that this study will contribute new knowledge to scant published data on the association between the quality and frequency of vital signs monitoring and in-hospital morbidity and mortality in a developing country. The study will investigate nursing's existing epistemology and praxis in the area of patient safety specifically in the area of vital sign monitoring.

1.2 Problem statement

The effectiveness of the current vital signs chart in enabling nurses to identify postoperative early warning signs of clinical and physiological deterioration in patients at risk of serious adverse events (SAEs) in adult surgical wards has not been studied in South Africa. It has furthermore not been established whether there is an association between the degree of completeness of recorded vital signs and patient outcomes in those at risk of a SAE and whether there is an association between the recorded values of basic vital signs and the clinical responses of nurses to patients at risk of a SAE. It is possible that performance of nurses in this respect could be improved through the introduction of a suitable monitoring system and improved training, but this hypothesis needs to be empirically investigated.

1.3 Research questions

In light of the above, the following questions were addressed by the study:

1. What published MEWS is most appropriate for the South African context (Study One: section 3.5.3)?
2. How was the existing vital signs chart operationalised by nurses for the identification of postoperative early warning signs of clinical and physiological deterioration in patients at risk of serious adverse events (SAEs) in adult surgical wards in one public hospital in Cape Town (Study Two: Objective 1, section 4.6.2.1, 4.6.2.2)?

3. What was the association between the number of recorded vital signs on the current observation chart and patient outcomes in those at risk of a SAE (Study Two: Objective Two, section 4.6.3)?
4. What was the association between the clinical responses of nurses to recordings on the current chart and patient outcomes in those at risk of a SAE (Study Two: Objective One, section 4.6.2.3)?
5. Would the introduction of an early warning vital signs chart and a training programme make a difference to the monitoring, recording and clinical responses of nurses (Study Three, Objective 2a, section 5.6.3)?
6. Would the introduction of an early warning vital signs chart and a training programme make a difference to patient outcomes (Study Three, Objective 2b, section 5.6.4)?

1.4 Aims and objectives

1.4.1 Overall aim of the study

To develop, validate and test the effectiveness of implementation in a public hospital of an early warning vital signs monitoring tool and training programme designed to improve hospital nurses' performance in early identification of postoperative clinical and physiological deterioration in adult patients. The aim of the study was achieved in three phases which were:

- The development and validation of the MEWS chart;
- A retrospective review of prior practice and the impact of clinical responses on patient outcome;
- The implementation and testing of the impact of the MEWS chart.

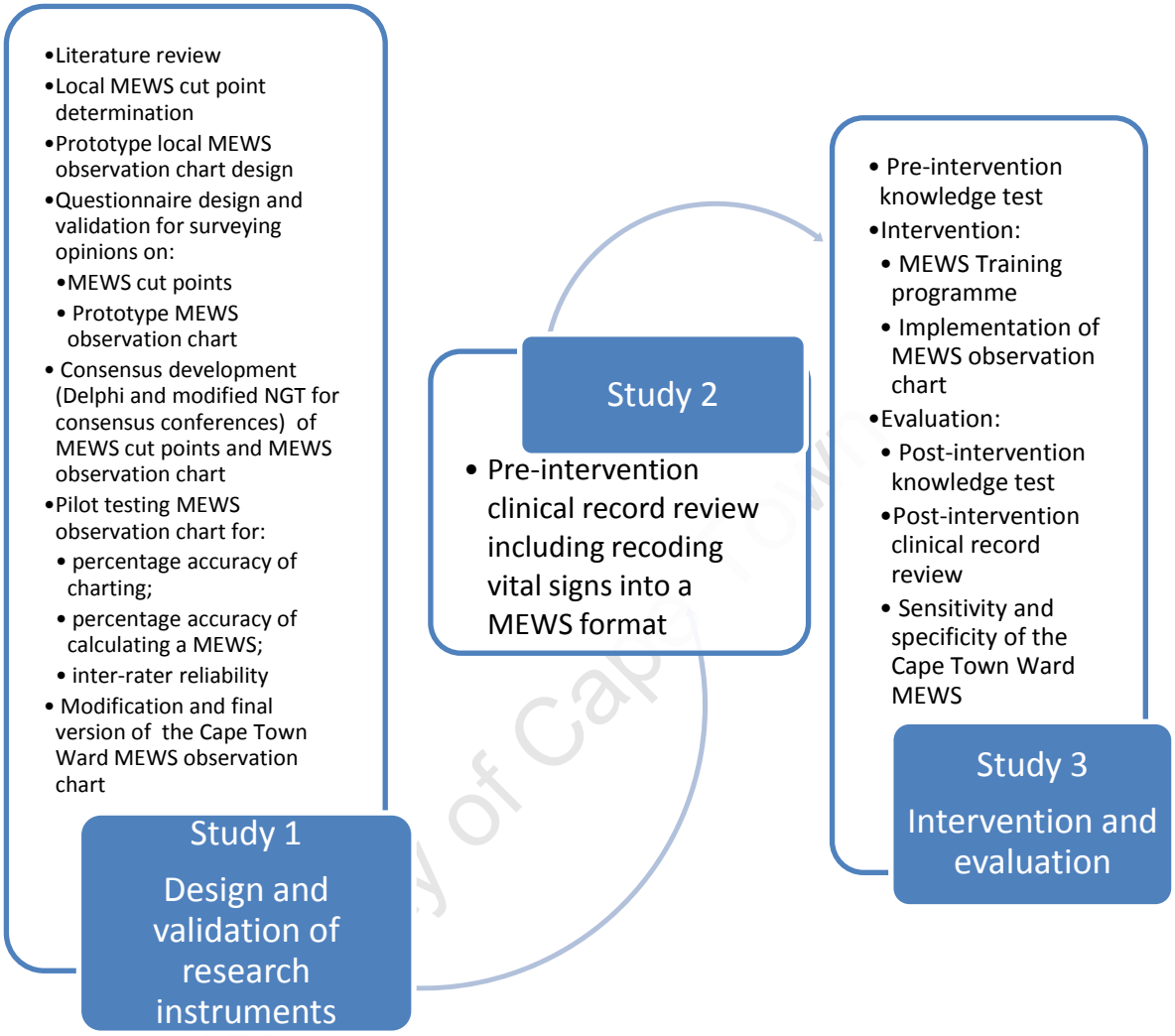


Figure 1-1: Diagram of the three-part study

Note on figure: MEWS denotes modified early warning score; NGT denotes nominal group technique

1.4.2 Study objectives

1.4.2.1 Study One: Developing and validating the MEWS and the observation chart incorporating the MEWS system

Aim: To develop and validate an observation chart for nurses incorporating a modified early warning scoring (MEWS) system for physiological parameters for bedside monitoring on general wards from available published evidence and local criteria, to meet the needs of a public hospital in South Africa.

Objectives:

- To identify best practice vital signs 'track' and 'trigger' interventions[i] (MEWS cut points (thresholds), weighted trigger points and callout algorithms, pen-and-paper observation charts with clinical indicators and calling criteria) aimed at improved recording and consistent interpretation of vital sign recordings and early clinical responses, for use in the South African context, from available published evidence.
- To construct a preliminary prototype MEWS range of cut points (thresholds) for physiological parameters with corresponding weighted trigger points (0, upper and lower 1 to 3) from published evidence.
- To design a preliminary prototype observation chart incorporating the preliminary cut points for physiological parameters with corresponding weighted trigger points (0, upper and lower 1 to 3), callout algorithm and clinical indicators.
- To use the preliminary prototype MEWS observation chart to establish local criteria for, and to determine the construct and content validity of a final MEWS observation chart, callout algorithm and 'calling criteria', through expert opinion and to modify the preliminary instrument based on the outcome.
- To pilot test the chart to establish accuracy of recording vital signs on the MEWS observation chart.

[i] See Operational Definitions for: track and trigger systems, MEWS, cut points, weighted trigger points, validity (construct and content), calling criteria, accuracy, aggregate weighted MEWS.

1.4.2.2 Study Two: Investigating current vital signs monitoring through retrospective record review

Aim: In order to establish a baseline prior to the intervention described in the following chapters, the aim of this study was to examine records of patients who did or did not have a SAE (unexpected death, admission to ICU or cardiac arrest) to investigate the quality and quantity of nurses' recordings of postoperative vital sign data and responses to signs of deterioration. A secondary aim was to recode the vital signs recordings into a MEWS and to explore the efficacy of a MEWS in identifying these events in preparation for evaluating the intervention in the next study.

Objectives:

Objective 1 – Examination of nurses' current practice of vital signs recording through retrospective record review

- To describe the number of physiological variables, range and proportion of times that ward nurses recorded these on existing observation charts as prescribed by medical doctors over an 8 hour period where 100% completeness will be rated Good; 95-99% Fair and <94% Poor.
- To describe the proportion of MEWS weighted trigger points (1 to 3) that were associated with a response[ii] by converting the recorded values of the patients' single parameter vital signs into a MEWS.

Objective 2 – Analysis of SAEs

- To assess the incidence of SAEs in postoperative patients on six purposively selected surgical wards;
- To explore any associations between SAEs and the parameters included in the Cape Town MEWS observation chart.

[ii] Discussion of the appropriateness of the therapeutic interventions in response to abnormal scores was considered to be outside the remit of this study.

Objective 3 – Sensitivity and specificity of the MEWS

- To establish the sensitivity and specificity of the Cape Town MEWS weighted trigger points (0 and upper and lower 1 to 3) of each physiological parameter where sensitivity refers to the ability of the MEWS chart to identify patients with established critical illness (SAEs) who trigger predetermined physiological thresholds and specificity means the ability of the MEWS chart not to trigger a response for inappropriate patients (without established critical illness who did not trigger).
- To establish the cut point of each parameter associated with SAEs.

1.4.2.3 Study Three: Evaluation of the effectiveness of the intervention

Aim: To implement and explore the effectiveness of a local MEWS training programme and consensus derived MEWS observation chart through a cluster randomised parallel group clinical trial of intervention versus standard care and patient record review.

Objectives:

Objective 1 - To establish whether the MEWS training programme resulted in a significant difference in knowledge test scores:

- at individual and cluster level between pre- and post-intervention test scores of nurses in the intervention arm who received training;
- at individual and cluster level between pre- and post-intervention knowledge test scores of nurses in the control arm who received no training; and
- at group level between post-intervention knowledge test scores of nurses in the intervention and control arms.

Objective 2 - To establish whether the MEWS training programme and observation chart resulted in a change in practice by a significant difference in:

- the number of physiological variables, range and proportion of times that ward nurses recorded these on the MEWS chart and existing observation charts in patient records respectively as prescribed by medical doctors over an 8 hour period at cluster level between the intervention and control wards;

- nurses' responses to high and low threshold vital sign recordings on the existing charts and MEWS observation chart between intervention and control wards respectively using the MEWS as a benchmark at cluster level; and
- the proportion of postoperative patients developing in-hospital SAEs at cluster level in the intervention and control wards. As the study was likely to be underpowered in terms of impact on SAEs this section of the study was regarded as a feasibility for a larger multi-centre trial.

1.5 Research setting

The single centre research setting was a 867-bed academic public (government) hospital in Cape Town, South Africa (The Hospital Annual Report, 2007/8 unpublished) purposively selected out of two such hospitals as English was the dominant language. With Central Hospital status, it offers specialised (tertiary) and super-specialised (quarternary) level health care services including transplant surgery. From 2010 secondary level services were also provided. The Hospital serves as a referral centre for up to 560 000 patients a year from within and beyond the borders of South Africa, employing 3663 staff and is a training hospital for medical, nursing and allied health professionals. Nurses on university degree programmes, college diploma and hospital level certificate programmes are allocated to the Hospital for clinical experience, each with a defined scope of practice.[50] In the most recent report available (April 2007 – March 2008) there were 25 546 non-obstetric admissions and 1 502 deaths (5.9%) (Research setting Annual Report, 2007/8 unpublished).

The traditional 'cardiac arrest team' comprising ICU nurses and doctors, had been replaced by ward response teams more than two decades previously. There was no hospital-wide emergency response system such as 'calling criteria' (triggers) consisting of predefined thresholds for deterioration in physiological variables and no early warning scoring system in place on the general wards.

There was purposive sampling of six adult wards in the Department of General Surgery and its two sub-specialities, the Divisions of Vascular Surgery and Orthopaedic Surgery all of which admit

patients for scheduled and unscheduled surgery (described in section 1.5). Data for the six research wards for this period are presented in Table 1-1.

Table 1-1: Research ward statistics for the period April 2007 - March 2008

TYPE OF WARD	BED NUMBERS	ADMISSIONS	DEATHS
A. General surgery	15	1 307	20
B. General surgery	30	895	9
C. Combined vascular and general abdominal surgery	32	75	9
D. Orthopaedic surgery	28	911	5
E. Orthopaedic surgery	32	456	8
F. Orthopaedic surgery	16	1 485	12
GRAND TOTAL	153	5 129	63 (1.2%)

Study Two was undertaken in six surgical wards comprising: two general, one vascular/general and three orthopaedic all of which admit patients for scheduled and unscheduled surgery. For Study Three there was random selection of these six wards for three intervention and three control wards.

1.6 Location of the work

The hiatus between science theory and nursing practice is discussed elsewhere[57] in relation to the learning cycle.[58] The aim of this project is to narrow the gap between known risk factors for adverse events following surgery and nurse education and practice in vital signs monitoring, moving from reflective enquiry to knowledge[59] and practice.[60] The role of inquiry in improving or 'transforming problematic situations' should not be underestimated (Dewey 1938 p.491).[61]

All investigations are socially contingent processes, governed by social power to control the nature and direction of inquiry.[62, 63] However, those of a positivist or pragmatic tradition would concur with John Dewey regarding the 'indispensible place of experiment in inquiry' (1938 p.34). Consequently, the demands for scientific rigour in medicine/health care practice are compelling

professionals to base their care on firm, falsifiable evidence (the positivist traditions), and abandon inductive principles.[64] Strength of evidence for practice may be assessed according to defined criteria.[65]. Only double blind parallel group randomised controlled trials can provide this evidence.[66] However, involving human subjects as participants in the experimental process, as opposed to observation studies, poses both practical and conceptual challenges. The apparent dichotomy between the positivist approach required for quantitative research and symbolic interactionism, which underpins much of the social science tradition in work with human respondents[67], can be best reconciled by a pragmatic approach.

Wright-Mills (1959)[68] describes a conflict, rather than a dialectic, between the natural and social sciences. This underlying epistemological paradox may generate an unacceptable degree of tension not only for researchers, but also in the interpretation and validation of data. Combined with the eclectic cognizance required, this may be influencing nurse researchers in their selection of projects.[69] This study catapults the researcher into "the messy world of practice"[70] fraught with uncertainty. Praxis - what the nurse must do to limit adverse events in a clinical setting is informed by what is known and understood (epistemology) in becoming (ontology) competent.

In addition to intuitive knowing in nursing, Carper (1978)[71] describes personal, aesthetic and ethical knowing, in contrast to the objective, scientific evidence-based practice (EBP), criticized for a perceived disregard of pluralism[72], more suitable for nursing's holistic care paradigm.[73] "The current development of EBP simply does not 'fit' for nursing" (Hudson et al. 2008:412)[73]. A recent UK study[74] of 216 practising nurses' perspectives of EBP, surprisingly revealed that they rejected experimental studies[75] and systematic reviews[76, 77] as the most highly regarded hierarchy of evidence, instead, rating 'own past experience' at the top of the hierarchy of evidence. This approach is in stark contrast to the sentiment: "Nursing needs to separate the rhetoric of 'holism' and 'expertise' from the science of predictive validity, accuracy and competence in judgement and decision making".[78]

Clinical decision-making in nursing practice is well documented[39, 79-82] employing information-processing models, intuitive-humanist and multidimensional models for cue and pattern recognition in various settings including medical triage. Clinical decision-making involves

knowledge of the biosciences, knowing the patient and past experiences.[79] [39] Andrews and Waterman[83] found that nurses do not use medical terms confidently and therefore fear looking stupid or being undermined or ridiculed and this can lead to a delay in reporting signs of deterioration.

What is lacking is a theory to guide nursing's praxis-epistemological-ontological approach to prevention of in-hospital SAEs. This study will explore nurses' practice of documenting and interpreting patients' vital signs following a surgical intervention and their responses to early signs of clinical deterioration. As such, the study provides a platform for postdoctoral work in the development of a praxis-epistemological-ontological model for nursing in the area of patient safety practice.

1.7 Summary and significance

There is documented evidence of clinical and physiological deterioration on general hospital wards for six to eight hours before cardiopulmonary arrest, often occurring after a period of slow and progressive physiological deterioration. An unanticipated outcome may be admission to ICU or death. In developed countries, vital signs charts usually incorporate early warning scoring (EWS) systems for recognizing deterioration and calling for more skilled assistance. In a developing country such as South Africa there is published evidence of only one public hospital having used an observation monitoring chart for adult patients incorporating an early warning 'tracking' system. Non-recognition of deterioration in clinical status has implications for patient survival. This three-part single centre study has been designed to develop, validate and test such an early warning vital signs observation chart for hospital ward use.

This is the first documented study to use consensus methods and expert opinion for the derivation of a MEWS. In South Africa vital signs charts used for monitoring adult patients in public hospital wards do not incorporate early warning 'tracking' systems. Non-recognition of deterioration in clinical status has implications for patient survival and seriously violates principles of professional practice. Failure to adequately monitor a patient's condition also has legal

implications. It is hoped that the study will lead to the development of a validated and feasible tool for bedside monitoring on general hospital wards.

2. LITERATURE REVIEW

An invited paper on this chapter for a special edition on adverse events has been published[iii] (see Appendix 2.1).[84] To understand the impact of serious adverse events (SAEs), the epidemiology of SAEs will be examined. The needs of critically ill patients on general wards are then presented before a review of possible solutions to problems of infrequent monitoring, interpreting signs of deterioration and calling for assistance. Finally, methodological issues for improving the quality of patient safety research are discussed.

2.1 Introduction: the epidemiology of serious adverse events (SAEs)

A serious adverse event (SAE) is defined as an untoward occurrence that: results in death; is life-threatening; requires prolongation of existing hospitalisation; results in persistent or significant disability or incapacity;[23] results in avoidable in-hospital cardiac arrest without a pre-existing not-for-resuscitation (NFR) order; and requires urgent and unanticipated admission to an intensive care unit (ICU).[3, 24] In the early warning score (EWS) literature SAE refers to deterioration in clinical status caused by human error, that is, failure to monitor patients' vital signs and/or failure of cognitive function to synthesise, decide and/or act on available information (adapted from Wilson, Harrison, Gibberd & Hamilton, 1999). Adverse events (AEs) may be avoidable and can have serious consequences.

In a UK study more than half (54%) of the admissions to ICUs could have been prevented by closer monitoring of vital signs and improved care.[85] It was estimated that in Holland between 1482 and 2032 potentially preventable deaths occurred in hospitals in 2004.[86] Of 1,804 SAEs reported in the UK during 2005,[87] 576 deaths were deemed to be potentially avoidable and related to patient safety issues. Of these reported deaths, 425 occurred in acute/general hospitals, of which 64 deaths were associated with failure to recognize or respond to patient deterioration.[88] The consequences of AEs may not only be devastating for patients and their families, but are distressing for staff[89] as the psychological impact of failure has a demoralizing effect.[90] SAEs

[iii] Journal of Nursing Management (ISSN 0966-0429).

decrease public confidence[13] and authorities in the developed world are also concerned at the increasing number of claims for malpractice.[91]

In Australia nationwide, AEs with high preventability were estimated to account for 1.7 million (8%) of the total hospital bed days at a cost of Aus$4.7 billion per year.[92] The costs for clinical negligence claims in the UK NHS during 2008/09 amounted to £769 million[93] and 6,080 claims of clinical negligence were received. These findings are not unique to the UK NHS[94] and in the USA costs of preventable AEs are estimated at between US$17 and $29 billion annually.[95]

In a widely cited American study of clinical antecedents to in-hospital cardiac or respiratory arrest, conducted in 1987 over four days, 54 patients (84%) had documented observations of at least one behavioural or physiological change 8 hours before an arrest.[35]

2.1.1 Background: measuring vital signs

SAEs can be reduced by limiting human error,[15] for example by recognising early warning signs of clinical and physiological deterioration, and responding appropriately. As mentioned above, patients often exhibit premonitory abnormalities in vital signs before an adverse clinical outcome[33] and within six[34] to eight hours[35] of cardiac arrest particularly if hypoxaemia and hypotension were not treated adequately.[36] It is the nurses' professional responsibility to understand the significance of patient observations[50, 96, 97] and patient survival often depends on the decisions of nurses to call for assistance.[39]

A variety of vital signs monitoring tools that incorporate early warning scoring systems designed to 'track' signs of deterioration and 'trigger' a rapid response to improve patient safety have been introduced across the UK[97] and Australasia.[56, 98]

The five most important prognostic variables for catastrophic physiological deterioration are respiratory rate, systolic blood pressure, pulse rate, temperature and central nervous system status; in addition, urine output is an early indicator of vascular compromise.[99, 100] Studies have examined combinations of early signs for association with in-hospital death[5, 8, 22, 101, 102] including monitoring oxygen saturation (SPO_2).[102] Antecedent signs of deterioration vary between 84% (54/64),[35] 66% (99/150),[34] 51% (24/47)[103] and 34% (185/544)[104] of patients. Even so, these figures

have to be interpreted with caution as in one study[35] 23% (15/64) of patients were expected to die imminently as the result of underlying pathology. Patients who are not for resuscitation (NFR) may have greatly increased abnormal observations but they have been excluded from EWS studies as their observations are not usually recorded, whereas including such patients in EWS studies provides important epidemiological information[91] and allows for timely discussion with families.[6]

The incidence of AEs and negligence of staff in caring for hospitalized patients is receiving serious attention at national level in developed health care systems.[11, 42, 98] There is particular concern about infrequent and incomplete monitoring and recording,[105] misinterpretation of clinical data, delays in reporting and little convincing evidence of appropriate interventions being carried out.[37]

2.1.2 Evaluation of published literature

In this chapter the literature describing the development, validity and reliability testing and utility of EWS/MEWS systems (classified in Table 2-1), for a population of adult inpatients outside critical care areas was included if in English and if full texts were accessible to the researcher. Literature was searched for surgical wards in particular but with a poor result. An *a priori* decision was made to selectively use citations about validation of triage EWS systems. Triage and ward MEWS assessment tools both use scored physiological parameters for rapid tracking of critical illness but they differ as triage assessment includes mechanism of injury and mobility[106] not suited for ward settings.

Literature on medical emergency teams (METs), Critical Care Outreach Services (CCOS) and other such organizational systems was also excluded unless there was reporting on vital sign monitoring of ward patients. The focus of medical emergency teams is a centrally organized system of hospital-wide resuscitation for life-threatening emergencies (and assessment for emergencies that are not immediately life-threatening)[12, 107] and cut points for scores are therefore mostly late signs of deterioration[108] whereas the present study focuses on ward-based early warning track and trigger systems to prevent cardiorespiratory arrest requiring resuscitation.

EWS systems are classified according to the number of parameters that trigger a response (Table 2-1).

Table 2-1: Classification of EWS track and trigger systems

Glossary	Abbreviation	Definition
Aggregate weighted track and trigger systems	AWTTS	the trigger is achieving a previously agreed trigger threshold (for predefined extreme physiological parameters) with the total score [16]
Combination track and trigger systems	Combination TTSS	involve single- or multiple-parameter systems in combination with aggregate weighted scoring systems [16]
Multiple parameter track and trigger system	MPTTS	Two or more predefined extreme physiological or clinical parameters trigger for summoning skilled clinical assistance [16]
Single parameter track and trigger system	SPTTS	One predefined abnormal physiological or clinical parameter triggers for summoning skilled clinical assistance [16]

To ensure effective ways of searching for and storing a bibliography, a citation system was set up using Endnote® Windows™ Version X2 (Thomson 2008) as well as a search alert for keywords on the TDNET electronic journal portal. Searches covered the period 1998 to the present but included earlier primary research articles of particular relevance and frequently referenced citations concerning in-hospital morbidity and mortality due to negligence (1960's, 1970's, 1980's and early 1990's) and the publication of the first early warning score in 1997. Search results are presented in Table 2-2 and resulted in approximately 300 particularly useful citations.

Table 2-2: Database research results

Database/search engine	Keywords	Results	Number of relevant papers
MESH database/PubMed	Patient safety AND ward AND vital sign monitoring	5	3
	in-patient mortality AND adverse events	76	4
	Early warning sign systems	138	14
	physiological monitoring AND adverse events AND nursing	34	1
	physiological monitoring AND adverse events AND classification	55	0
EBSCO CINAHL database	monitoring physiological deterioration AND adults AND wards	0 but showing 68,639 references	Focus narrowed as listed below
	Post-operative AND vital sign assessment	202	2
	physiological deterioration	17	7
Google search engine	The same keywords but limited to the SA context and broadened to include theses and dissertations	7	7
Total		**534**	**38**

There is an absence of published EWS literature describing the use of consensus methods for the derivation and validation of cut points for EWS but not for medical emergency team 'calling criteria'.[109] There is a paucity of published literature on EWS training programmes, specifically concerning design and development, implementation process and evaluation with the exception of the 'Acute Life-threatening Events - Recognition and Treatment' (ALERT) course that originated in Portsmouth.[110] There is limited published literature on the factors impacting on implementation of EWS systems. The association between effective use of the EWS tools and educational level of nurses appears not to have been studied.

Key issues addressed in the EWS literature are outlined in the next section.

2.1.3 Key issues

- Problems associated with having critically ill patients on general wards:
    - monitoring of vital signs;
    - interpreting signs of clinical deterioration;
    - calling for skilled clinical assistance.
- Solutions:
    - Patient safety: international, national and local organizational imperatives.
    - Improving the quality of AE research.
    - Introduction of EWS systems:
        - History, benefits and limitations;
        - Evaluation of validity and reliability of EWS and performance.

2.2 Problems associated with having critically ill patients on general wards

Critically ill patients are usually admitted to high care or intensive care units for close, electronic even invasive monitoring of vital signs. However, in the UK[111] and Israel[112] a higher than usual number of sicker and more dependent patients are admitted to general wards as a result of fewer acute beds and no corresponding increase in staff resources. Patients discharged from ICUs to wards are at risk of AEs[53, 98] and have a higher mortality than patients admitted from operating and recovery rooms and accident and emergency departments.[113]

Suboptimal care is ascribed to failure to monitor basic clinical and physiological parameters involving the patient's airway, breathing and circulation, oxygen therapy and fluid balance; likewise, lack of knowledge may be associated with the inability to recognize deterioration in a patient's condition and the clinical urgency of a situation, which, when exacerbated by a lack of supervision, failure to summon assistance, poor communication and delay in responding to deteriorating vital signs, compromises patient safety which could all point to failures of organization.[37, 110]

In the UK older and more acutely ill patients are being cared for in general wards by fewer qualified nurses who are not being paid for study leave for post-registration education and by less experienced, temporary nurses.[114] As these examples illustrate, monitoring problems still persist in the developed world, despite the increasing sophistication in vital signs monitoring in the developed world.

2.2.1 Infrequent monitoring of vital signs

Of concern is infrequent and incomplete monitoring and recording of vital signs on general wards.[105, 112] The majority of hospitalized patients are at low to average risk for immediate mortality and are not in ICUs but in wards.[112]

UK studies revealed that nurses only recorded respiratory rate between 50-55%[115] of the time,[97] and that doctors also neglect to do so.[116] Infrequent monitoring of basic vital signs can result in a delay in early identification of deterioration in a patient's condition and slow transfer to ICU, termed a 'preventable adverse event', that is associated with a 60% increase in hospitalisation costs.[117] In a study using 11 predetermined physiologic threshold criteria to establish if delayed transfer of patients from general wards to ICUs was associated with increased morbidity and mortality, there was a 30% increase in mortality where there was a delayed transfer to ICU of four hours or more.[118]

2.2.2 Interpreting signs of clinical deterioration

There is documented concern regarding misinterpretation of clinical data and little convincing evidence of timely response to signs of deterioration.[37, 87] This is of concern as the core function of the nurse in avoiding SAEs should go beyond the recording of patients' physiological vital signs[119] and it is the nurse's professional responsibility to understand the significance of patient observations.[50, 96, 97] Misinterpretation of clinical data is associated with poor clinical reasoning skills and in some cases, nurses have been found to overestimate the risk and the need to intervene in studies using computer-based clinical scenarios.[78]

These findings have serious implications for patients at risk of avoidable SAEs. Multidisciplinary teamwork means that medical practitioners rely on nurses to document and interpret vital signs and to report deterioration.[37]

2.2.3 Calling for more skilled clinical assistance

There is documented concern regarding delays in reporting abnormal physiology.[37] Patient survival frequently depends on decisions of nurses to call for assistance promptly.[39] Reporting abnormal clinical observations to doctors too inexperienced to respond appropriately, reportedly delays intervention.[91]

Three Australian studies reporting nurses' decisions to call for assistance are cited next. In a study of in-hospital calls to medical emergency teams, 98% were from nurses.[40] One study reports that ward nurses delayed calls to medical emergency teams after documenting concerns about patients' vital signs resulting in delayed treatment for 19 (11.3%) of the 168 patients for up to one hour; for 6 (3.6%) patients for 1-2 hours; for 1 (0.6%) patient for 2-3 hours; and 15 patients (8.9%) waited more than 3 hours for treatment.[120] Data from a questionnaire distributed to nurses in wards, emergency departments, recovery rooms and the operating room showed that calls to medical emergency teams would only have been made for a change in vital sign recordings in 2.8% of incidents of at-risk patients.[107] In the UK early identification of critically ill patients on the ward by a 'patient-at-risk team' and active management reduced the incidence of cardiopulmonary resuscitation before ICU admission to 3.6%, compared to 30.4% for patients not seen ($p < 0.005$).[2]

There may be several reasons why nurses delay calling for assistance. A lack of critical care skills at undergraduate and postgraduate level amongst nursing and medical staff has been reported.[108] A UK study found that nurses who did not use medical terms confidently feared looking stupid and this can lead to a delay in reporting signs of deterioration.[83]

Although 70-80% of AEs in complex health care systems may be due to human error, organizational systems themselves contribute to the problem[92, 121] and as discussed below, the EWS literature provides some solutions.

2.3 Solutions

2.3.1 Patient safety: an international, national and local organizational imperative

The International Partnership for Acute Care Safety (IPACS) initiative, endorsed by the World Health Organisation (WHO), has commenced a worldwide study of antecedents to cardiac arrest, death and emergency intensive care admission[22]. The incidence of AEs and negligence in hospitalized patients is receiving serious attention at national level in developed health systems.[3] In the USA concerns have been raised since the 1950's[122-126] and has resulted in different responses. The Institute for Healthcare Improvement (IHI) initiated the 100,000 Lives Campaign[127] and the Agency for Healthcare Research and Quality (AHRQ) published Patient Safety Indicators (PSIs) in the early 1990s. Most recently, in the UK, the National Patient Safety Agency[87] has explored the reasons underlying 66 deaths resulting from failure to recognise patient deterioration.

There are several studies reporting concerns about the safety of the acutely ill patient in a ward setting originating from developed countries,[52] particularly the UK,[11, 22, 37, 87, 128] Australasia,[67, 74, 81, 108, 109] the USA,[127] and Canada[129, 130] although not specific to adult post-operative patients. In the UK national guidelines are available for the management of acutely ill ward patients[128] as well as EWS charts[131, 132] and calling (trigger) criteria.[36, 37, 43, 133] A locally developed and validated MEWS is described for Australian private hospitals.[134] Achieving good patient outcomes in complex health care environments is challenging but local organizational systems may improve patient safety[135] particularly if clinicians are trained as 'physiology police' to detect early signs of physiological deterioration.[85]

Patient safety should feature prominently in hospital management systems. A distinction needs to be drawn between a person approach that emphasizes human error and blaming; and a system approach, that looks for solutions to clinical mishaps within the organization and encourages reporting of AEs and 'near misses' and learning from these events.[121] A combination of both approaches is recommended.[89] Human error is a prominent cause of avoidable AEs and

accounts for 57% of all cases[15] even for the best-trained and best-qualified healthcare providers. Consequently insight into the causes might help in the development of prevention strategies[15] that move away from blaming clinicians who may have erred towards an understanding of how complex systems fail. Institutions need to develop a system that is as "failsafe" as possible. The role of factors such as fatigue[136] and sleep deprivation[137] needs further research as well as improved communication systems.

To encourage reporting, effective communication systems need to be in place. A standardized communication system designed for nurses to report a critical situation is the Situation-Background-Assessment-Recommendation (SBAR) technique[138] in use in the USA and UK. However, there is little empirical data to show the effectiveness of the SBAR.[139]

The EWS system is an organizational approach aimed at identifying and responding to deteriorating patients to prevent SAEs.

2.3.2 Improving the quality of patient safety research - issues of methodology

Patient safety research is a challenging form of service delivery and organisational research that often has to deal with some very rare events.[140] A 4-part series on the epistemology of patient safety research includes different study designs and methods of measuring outcomes in the evaluation of patient safety interventions to support the position that ''one size does not fit all''.[140-143] There is documented evidence of a massive increase in published papers on patient safety over the past 2 decades[144] but concerns about the quality of patient safety research have led to the UK Medical Research Council sponsoring research to provide methodological guidance on evaluation of patient safety interventions.[13] The terms 'adverse event' and 'error' are not used consistently in patient safety studies. Most of the leading studies have used retrospective medical record reviews, a research design known to have inherent biases.[89] Validity and reliability are two essential characteristics of any outcome measure and these characteristics can be examined using a variety of methods.

There is an absence of published EWS literature describing the use of consensus methods for the derivation and validation of cut points for EWS, although these methods have been used to determine MET 'calling criteria'.[109]

2.3.2.1 Consensus methods: the Delphi, nominal group technique (NGT), consensus conference and RAND appropriateness model

Consensus methods such as the Delphi process, nominal group technique (NGT),[124, 125] consensus conferences[145] and the RAND-University of California at Los Angeles (RAND-UCLA) appropriateness model[146] (Table 2-3) are being used increasingly as tools to solve problems in medicine and health. Their main purpose is to establish agreement on controversial subjects[147] or where there is clinical uncertainty.[145] Agreement for consensus methods is at two levels: individual respondent agreement and agreement with each other.[148] The features of consensus methods described by Jones and Hunter (1995)[148] (adapted from Pill[149] and Rowe[150]), include anonymity by private ranking, iteration by repeated rounds, controlled feedback and statistical group response by giving summary responses of the full group rather than just a consensus statement.

Table 2-3: Summary of consensus methods used for solving problems in health care

Consensus method	Characteristics/Advantages	Disadvantages
Delphi First introduced in 1948[147]	Uses expert panels Requires surveys by questionnaire and/or electronic communication (e-mail) for multiple rounds Inexpensive data collection method, relying on repeated rounds of comments from experts Reliability increases with the size of the group and the number of rounds [147] After each round data are analysed and collated into one document in preparation for the next round[151] The outcome is a combined opinion achieved in a structured and anonymous way[151] A modified Delphi survey included a literature review[152]	Members drop out often from fatigue[147] Decisions are limited by the group members and their past experience or work in the field[151] Criticized for being less representative than the RAND-UCLA appropriateness multidisciplinary panels[153] There is the potential for bias[151] and not having inter-rater reliability testing[152] Is generally inferior to the nominal group technique, albeit to a small degree.[148] The difficulties relate to practical rather than theoretical considerations and more research is needed to clarify the concept expertise.
Nominal Group Technique (NGT) First described in 1971 by Delbecq and Van de Ven[154]	Is used to create a structured environment in which experts are given the best available information for considering solutions that are more justifiable and credible than may be the case otherwise[147] Is used for obtaining consensus in an orderly manner from persons closely associated with a problem area, and is based on the National Institutes of Health (NIH) and the Glaser approach to consensus[147] There is no hard and fast rule about the number of experts to include in a nominal group but 9-12 are recommended and lay persons can be included[148] The modified NGT[148] is facilitated by an expert or credible non-expert while another person takes the role of non-participant observer collecting qualitative data from the discussion but is not concerned with analysis of the group process[148]	Face-to-face consensus methods place more responsibility on the leader than is the case for the Delphi technique, and the NGT therefore requires objective and skilled leaders.[147] Jones and Hunter (1995) modified the NGT by having a different mix of participants in further rounds[148] as there is a potential for bias in the selection of experts

Consensus method	Characteristics/Advantages	Disadvantages
Consensus conference Used by the National Institutes of Health (NIH) since 1977[147]	Consistsof expert multidisciplinary member panels and often involves national task forces and committees and national and international leaders in the field Conference proceedings last from 1.5 to 2.5 days followed by dissemination and evaluation of recommendations[145]	Resource intensive Includes pre-conference preparation of questions and answers by experts in the field
RAND-UCLA appropriateness method Developed in 1984 by the Health Services Utilization Study[155]	A systematic method combining expert multidisciplinary clinical opinion and evidence[153] A rough screening test for specific medical and surgical procedures[153] Measures appropriateness of health services and appropriateness of health settings for quality and cost considerations[155] Can have a 9-12 member multidisciplinary expert panel[146] Evidence of good reproducibility[153] A modified RAND appropriateness model combined characteristics of both the Delphi and nominal group technique[156] Discussion rounds can be scored using continuous integer scales of 1-9[146]	Resource intensive Patient preferences are often neglected[155] There is concern about the method's subjectivity and unreliability[153]

All consensus methods are time efficient for data collection, having relevance for practical clinical issues,[157] and providing a mixed method approach of both qualitative and quantitative analytical processes.[158] Factors to consider to maximise the outputs derived from using consensus techniques include the characteristics of participants, level of evidence presented to the group, number of rounds, defining agreement criteria and the nature of the task at hand.[159]

Most consensus methods have been modified over time (Delphi),[152] (RAND appropriateness model)[152] (nominal group).[148] Validity and reliability of formal consensus development methods are uncertain and this has limited its use, nevertheless consensus methods have been

demonstrated in specific clinical areas.[160] In 2004 a total of 200 research articles described the use of the nominal group technique.

Consensus methods such as the nominal group technique (NGT),[126, 127] consensus conferences[145] and the RAND-UCLA appropriateness model[146] with the exception of the Delphi method, have used ranking sheets to establish agreement.

2.3.2.2 Ranking sheets for agreement using consensus methods

When using consensus methods a ranking sheet for agreement can consist of continuous integer scales of 1-9 ranging from "strongly disagree" (1) to "strongly agree (9)[152] and from "extremely inappropriate" (1) to "extremely appropriate" (9).[155] The question of when to assume achievement of consensus is not answered in the literature but it is important to establish the level of consensus in advance and there are a number of options such as percentage of agreement amongst participants.[147] This can range from >70%[152] to 80%.[151]

Jones and Hunter (1995)[148] describe the first rule as the need for the consensus group to establish whether strict or relaxed 'rules' for agreement will apply. For strict rules, all ratings are within a predefined 3 point region (1-3 = no intervention, 4-6 equivocal, 7-9 = intervention indicated) whereas for relaxed rules, ratings fall within a 3 point region but not within a predefined region. "The second rule tests whether extreme rankings are having an undue influence on the final results and consists of assessing the strict and relaxed definitions by including all ratings for each statement and then by excluding one extreme high and one extreme low rating for each statement" (Jones & Hunter, 1995 p. 379). Establishing rules of agreement enhance the attributes of transparency and democracy of decision making.[160, 161] One study[146] employing a modified RAND appropriateness method, defined consensus as a panel median of 7 or more without disagreement, and disagreement being when at least 33% of panel members rated in both the upper (7, 8, 9) and lower tertiles (1, 2, 3).

As for considerations of appropriate consensus methods, pertinent to the present study is good questionnaire design.

2.3.2.3 Questionnaire design

To increase questionnaire content and construct validity and to meet the criteria for good questionnaire design, the design should be guided by an extensive literature search, the research aim and study objectives. These considerations include attempts to collect unambiguous and easy to count answers for quantitative data and analysis.[162] To ensure that responses are as complete as possible to limit bias and reduced statistical power, the questionnaire should include instructions urging respondents to answer every question.

Structured questionnaires consist of fixed, closed questions (pre-coded response choices) for the collection of unambiguous and easy to count answers for quantitative data and analysis.[162] A limitation of a structured questionnaire is that some respondents may be 'forced' to select inappropriate pre-coded answers if these are not sufficiently comprehensive. The questionnaire should have a clear relationship to the aims of the study, and be reliable, valid and responsive to changes and the items included should have been constructed from relevant literature.[162]

Other factors to consider in the design of a questionnaire are the layout, electronic or paper format, quality of printing, visually easy to read and comprehend, clear and easy to understand instructions at the beginning of the questionnaire and a 'thank you' statement at the end.[162] The authors suggest that response scales are selected on the basis of ease of constructing, administering and analysing the scale.

A systematic review to identify methods to influence the completeness of response to self-administered questionnaires to limit bias and reduced statistical power, included the use of shorter questionnaires, monetary incentives and the inclusion of instructions urging respondents to respond to every relevant question.[163]

Determining the number of experts for content and construct validity testing of a questionnaire has always been somewhat arbitrary and depends on how many experts are agreeable and accessible but the minimum number should be three.[164]

The final solution to be considered in the EWS literature to limit SAEs is the early warning scoring system.

2.3.3 Introduction of Early Warning Scoring systems

Limiting human error may be achieved by a simple scoring system for early recognition of abnormal physiological measurements. Serious physiological abnormalities that precede cardiac arrest, unanticipated admission to ICU and death are reported in a large study undertaken in the UK, Australia and New Zealand.[165]

2.3.3.1 History and benefits of Early Warning Scoring systems

In 1997 Morgan, Williams and Wright (1997) in the UK were the first to develop and publish the EWS of five physiological parameters not to predict outcome[166] but to serve as a track and trigger system (TTS) to identify early signs[108] of deterioration. The early warning scoring systems that have been introduced across the UK[97] have been modified (MEWS) and a standardized EWS (SEWS)[167-169] was developed in Scotland[168] in 2003.

EWS systems are classified by the number of parameters that trigger a response (Table 2.1)[11, 16] and points are allocated to disturbed physiological values in a weighted manner to guide intervention[3, 5, 31, 32] and to monitor the effectiveness of medical interventions.[8] Various EWS systems (described in Table 2-1) are in use in the UK and Australia. An evaluation of the performance of single-parameter[43] and multiple-parameter track and trigger systems[133] is briefly summarised in Table 2-5.

In the UK Patients At Risk Teams tend to be 'nurse led', whereas in Australasia Medical Emergency Teams replaced traditional cardiac arrest teams[170] and are 'doctor led' so results from Australia cannot be extrapolated to England and Wales and vice versa.[171]

2.3.3.2 Evaluation of EWS Systems

MEWS observation charts used by nurses in the UK[131] incorporate red, yellow and orange colour banding of values for each parameter indicating 'cut point criteria' for visual warnings of

physiological deterioration that could lead to an AE. Cuthbertson (2008)[25] suggests that the score with the most favourable balance between sensitivity and specificity should be taken as the optimal cut point or trigger.[25] Even though aggregate scores may not trigger if one variable falls outside the predetermined score, this has not been reported as a practical problem[172] and single parameters with high scores may not always translate into an increased overall risk in single parameter track and trigger systems.[8]

In view of the nationwide implementation of EWS/MEWS observation charts in certain developed countries it seemed surprising that a search of CINAHL and PubMed MESH databases failed to produce a research instrument or criteria to validate EWS/MEWS vital signs observation charts.

2.3.3.3 Validity testing of EWS systems

There is no ideal MEWS system, but the optimal cut point for EWS should be the score with the most favourable balance between sensitivity and specificity.[25] In the context of consensual validation of triage scales for a developing country, the relationship between patient acuity level (severity of illness) and outcome depends on confounding variables such as variability in triage nurse decisions, and delayed and ineffective treatment.[27]

Construct validity ensures that the layout and general organizational aspects of the data tool have been attended to. The more commonly held view of validity testing is depicted as a 'bull's eye' target where there is a predetermined 'gold standard', thereby satisfying requirements for criterion validity. In a hierarchy of validity tests criterion validity is the best and is used extensively in the developed countries.[27] In addition to criterion validity the remaining two C's in the trinitarian view of validity are content and construct validity.[173] These three validity testing methods have been reconceptualised as being different aspects of construct validity.[28-30]

2.3.3.4 Accuracy, reliability and agreement testing of EWS systems

The calculation of an EWS is preceded by several complex processes that affect reliability: 1) an accurate method of collecting raw vital signs data; 2) ascribing the correct weighted trigger point (0, upper and lower 1 to 3) and cut point (threshold) according to the degree of physiological derangement; and 3) the arithmetic addition of weighted trigger points to form an aggregated MEWS (total score); but also 4) the transcription of raw data onto the paper chart.[44]

Importantly, the results of inter-rater agreement studies depend on the unambiguousness and completeness of the system and the accuracy of the nurse.[17] Similarly, there are problems with repeat measures as the physiology can change particularly if readings by two observers are not done simultaneously.

Instrumentation in vital signs monitoring involves electronic measurement devices and observation charts for recording measured readings. Potential confounding variables impacting on the reliability of an instrument include reliability of the electronic measurement devices[174] that need regular calibration[44] and variability in nurse decisions,[27] the so-called 'human element of reliability'.[174] The human element of reliability is evident at three levels: firstly, competence in taking physiological measurements (which is outside the scope of this study). There is evidence of inter- and intra-rater reliability variability in the measurement of physiological parameters.[128] Secondly, there is human variation in the accuracy of recording findings on the observation chart[175] and thirdly, the potential for variation in clinical responses to triggered EWS[44] (single- or multiple-parameters). Reliability testing of charting vital signs on the MEWS chart therefore does not establish accuracy of MEWS recordings.

Variability may increase random error. In one study better levels of agreement were recorded on decisions whether a patient had triggered or not than for early warning scores allocated and simpler systems had better reliability.[174] Most importantly, few reported studies have tested the accuracy of EWS calculation and charting[44] but those that have, found accuracy to be lacking with serious implications for quality of care.[175]

The EWS system is dependent on accurate recording of vital observations, "otherwise these scores are meaningless and no action is taken" (Ismail & Davies, 2007:150).[176] Traditional pen-and-paper recording on MEWS charts is limited by human variations in both the accuracy of the score and the frequency of clinical observation recordings[176] besides the significantly longer time it takes to calculate an aggregate score compared to digital (PDA) systems.[44, 175]

In a classroom, manual EWS charting by 26 nurses was correct in 58% (152/260) cases compared to 96% (250/260) for digital systems (difference in proportions 38%, 95% confidence interval 31-44%, p<0.0001 McNemar's test).[175] In this and another study[14] the average accuracy of EWS calculations for the traditional method reduced significantly as the value of the true MEWS (an indication of severity of illness) increased. In another UK study incorrect or missing entries by 21 nurses away from clinical areas occurred in 29% (24/84) of EWS from five fictitious vital signs datasets computed using the traditional method that was also associated with 14% (12/84) incorrect clinical actions being indicated, compared to 10% (8/84) incorrect/missing entries and only 5% (4/84) incorrect clinical actions being indicated using a digital method.[44]

The results of a prospective audit of 30 postoperative patients' observation charts from General, Vascular and Orthopaedic wards in one UK hospital revealed that the recently implemented MEWS was documented in 69% of patients and in those patients only 42% had a correct MEWS.[176] This implies an accuracy of MEWS recordings for only 29% of postoperative surgical patients and a forecasting of a great likelihood that the MEWS could 'misfire' (Ismail & Davies, 2007:150).[176]

The complex nature of introducing an EWS, and an educational intervention programme followed by an audit, would make a RCT of an early warning scoring system almost impossible[177, 178] as a RCT is strictly controlled and traditionally, only one specific intervention works under very specific conditions.[73] Although RCTs are considered the strongest form of evidence, a multi-centre validation of the EWS might be more realistic in producing a score with optimal sensitivity and specificity.[179] Alternatively, a stepped wedge design is proposed where it is impossible to deliver the intervention simultaneously to all participants.[180] A cluster RCT study is a further option.

Table 2-4 and Table 2-5 contain a hierarchy of evidence[181, 182] of a preliminary summary of aggregate weighted track and trigger systems (EWS/MEWS) used in adult general ward settings that have been subjected to various levels of scientific enquiry. Seven studies were reviewed for validity and reliability of EWS/MEWS systems and 11 for performance. Only observational and no experimental studies on EWS systems were found in the available literature and this is supported in a 2007 Cochrane review.[183] In contrast, the Cochrane review describes two cluster-randomised control trials on the effectiveness of the medical emergency team system which is beyond the scope of this study.

Table 2-4: MEWS subjected to scientific enquiry for reliability and validity testing

EXPERIMENTAL STUDIES	Authors	Study objectives	Outcome measures	Sample size	Findings
NONE					
OBSERVATIONAL COHORT STUDIES (Analytical)					
Prospective studies	**Authors**	**Study objectives**	**Outcome measures**	**Sample size**	**Findings**
Prospective cohort study Validation of a modified Early Warning Score in medical admissions No comparison group	Subbe et al. 2001a[8]	To collect physiological data (systolic blood pressure, heart rate, respiratory rate, temperature, AVPU (conscious level)) prospectively on all patients admitted to the medical admissions unit and then to calculate a MEWS from previously published scoring criteria [5, 10].	Death, ICU admission, HDU admission, cardiac arrest, survival, hospital discharge at 60 days	Vital sign readings of 673 patients on a medical admissions unit were recorded twice daily for 5 days Single centre study	Scores of 5 or more ['critical score'/'ScoreMax'] were associated with increased risk of death (OR 5.4, 95%CI 2.8-10.7), ICU admission (OR 10.9, 95%CI 2.2-55.6) and HDU admission (OR 3.3, 95%CI 1.2-9.2). Scores of 4 demonstrated that patients were at increased risk of catastrophic deterioration requiring higher levels of care.
A prospective observational study The value of Modified Early Warning Score (MEWS) in surgical in-patients No comparison group	Gardner-Thorpe et al. 2006[6]	To calculate the sensitivity, specificity, positive predictive value and negative predictive value of the aggregated MEWS.	The aggregated MEWS as a predictor of critical care admission	334 patients Single centre study	Sensitivity of the aggregated MEWS threshold of 4 was 75% for ITU/HDU admission with a specificity of 83% for respiratory rate, heart rate, systolic blood pressure, urine output, temperature and AVPU level of consciousness. An early warning system is an important risk management tool for all surgical in-patients.
An observational, population-based single-centre study Worthing physiological scoring system (PSS): derivation and validation of a physiological early-warning system for medical admissions. No comparison group	Duckitt et al. 2007[7]	To derive and validate a physiological EWS system for medical admissions using respiratory rate, heart rate, arterial pressure, temperature, oxygen saturation and conscious level (AVPU)	A simple validated scoring system to predict mortality in medical patients with precise 'intervention-calling scores' derived from the data with an intervention-calling score set at 2	4286 patients Single centre study	Sensitivity of the Worthing PSS at a cut point of 3 for the aggregated score was 63% comparing well with the EWS (60%); specificity was 72% compared with the EWS (67%) but for an 'intervention-calling score' above 2 mortality increased >10%

OBSERVATIONAL COHORT STUDIES	Authors	Study objectives	Outcome measures	Sample size	Findings
Prospective cohort study Reproducibility of physiological track-and-trigger warning systems for identifying at-risk patients on the ward	Subbe et al. 2007[174]	To assess inter-rater and intra-rater reliability of the physiological measurements, aggregate scores and triggering events of 3 track and trigger systems (TTs): the MET, the MEWS and the ASSIST	Reproducibility of TTs using systolic blood pressure, temperature, respiratory rate, pulse rate, level of consciousness, urine output as variables	424 sets of observations from general medical and surgical wards Single centre study	Significant variation in the reproducibility of the TTs used by different health care professionals. Better levels of agreement on triggers than on aggregate scores. Simpler systems had better reliability.
Retrospective and prospective studies					
An early warning scoring system for detecting developing critical illness	Morgan et al. 1997[10]	To devise a simple scoring system which could be readily applied by junior doctors and nursing staff to identify patients developing critical illness	An early warning scoring system using systolic blood pressure, heart rate, respiratory rate, temperature, AVPU (conscious level)	100 patients on surgical wards Single centre study	A scoring system with deviations from normal scores (0) ranging from 1-3 (upper and lower) proved to be not too sensitive after testing.
Comparative cohort study Can physiological variables and early warning scoring systems allow early recognition of the deteriorating surgical patient? Comparison group	Cuthbertson et al. 2007[101]	To test the ability of physiological variables (heart rate, respiratory rate, oxygen saturation, blood pressure and temperature), either alone or in existing EWS systems, to predict major deterioration in a patient's condition and attempt to derive functions with superior accuracy	EWS systems with good discriminatory power. Physiological variables with discriminant functions which have a high predictive ability to detect differences between patients requiring admission to ICU	136 patients Single centre study	Significant physiological differences between patient groups with regard to heart rate (p <.001, AUC=0.7), respiratory rate (p <.001, AUC=0.71) and oxygen saturation ((p <.001, AUC=0.78) but not for systolic blood pressure or temperature. Discriminant functions were derived for heart rate and respiratory rate that have a high predictive ability (p <.0001, AUC=0.86-0.90) to determine differences between groups of patients 6-8 hours before admission to ICU. Existing EWS have comparatively good discriminatory power (AUC=0.83-0.86) but many rules. Discriminant functions are more difficult to calculate at the bedside.

Meta-analysis					
Systematic review and retrospective cohort study	**Authors**	**Study objectives**	**Outcome measures**	**Sample size**	**Findings**
Systematic review and evaluation of physiological track and trigger warning systems for identifying at-risk patients on the ward	Gao et al. 2007[22]	To describe published track and trigger systems (TTs) and the extent to which each has been developed according to established procedures; to review the published evidence and available data on the reliability, validity and utility of existing systems; and to identify the best TT for timely recognition of critically ill patients.	A systematic review of published papers and retrospective cohort study.	36 papers and 15 datasets representing 30 hospitals in the UK and 1 in Wales	None of the published studies met all methodological quality standards. All TTs in the 15 datasets were different and were modified for local needs, having different physiological variables, scores and trigger thresholds. Sensitivities and positive predictive values of datasets were low, with median (quartiles) values of 43.3 (25.4-69.2) and 36.7 (29.3-43.8) respectively. Of the 25 EWS, 7 included the parameter 'concern'. Available local TTs showed little evidence of reliability, validity and utility and available data were insufficient to identify the best TT system.

Legend: HDU = high dependency unit

• *Discussion of studies evaluating reliability and validity testing of the MEWS*

There are few published validation studies for EWS systems. It appears that the majority of studies on MEWS are observational in nature. Seven studies were reviewed (Table 2-4).

Two studies addressed case mix and clinical setting[8, 101] as limitations of the MEWS, that is, cut points for each parameter may not be generalizable across broad diagnoses (respiratory disease, cardiac disease) and settings (patients not needing admission to ICU and those that do).

Studies were limited by factors such as single-centre locations (all), having a limited number of patients (most) or limited complete data,[7] short periods of data collection,[8] taking and recording repeated measurements within an hour but not reporting improvement or deterioration after interventions,[174] possibly biased samples due to the legitimate exclusion of patients not willing or unable to give consent[174] and not identifying patients who, if managed differently, could have remained on general wards instead of being admitted to ICU.[8]

All of the studies listed in Table 2-4 measured heart rate and respiratory rate; five studies measured systolic blood pressure, temperature and level of consciousness (AVPU); and only two studies measured urine output and oxygen saturation. The same six variables were described in two studies, excluding oxygen saturation while one study measured the same six variables excluding urine output.[7] Urine output and oxygen saturation were excluded in two studies.[8, 10] Of the six papers included in the systematic review[22] that described the MEWS (excluding Subbe et al. 2001), all measured heart rate, respiratory rate, blood pressure, urine output and consciousness; four measured temperature; and two measured oxygen saturation. This is a surprising finding for urine output measurement, not consistent with results summarized in Table 2-4 and found to be missing in 97.1% of sets of observations in one of the five studies.[174]

There was one systematic review[22] of the validity, reliability and utility of published physiological TT warning systems used outside critical care areas. Guidelines for the review of methodological quality standards, validity criteria for clinical decision rules and criteria for the quality of TT datasets are cited for the analysis of 15 physiological datasets, but not for the systematic review. Although the authors included a review of their previous cohort study,[16] they appear to meet requirements for Preferred Reporting Items for Systematic reviews and Meta-

Analyses (PRISMA) concerning "an assessment of the validity of the findings of the included studies, for example through the assessment of risk of bias" (Liberati et al. 2009:W66)[184] by reporting that "[N]ot all components of the composite outcomes were recorded in every dataset, which may introduce some bias" (Gao et al. 2006:677).[16]

In the review[22] the number of monitored parameters described in publications for single-parameter track and trigger systems (SPTTS) varies greatly: in Australasia (5 to 32); USA (12 to 19); England (8); and Canada (15). Multiple-parameter track and trigger systems (MPTTS) were only published for England (7). For aggregate weighted track and trigger systems 5 parameters were recorded for Wales; 6 for Scotland; and for England this ranged from 5 to 21. Combination systems are only reported for England (6 parameters).

The review concludes that evidence is lacking for the sensitivity, specificity and predictive validity of published TTS, and for the best system for early recognition of critical illness.[22] This implies that if ward staff were to rely only on these systems, a high number of patients requiring intervention may be missed, therefore clinical judgment is imperative.[22]

Table 2-5: MEWS subjected to evaluation of performance

EXPERIMENTAL STUDIES	Authors	Study objectives	Outcome measures	Sample size	Findings
NONE					
OBSERVATIONAL STUDIES (Analytical)					
Prospective studies:	**Authors**	**Study objectives**	**Outcome measures**	**Sample size**	**Findings**
Prospective cohort Prospective evaluation of a modified Early Warning Score to aid earlier detection of patients developing critical illness on a general surgical ward No comparator group	Stenhouse et al. 2000[5]	To prospectively evaluate the EWS for respiratory rate, heart rate, temperature, CNS (AVPU), urine output and systolic blood pressure for 1 month. After modifying scores for urine output, temperature and systolic blood pressure the EWS were prospectively evaluated for a further 9 months.	Earlier detection of critical illness on a general surgical ward	206 patients on 2 general surgical wards Single centre study	After 1 month scores were modified for urine output, the sensitivity of scores for temperature was decreased and scores for systolic blood pressure were normalized (i.e. interpreted as % deviation from the patient's norm). Patients with a total score of 4 were reviewed by ward medical staff leading to earlier referral to the ICU of 26 patients compared to 11 patients from a surgical ward not using the MEWS. Early warning resulted in patients admitted to ICU having lower APACHE II scores and therefore less physiological derangement. *The Acute Physiology and Chronic Health Evaluation score is not an early warning scoring system but is used in ICUs to grade patients' health status.
Prospective cohort Effect of introducing the Modified Early Warning score on clinical outcomes, cardio-pulmonary arrests and intensive care utilization in acute medical admissions	Subbe et al. 2003[185]	Primary aim: to prospectively measure the effect of introducing the MEWS on the rates of ICU and HDU admission, cardio-pulmonary arrest and mortality over a 3 month period. Secondary aim: to collect physiological data (systolic blood pressure, heart rate, respiratory rate, temperature, neurological status (AVPU score)) from patients prior to critical care admission, cardio-pulmonary arrest or death in order to improve the discrimination of the score.	The ability of the MEWS to identify patients at risk	1695 study patients (medical admissions unit, medical HDU, ICU, following cardio-pulmonary arrest and death) 659 control patients (data from a 2001 study) Single centre study	Overall, mortality was unchanged between the control group and the study group (patients with a MEWS) irrespective of risk band. There was an increased incidence of cardio-pulmonary arrests in the study group in patients with a MEWS 3 or 4 (intermediate risk). A scoring system did not change outcomes in acute medical admissions. A MEWS of 4 triggered urgent medical referral and critical care outreach team review. Respiratory rate was the best discriminator to identify patients at risk. The MEWS is suitable for identifying patients at risk of deterioration.

OBSERVATIONAL STUDIES (Analytical)					
Prospective studies:	**Authors**	**Study objectives**	**Outcome measures**	**Sample size**	**Findings**
Use of a patient information system to audit the introduction of modified early warning scoring. No comparator group	Quarterman et al. 2005[177]	To audit the introduction of MEWS for physiological parameters (airway, respiratory rate, systolic blood pressure, heart rate, AVPU score, temperature, urine output) using the Sunrise Clinical Manager 3.03 patient information system	The relationship between patient outcome, trigger score, age and medical speciality.	365 admissions in 10 medical and general surgical and orthopaedic wards Single centre study	The study showed a significant relationship between trigger score and patient outcome. Increasing MEWS score was associated with worse outcome across a range of specialities (medical and surgical) and nursing staff should use a patient information system to audit MEWS scores. An aggregated MEWS of 3 or more triggered the need to call for assistance but survival was worse at this level ($p< 0.004$)
Longitudinal surveys The effect of a critical care outreach service and an early warning scoring system on respiratory rate (RR) recording on the general wards Comparator group	Odell et al. 2007[4]	To determine whether the implementation of a Reading-Modified Early Warning Scoring (R-MEWS) system is associated with an increased recording of respiratory rate in hospital inpatients, and whether the presence of a critical care outreach service has a further impact on the recording of patients' vital signs (respiratory rate, heart rate, systolic blood pressure, level of consciousness, urine output).	The link between RR recording rates and the Reading-MEWS	2638 adult, non-obstetric acute inpatients in 2 hospitals between 2001 and 2005	RR recording increased from 6.0% (1st survey) to 77.9% (last survey), which correlated with the incremental implementation of the R-MEWS system and may have been enhanced by a critical care outreach service
Research design not reported but appears to be a **prospective study**. Long-term effect of introducing an early warning score on respiratory rate charting on general wards	McBride et al. 2005[186]	To study the short- and long-term effects of introducing a new patient vital signs chart and the modified early warning score (MEWS), which incorporates respiratory rate on the prevalence of respiratory rate recording in six general wards	The effects of a MEWS on respiratory rate recordings on general wards	6 general wards Single centre study	There was a long-term beneficial effect of introducing the MEWS system on respiratory rate recording into the general wards.

OBSERVATIONAL STUDIES	Authors	Study objectives	Outcome measures	Sample size	Findings
Retrospective and prospective cohort study Prediction of in-hospital mortality and length of stay using an early warning scoring system: clinical audit Comparator group	Paterson et al. 2006[168]	To assess the impact of a standardized early warning scoring (SEWS) system on physiological observations (respiratory rate, temperature, blood pressure, heart rate, conscious level and oxygen saturation) and patient outcomes (in-hospital mortality, length of stay, transfer to critical care) including staff satisfaction in unselected acute admissions on admission.	Completeness of documentation of physiological parameters, in-hospital mortality, and hospital length of stay	2 cohorts of medical & surgical emergency admissions to one area; A total of 848 patients : 413 pre-SEWS & 435 post-SEWS Single centre study	A SEWS improved documentation of physiological parameters (P<0.001-0.005) with the exception of oxygen saturation (P=0.069), and at a score of ≥4 correlated with in-hospital mortality, and helped predict length of stay: in-hospital mortality decreased, there was an increased staff awareness of critical illness and prompt, earlier intervention.
Cross-sectional studies	**Authors**	**Study objectives**	**Outcome measures**	**Sample size**	**Findings**
Cross-sectional survey Signs of critical conditions and emergency responses (SOCCER): a model for predicting adverse events in the inpatient setting	Jacques et al. 2006[108]	To establish the association between recordings of disturbed physiological variables and adverse events using criteria not restricted to MET calling criteria	The association between recordings of disturbed physiological variables and adverse events using criteria not restricted to MET calling criteria	3046 inpatients multicentre study	Confirmation of current MET call criteria but these need to be expanded and to be modeled to meet individual hospital patient needs.
Cross-sectional correlational survey Identifying level one patients. A cross-sectional survey on an in-patient hospital population Comparator group	Morrice & Simpson 2007[187]	To identify the characteristics of level one patients (using the Intensive Care Society (ICS) Levels of Care) 'at risk' of deterioration on general wards and to explore how these differed from the other levels of care (zero and two) after modifying the existing MEWS but not validating it) by comparing physiological and demographic variables using 3 validated tools: EWS, TISS-28 and APACHE II.	A comparison of physiological (systolic blood pressure, heart rate, respiratory rate, temperature, central nervous system, urine output) and demographic variables using 3 validated tools: EWS, TISS-28 and APACHE II .	Stage 1: 351 general adult inpatients Stage 2: 67 patients Single centre study	[*Only EWS data are reported on in this review*] Blood pressure, heart rate and temperature were not useful in identifying 'at risk' patients. EWS were useful for identifying level one patients but a triggering level of 4 for total EWS was not sensitive enough for the ICS Classification of Levels of Care. EWS triggered at a score of 4. Study results did not support the view that a physiological scoring system such as the EWs would correspond well with the ICS level of care.

Opinions of respected authorities based on clinical experience, descriptive studies, or reports of expert reviews	Authors	Study objectives	Outcome measures	Sample size	Findings
Review and performance evaluation of aggregate weighted 'track and trigger' systems No reference to PRISMA or earlier guidelines for a systematic review	Smith et al. 2008a[133]	To describe the aggregate weighted 'track and trigger' systems (AWTTS) in clinical use and assess their ability to discriminate between survivors and non-survivors of hospital admission, based on an initial set of vital signs (heart rate, systolic and diastolic blood pressure, respiratory rate, temperature, neurological status using AVPU or GCS, oxygen saturation)	A systematic literature review of AWTTS to analyze their ability to discriminate between survivors and non-survivors of hospital admission	33 unique AWTTS A database of 9987 admission vital signs datasets	Wide range of AWTTS in use but similar. 12 (36%) discriminated reasonably well. The top four included age; the top two included temperature. Physiology can be used to predict outcome, but further work is required to improve AWTTS models. Most differ only in minor variations in weightings for physiological abnormality and/or the cut points between physiological weighting bands. For temperature there are 19 weighting systems; 15 for respiratory rate, 15 for blood pressure; 12 for heart rate and 6 for AVPU.
A review, and performance evaluation, of single-parameter ''track and trigger'' systems (SPTTS)	Smith et al. 2008b[43]	To describe the SPTTS in clinical use and measure their sensitivity and specificity when using admission vital signs data (heart rate, respiratory rate, systolic blood pressure, temperature, oxygen saturation (high and low of each) and reduced consciousness) for predicting in-hospital mortality	A systematic literature review of physiologically-based, SPTTS for predicting in-hospital mortality	A database of 9987 admission vital signs datasets 39 unique classes of SPTTS identified (30 evaluated)	Considerable variation in the physiological variables used, and significant variation in the physiological values used to trigger a medical emergency or critical care outreach team; marked variation in sensitivity (7.3—52.8%) but too low to confidently identify patients at risk of in-hospital death, specificity (69.1—98.1%), positive predictive values (13.5—26.1%), negative predictive values (92.1—94.2%) and the potential number of calls triggered (234—3271).

• *Discussion of studies evaluating performance of the MEWS*

Of the 11 studies reviewed (Table 2-5), one met all inclusion criteria,[5] describing a population of adult patients in surgical wards outside critical care areas and emergency departments. Two studies were included because they were undertaken on surgical wards including other specialities;[177, 186] one involved the association between a MEWS and respiratory rate recording;[4] one tested a validated EWS;[187] and three were relevant systematic literature reviews.

There is considerable variation in the physiological variables used in TTS, and significant variation in the physiological values used to trigger a response; as well as marked variation in sensitivity but less for specificity and variation in the potential number of calls triggered.[43]

Nine studies (Table 2-5) included EWS that measured respiratory rate; eight that measured systolic blood pressure, level of consciousness (AVPU) and heart rate; seven that included temperature, four that measured urine output, three that measured oxygen saturation and only one study included monitoring the airway. Respiratory rate was found to be the best discriminator of clinical outcomes.[185]

Recording of vital signs, particularly respiratory rate, improved with the introduction of MEWS vital signs charts.[4, 186] A large Australian cross-sectional study by record review of 26 early signs and 21 late signs concluded that many abnormal physiological variables were strongly associated with SAEs.[108] The four most effective aggregate weighted track and trigger systems able to discriminate between survivors and non-survivors incorporated age and the top two incorporated temperature monitoring.[133] Of 23 aggregate weighted track and trigger systems, only one incorporated 'nurse concern'. Reported early signs frequently associated with SAEs included systolic blood pressure 80-100 mmHg, alteration in mentation and oxygen saturation 90-95%.[188] Severity of illness is indicated by the value of the EWS.[175]

An EWS of 4 seemed to be able to identify more surgical ward patients at risk of deterioration than other monitoring systems, and these patients were admitted to ICU before catastrophic deterioration.[5] Similar results were obtained for the standardized early warning score (SEWS)[168] and for prospective validation of a MEWS on 709 patients' data in an acute medical admissions unit, whereas scores of ≥5 were associated with increased risk of death[8] and results were confirmed a year later.[185] A significant relationship was shown between increasing MEWS score

and worse outcome across a range of specialities (medical and surgical),[177] however, a triggering level of 4 for total EWS is not sensitive enough for the Intensive Care Society (ICS) Classification of Levels of Care.[187] Intensive staff training prior to implementation of early warning scoring systems[168] has beneficial effects.

2.3.3.5 Limitations of EWS

Despite their clinical usefulness, EWS have limitations. There is no single validated scoring tool across diagnoses[167, 189] or disciplines[38] and yet incorporating the diagnosis into a scoring system might make it too complex and less effective.[8] The specific physiological variables chosen and the scores allocated to values of most EWS have not been prospectively validated[38, 101] nor is the implementation based on robust research evidence.[183] If single parameters are ignored, severely ill patients can be missed. If scoring is not accurate, scoring systems have the potential of increasing workload[190], triggering incorrect thresholds and a cascade of unnecessary events.

Not all aggregate weighted track and trigger systems (Table 2-1) include the Glasgow Coma Scale (GCS) for assessment of conscious level, preferring the Alert/Responding to Voice/Responding to Pain/Unresponsive (AVPU) system because, although it may be possible to convert from GCS to AVPU, to convert from AVPU to GCS may not be possible.[133] TTs (Table 2-1) do assist in identifying parameters that predict death but the important question is how do clinicians establish who will survive and who should be treated in the intensive care unit as some patients may be harmed by intensive care interventions.[170]

Skin tone, sweating, nausea and other clinical signs such as nurses' intuitive assessment of the patient being 'just not right'[39] are documented but it is not clear whether EWS charts are designed to include clinical signs such as, for example, 'patient looks well/unwell'.[131]

Better monitoring of patients implies better care, but evidence is needed about the consequences of inadequate vital sign monitoring and about EWS that have been evaluated for performance.

Over the past decade there has been a substantial increase in the number of studies into patient safety[144] but there are concerns about the quality of much of this research and there is lack of consensus about methods.

2.4 Summary

There is agreement amongst EWS researchers and published evidence that critically ill patients are being cared for on general hospital wards and that SAEs such as deterioration in clinical status caused by human error (failure to monitor patients' vital signs and/or failure to recognize deterioration or to delay calling for skilled assistance) may result in avoidable cardiac arrest, admission to ICU or death. SAEs have devastating consequences and are costly. SAEs can be prevented by limiting human error.

There is agreement in the developed countries (UK, Australasia, USA) that track and trigger early warning vital signs monitoring tools (EWS/MEWS and other modifications) alert nursing and medical staff to premonitory abnormalities in physiology before an adverse clinical outcome and within six to eight hours of cardiac arrest. Opinion is divided on the physiological variables to include in MEWS (respiratory rate, systolic blood pressure, pulse rate, temperature, central nervous system status, oxygen saturation, urine output). It appears that clinical signs of deterioration (pallor, sweating, looking unwell) are not often included in MEWS observation charts. There is limited agreement about the MEWS cut points or aggregate scores and therefore little agreement about the best MEWS for sensitivity and specificity as the ideal MEWS does not exist.

EWS researchers acknowledge that it is the nurses' professional responsibility to understand the significance of patient observations and patient survival often depends on the decisions of nurses to call for assistance.

Solutions aimed at improving the safety of hospitalized patients include: making patient safety an international, national and local organizational imperative not only for the developed countries but also for developing countries; developing theoretical mortality/AE prediction models to guide practice; introducing EWS observation charts; and improving the quality of AE research.

Studies reviewed for validity and reliability of EWS/MEWS systems and for performance revealed that only observational and no experimental studies on EWS systems were found in the available literature, supported in a 2007 Cochrane review. Evidence is lacking for the sensitivity, specificity and predictive validity of published TTS, and for the best system for early recognition of critical illness. Few reported studies have tested the accuracy of EWS calculation and charting but

those that did, found accuracy to be lacking with serious implications for quality of care. There is no published comparable study on the development, validation, implementation and evaluation of a MEWS vital signs observation chart. It seems that consensus models have not been extended to measuring the appropriateness of indicators (parameters) of early warning signs of clinical and physiological deterioration.

The next chapter describes the development and validation of the Cape Town Ward MEWS using consensus methods.

3 STUDY ONE: DEVELOPING AND VALIDATING THE CAPE TOWN WARD MEWS OBSERVATION CHART

3.1 Background and significance

In this chapter the available published evidence on 'track' and 'trigger' early warning scoring (EWS) systems that was described in the previous chapter was used to design a preliminary modified early warning scoring (MEWS) system for use on general hospital wards. A questionnaire was designed to survey opinions on the local modified early warning scoring (MEWS) system. Experts evaluated the index of content validity (CVI) of the questionnaire.

There was a low response to the survey so consensus methods (modified nominal group and Delphi) were employed for agreement on baseline MEWS from the questionnaire data or failing that, derivation of new MEWS cut points (thresholds) for the physiological parameters. Available published evidence on consensus methodology was explored and a ranking sheet for consensus seeking amongst experts was designed. The ranking sheet was not validated.

Following five rounds (two NGT; three Delphi) the consensus derived MEWS observation chart was tested for accuracy of charting using prospective vital signs datasets. The predetermined 90% cut point for accuracy in charting was achieved for all physiological parameters except respiratory rate (81.0%). The final version of the Cape Town MEWS observation chart was approved by consensus.

Available published evidence on the development of an early warning scoring system in a developing country and the utility of a MEWS observation chart on South African general wards was limited and is presented next.

3.2 Literature review

All EWS studies reviewed in Chapter 2 including the design of observation charts are from well resourced countries except one that reports the implementation of a MEWS in a public hospital in KwaZulu-Natal (KZN) in South Africa[52] and five studies describing a Cape triage MEWS (TEWS) for emergency departments (ED).[191 192, 193 27, 106] The focus of the literature review for Study One is EWS literature from developing countries and publications on validation of MEWS scales for a developing country using consensus methods in particular. There is a paucity of such publications. The recognition of and response to acutely ill adult patients on general wards is an unexplored research area in South Africa. What is available are guidelines for conducting mortality reviews by the Department of Health in KZN,[194] the SA Patients Charter,[47] Batho Pele Principles[48] and Bill of Rights[49] advocating public awareness of patients' rights and litigation. An extensive literature search revealed no published studies on avoidable in-hospital SAEs of adults or national monitoring programmes for SAEs, and no practice guidelines for developing countries.

3.2.1 Development of EWS/MEWS systems in a developing country

Currently the South African National Research Database holds no published evidence on the use of consensus methods for establishing interventions for the recognition and management of the deteriorating adult patient.[195] From the developed countries there is an absence of published EWS literature describing the use of consensus methods for the derivation and validation of cut points for EWS but not for MET 'calling criteria',[109] most studies having employed observational cohort methods.

One study describes triage medical experts from South Africa and the UK having used the Delphi consensus method to identify clinical criteria that define triage priority in a major incident setting.[151] For this study agreement of 80% was chosen arbitrarily before the study commenced. Another South African study advances the use of the Delphi consensus method for validation of a triage MEWS for emergency departments (ED).[27] In South Africa the MEWS has been adapted as the South African Triage Scale after validation on the local national population.[106]

Consensus conferences have been employed in developed countries for validating medical emergency team (MET) calling criteria[109] but not for the derivation and validation of MEWS. The Delphi consensus method employed for triage assessment as described above,[27 151] that relies on repeated rounds of comments from experts, is generally inferior to the nominal group technique, albeit minimally.[148] Difficulties relate to practical rather than theoretical considerations and more research is needed to clarify the concept 'expertise'. Delphi reliability increases with the size of the group and number of rounds but members stop participating often from fatigue.[147]

3.2.2 Utility of a MEWS observation chart on South African general wards

"Observation charts are one of the primary tools for recording vital signs and other clinical information in hospitals, and thus have a key role in assisting with the identification of patients who are deteriorating" (Australian Commission on Safety and Quality in Health Care, 2009:2) but research about these charts is sparse.[45] The design of an existing observation chart in one UK hospital was shown to have a significant effect on the ability of clinical staff to detect patient deterioration, ranging from 0% to 100% detection, prompting the design of a new chart that incorporated an early warning scoring system.[196] After training there were significant improvements in the average detection rates of parameters previously poorly recognised: detection rates of tachypnoea and hypoxia increased by 41% (p,0.05) and 45% (p,0.05) respectively and for tachycardia and pyrexia detection increased by 29% (p,0.05) and 16% (p,0.05) respectively.

With one exception, observation charts for adults in South African public wards do not seem to incorporate early warning 'tracking' systems, nor do they indicate normal values (except for temperature) or physiological abnormalities or prompt a trigger if an abnormality is observed. Carter (2008)[52] implemented a MEWS system without the use of colour on surgical wards in a public hospital in KZN and it is the only available evidence from South Africa. Although the focus of the paper is on critical care outreach services (CCOS) (UK) which was an exclusion criterion for the literature review for this study and therefore not examined here, findings on the MEWS are important.

Carter (2008)[52] reports that a MEWS and referral algorithm from the developed countries was the basis of a formal case-based training programme on early identification of critical illness on general wards. Results were somewhat mixed after implementing the MEWS system:

- 76.4% (185/242) of observation cycles were scored;
- compliance varied between wards;
- night staff were less compliant in scoring observations (61.5% of observation were not scored) than day staff (38.5% of observations were not scored);
- calculation of the MEWS was inaccurate in 9% of cases;
- respiratory rate was not recorded in only 7.5% of cases but may as well not have been recorded as 77% of patients had recordings of 20 breaths/minute which is highly unlikely;
- in some instances patients who had a co-morbid condition such as tuberculosis of the abdomen for which they were treated conservatively and for whom active intervention would have been considered inappropriate, may have accounted for unnecessary triggering of the algorithm and calling for a doctor, as the treatment regime may not have been communicated to all nurses;
- aggregate scores ranged between 3 and 10 with a mean of 6 indicating increased severity of illness particularly as a score of 3-5 required the patient to be reviewed within one hour;
- scoring for urine output was problematic;
- nurses did not record referral of deteriorating patients to medical staff nor the actions they may have taken;
- initial audit results were disappointing as 59% of patients did not have scoring forms but after altering the observation chart only 17% of patients had the incorrect form.

The observation chart used by Carter[52] did not incorporate colour bands for each parameter, instead the MEWS cut points for variables were inserted at the bottom of the existing chart, and the referral algorithm was on the reverse side, requiring nurses to record the vital signs in the usual manner and then to interpret these using MEWS values. A scoring scale should demonstrate utility and relevance.[197] Further limitations of the KZN chart include the absence of clinical indicators of deterioration that are not directly measurable such as 'looks unwell' found on

published charts (Dr Fiona McIlveney UK NHS Forth Valley).[131] These variables require skills of observation, intuition, knowledge and experience for interpretation and may be as important as the physiological variables.[39, 40, 83]

There is a need for this study as there is a paucity of published research on EWS/MEWS from South Africa and even less from other developing countries. MEWS charts establish severity of illness and standardize responses by incorporating a callout algorithm. There is published evidence that MEWS used in developing countries should be locally derived and validated using consensus methodology.[27]

3.3 Aims and Objectives

The aim of the study was to develop and validate an observation chart for nurses incorporating a modified early warning scoring (MEWS) system for physiological parameters for bedside monitoring on general wards from available published evidence and local criteria, to meet the needs of a public hospital in South Africa.

To develop the MEWS tool, the following objectives were identified:

1. To identify best practice vital signs 'track' and 'trigger' interventions (MEWS cut points (thresholds), weighted trigger points and callout algorithms, pen-and-paper observation charts with clinical indicators and calling criteria) aimed at improved recording and consistent interpretation of vital sign recordings and early clinical responses, for use in the South African context, from available published evidence.
2. To construct a preliminary prototype MEWS range of cut points (thresholds) for physiological parameters with corresponding weighted trigger points (0, upper and lower 1 to 3) from published evidence.
3. To design a preliminary prototype observation chart incorporating the preliminary cut points for physiological parameters with corresponding weighted trigger points (0, upper and lower 1 to 3), callout algorithm and clinical indicators.
4. To use the preliminary prototype MEWS observation chart to establish local criteria for, and to determine the construct and content validity of a final MEWS observation

chart, callout algorithm and 'calling criteria', through expert opinion and to modify the preliminary instrument based on the outcome.

5. To pilot test the chart to establish accuracy of recording vital signs on the MEWS observation chart.

3.4 Methods for the validation study

3.4.1 Research description and design

A descriptive analytical study design was employed for developing and validating a prototype observation chart that incorporated an existing MEWS. This then informed the development and validation of the final Cape Town Ward MEWS chart that was subsequently subjected to pilot testing for accuracy of charting. The diagram of Study One is presented in Figure 3-1.

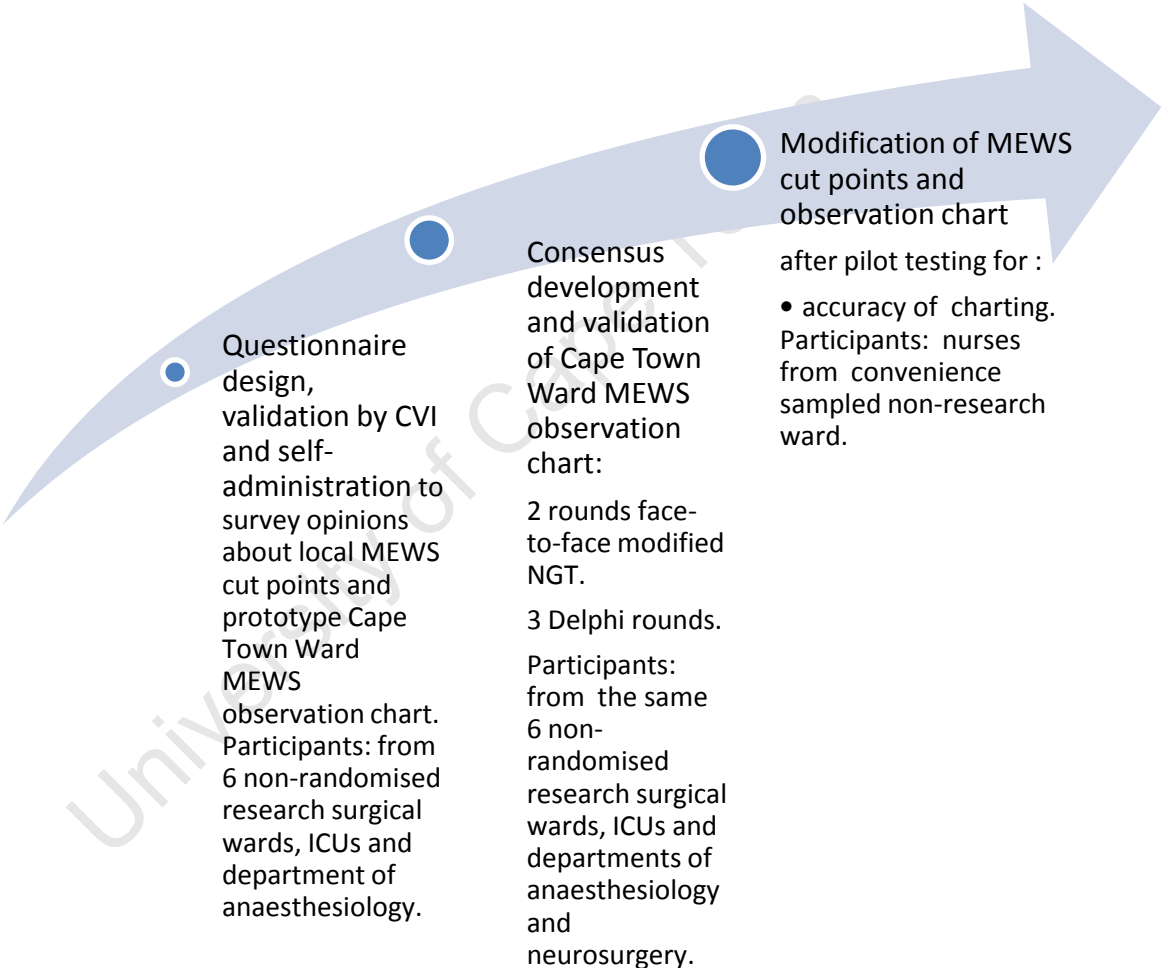


Figure 3-1: Diagram of Study One

NOTE on Figure 3-1: NGT denotes nominal group technique. CVI denotes Index of Content Validity.

3.4.2 Participants: sampling

The researcher took the role of leader in the research activities.[i] Inclusion criteria for participants for internal validation of the questionnaire, the survey and consensus development and validation of the MEWS and sampling are summarised in

Table 3-1. Pilot testing the MEWS chart for accuracy of charting was conducted on one purposively sampled non-research ward.

Table 3-1: Subjects and sampling methods for research activities

Research activity	Sampling method	Inclusion/exclusion criteria	Respondents/Participants	Rationale
Internal validation of Questionnaire using index of content validity (CVI) criteria	Purposive sampling	Experts in clinical physiology and health sciences research were included. All other participants were excluded.	Two Clinical experts in vital sign physiology: • a PhD specialist anaesthesiologist • a Master's CCN/lecturer • One international health science researcher scrutinized the final version of the questionnaire after modification	Expert knowledge
Self-administration of Questionnaire	No random selection; sample size was determined by the number of eligible respondents	At least one of the following: • Registration with the SANC as a CCN. • A specialist qualification in anaesthesiology. • A specialist qualification in surgery. • A specialist qualification in emergency medicine. • Current position as registrar. There were no exclusion criteria. The sample included all those who met the	• All medical staff providing services to the 6 research wards (N=50) • All trained CCNs working in ICUs in the Hospital (N=48) were eligible to complete the questionnaire These estimated numbers were obtained from the departmental secretary and nursing management personnel respectively at the research site	To establish baseline cut points for physiological parameters for the local MEWS. CCNs rather than ward nurses were selected because CCNs have accredited competence in patient monitoring

[i] A registered critical care nurse (CCN)

Research activity	Sampling method	Inclusion/exclusion criteria	Respondents/Participants	Rationale
		criteria (n=98 potential respondents)		
Consensus development and validation of the MEWS	Purposive sampling	Medical experts in clinical physiology and health sciences research (including CCNs) and senior ward nurses with expertise in bedside monitoring.	• 1 PhD specialist anaesthesiologist who had validated the questionnaire • 1 PhD emergency medicine specialist with experience in implementing a triage early warning system (TEWS) in Cape Town[193] [192] [106] • 2 CCNs/lecturers with a Master's degree one of whom had validated the questionnaire and one who had participated in the survey by questionnaire • 1 PhD neurosurgeon • 6 'head' nurses from each of the 6 research wards; • 2 surgical nurse operational managers • 1 PhD specialist surgeon	A mixed panel of experts represents the diversity found on a ward who are all involved in bedside monitoring to some extent
PILOT TESTING MEWS chart: • Accuracy (% correctness) of charting	Purposive sampling of one non-research ward. Convenience sampling of ward nurses on duty on two consecutive days.	A Surgical ward not involved in the study Patients who gave verbal consent to participate in the study (having vital signs taken and recorded by 2 nurses). Copies of the information sheet were given to each patient. Nurses who gave verbal consent to use the MEWS chart for postoperative recording of vital signs	Registered Professional Nurses (RPNs) but a Registered Staff Nurse (RSN) participated voluntarily for one observation time-point when the RPN was unavailable	After 'on the spot' training on the ward, it was expected that RPNs would have competence in ascribing and transcribing correct physiological parameters on the MEWS chart

Note on table: CCN - critical care nurse; ICU – intensive care unit.

3.4.3 Instrument construction and scaling and validation methods

Three instruments were developed: a) preliminary prototype MEWS observation chart, b) questionnaire and c) consensus ranking sheet.

A summary of validation methods for the three data tools is presented in Table 3-2.

Table 3-2: Validation methods for Study One research instruments

Research instrument	Validation method
Observation chart incorporating published MEWS cut points and weighted trigger points	**1.** Statistical analysis of questionnaire data **2.** Consensus methods (Delphi and modified NGT) **3.** Statistical analysis of pilot test data: ○ Statistical analysis of percentage correct responses
Self-administered questionnaire	**1.** Statistical analysis of expert panel's evaluation of: ○ Index of Content Validity (CVI) ○ Construct validity
Consensus ranking sheets	None

3.4.3.1 Development of preliminary MEWS cut points with corresponding weighted trigger points and prototype Observation Chart

A preliminary scoring system for physiological parameters was developed (Table 3-3) and thereafter a preliminary prototype 'observation chart' incorporating the existing MEWS was developed (Figure 3-2) in three phases.

Phase 1. The starting point was to search the literature for existing, preferably validated physiological parameters with MEWS cut points (thresholds) and corresponding weighted[ii] trigger points (0='normal', upper and lower score of 1 to 3) that are associated with in-hospital death. The preliminary range of parameters and scores constructed from the literature is presented in (Table 3-3).

[ii] The allocation of points to routine vital sign measurements on the basis of their derangement from an arbitrarily agreed 'normal' range (Smith, 2007).

Table 3-3: Modified Early Warning Scoring System constructed from the literature

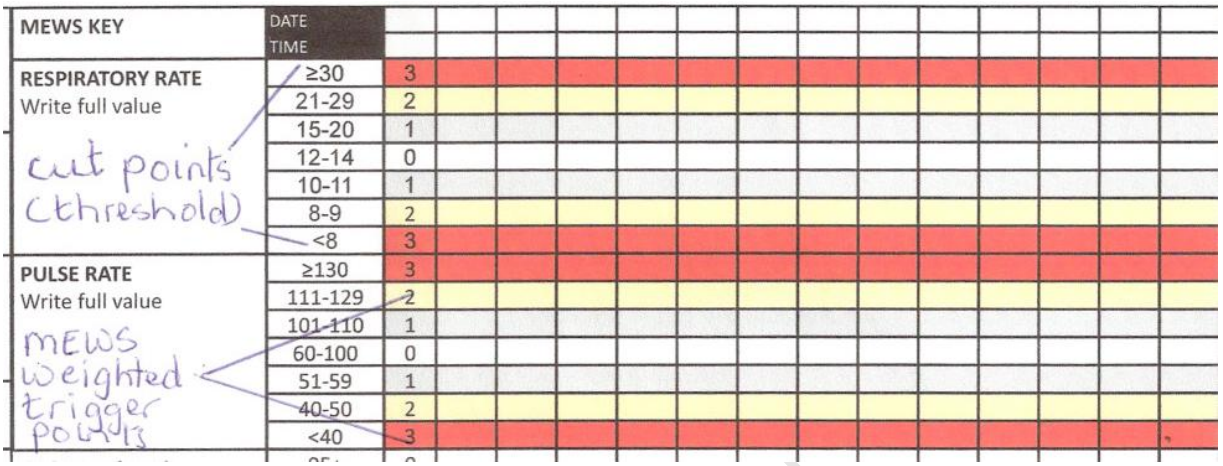
	3	2	1	0	1	2	3
Respiratory rate/min		9 or less		9-14	15-20	21-29	30 or more
SaO_2	<85	85-89	90-92	93+			
Heart rate/min		40 or less	41-50	51-100	101-110	111-129	130 or more
BP systolic	70 or less	71-80	81-100	101-199		200 or more	
Temperature ^{o}C		35 or less		35-38.4		38.5 or more	
NEUROLOGICAL STATUS Glasgow Coma Scale				15	14 Change in mentation	GCS 13-9	GCS ≤8 or unresponsive
OR AVPU				Alert	Reacting to voice	Reacting to pain	Unresponsive
Urine mls/kg/hr	<0.5ml/kg/1h or less		1ml/kg/1h or less	If normally anuric score 0	3ml/kg/1h or more		
Aggregated score = GCS 15 = A; GCS 14 = V; GCS 13—9 = P; GCS ≤8 = U							
Interpretation: Aggregated MEWS: 3 = critical score							

(Adapted from Subbe, C.P., Kruger, M., Rutherford, P and Gemmel, L., 2001; Harrison, G.A., Jacques, T., McLaws, M., and Kilborn, G., 2006[102]; Morrice, A., Simpson, H.J., 2007[187]; http://www.nice.org.uk/nicemedia/media/sharedlearning/96_Observation%20Chart%20NICE.pdf[128], ACT Health Policy: Modified Early Warning Scores 2009[198]).

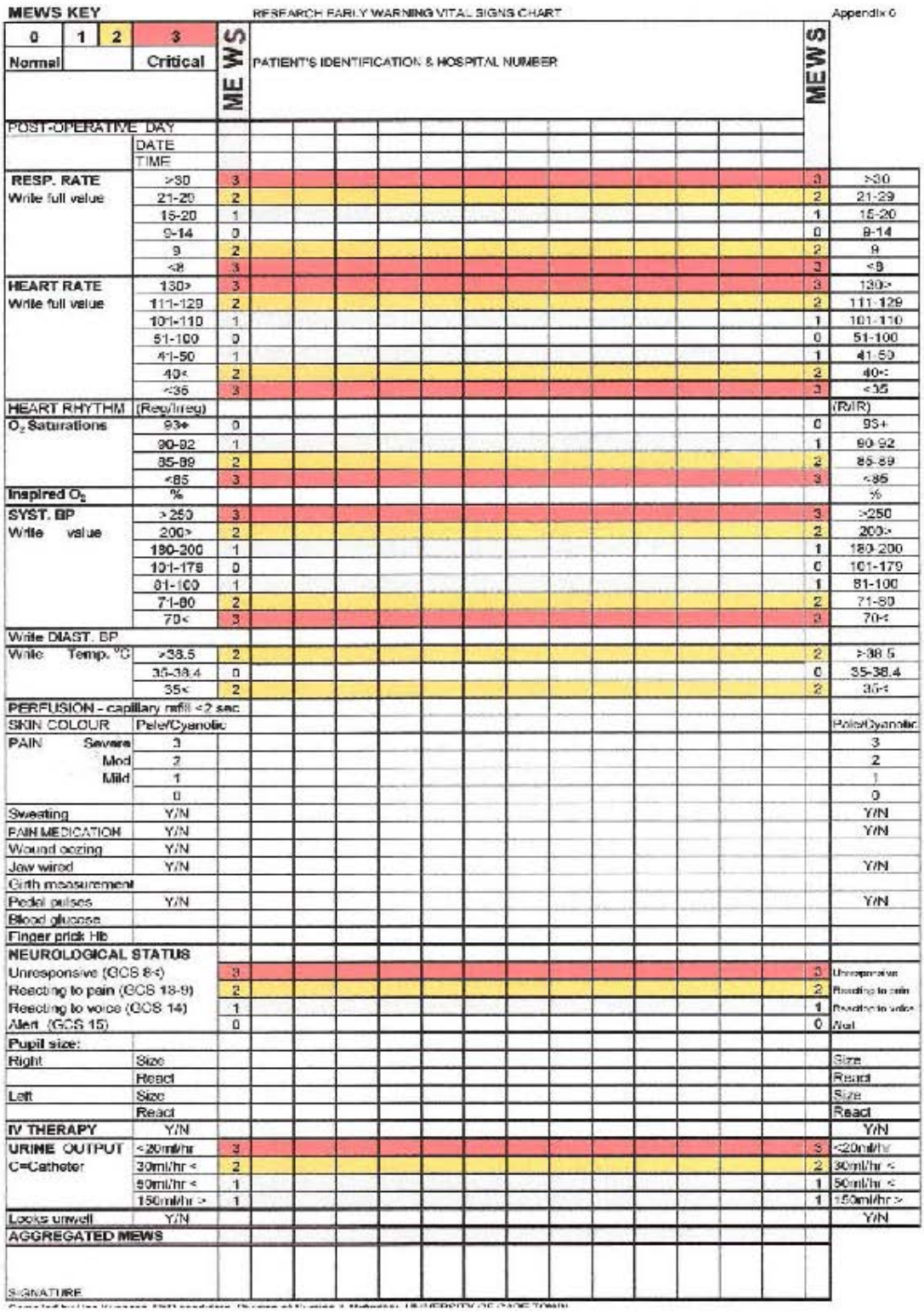
Phase 2. This was followed by a search for existing observation charts used by nurses that incorporated a MEWS but also criteria for clinical signs of deterioration (for example 'skin pallor'). The next step was to do an 'eyeball' comparison between all charts, using subjective criteria such as layout, content and degree of ease of use.

Phase 3. The seven physiological parameters (respiratory rate, oxygen saturation (SaO_2), heart rate, systolic BP, temperature, neurological status, urine output) selected from the published literature in the table above each had a range of MEWS cut points (thresholds) and corresponding weighted trigger points (0, upper and lower 1 to 3) (Table 3-4) and were incorporated into the preliminary prototype observation chart (Figure 3-2).

Table 3-4: Example of MEWS cut points and weighted trigger points



Each variable was partitioned for the recording of actual readings (eg. respiratory rate of 21; systolic of 125) for that cut point range. In contrast, on the existing chart used at the Hospital, actual values were represented by symbols (x, •) plotted in graph form as an estimation of actual readings. Although severity of illness was indicated on the chart as a MEWS of 3 being critical, a callout algorithm was not included in the preliminary tool.



MEWS KEY

0	1	2	3
Normal			Critical

RESEARCH EARLY WARNING VITAL SIGNS CHART

Appendix 6

		MEWS	PATIENT'S IDENTIFICATION & HOSPITAL NUMBER	MEWS	
POST-OPERATIVE DAY					
	DATE				
	TIME				
RESP. RATE	>30	3		3	>30
Write full value	21-29	2		2	21-29
	15-20	1		1	15-20
	9-14	0		0	9-14
	9	2		2	9
	<9	3		3	<9
HEART RATE	130>	3		3	130>
Write full value	111-129	2		2	111-129
	101-110	1		1	101-110
	51-100	0		0	51-100
	41-50	1		1	41-50
	40<	2		2	40<
	<35	3		3	<35
HEART RHYTHM	(Reg/Irreg)				(R/IR)
O_2 Saturations	93+	0		0	93+
	90-92	1		1	90-92
	85-89	2		2	85-89
	<85	3		3	<85
Inspired O_2	%				%
SYST. BP	>250	3		3	>250
Write value	200>	2		2	200>
	180-200	1		1	180-200
	101-179	0		0	101-179
	81-100	1		1	81-100
	71-80	2		2	71-80
	70<	3		3	70<
Write DIAST. BP					
Write Temp. °C	>38.5	2		2	>38.5
	35-38.4	0		0	35-38.4
	35<	2		2	35<
PERFUSION - capillary refill <2 sec					
SKIN COLOUR	Pale/Cyanotic				Pale/Cyanotic
PAIN Severe	3				3
Mod	2				2
Mild	1				1
	0				0
Sweating	Y/N				Y/N
PAIN MEDICATION	Y/N				Y/N
Wound oozing	Y/N				
Jaw wired	Y/N				Y/N
Girth measurement					
Pedal pulses	Y/N				Y/N
Blood glucose					
Finger prick Hb					
NEUROLOGICAL STATUS					
Unresponsive (GCS 8<)		3		3	Unresponsive
Reacting to pain (GCS 13-9)		2		2	Reacting to pain
Reacting to voice (GCS 14)		1		1	Reacting to voice
Alert (GCS 15)		0		0	Alert
Pupil size:					
Right	Size				Size
	React				React
Left	Size				Size
	React				React
IV THERAPY	Y/N				Y/N
URINE OUTPUT	<20ml/hr	3		3	<20ml/hr
C=Catheter	30ml/hr <	2		2	30ml/hr <
	50ml/hr <	1		1	50ml/hr <
	150ml/hr >	1		1	150ml/hr >
Looks unwell	Y/N				Y/N
AGGREGATED MEWS					
SIGNATURE					

Figure 3-2: Prototype MEWS observation chart incorporating preliminary MEWS cut points

3.4.3.2 Construction and validation of a questionnaire to survey opinions on a local MEWS

Phase 1. The prototype MEWS observation chart was ready to be validated but no published instrument with criteria to validate such a chart was available so a semi-structured questionnaire was constructed (Appendix 3.1) to survey nurses and doctors' opinions concerning the prototype chart (Figure 3-2).

Phase 2. The 65-item questionnaire (with two optional items) (3.1) dealt with five constructs relevant to the prototype MEWS observation chart (Figure 3-2) shown with excerpts:

- Section A – ranked importance of 7 physiological and 10 clinical variables.

SECTION A: VARIABLES: early warning physiological and clinical signs of deterioration.

A1. Please rank the order of importance of each of the following **physiological** variables for **early recognition** of signs of **deterioration**. 1 = most important and 7 = least important.

		Ranking
A1.1	Respiratory rate	
A1.2	Heart rate	

A2. Please rank the order of importance of each of the following **clinical** variables for **early recognition** of signs of **deterioration**. 1 = most important and 10 = least important.

		Ranking
A2.1	Perfusion – capillary refill	
A2.2	Skin colour – pallor/cyanosis	

- Section B – agreement with preliminary existing MEWS.

SECTION B: (MODIFIED) EARLY WARNING SCORE (MEWS) [explanation given]

The scoring system below with the respective values for each physiological parameter is taken from the literature. The values for discrete physiological parameters (for example: heart rate of 40 bmp) are scored (MEWS = 2) but an aggregate weighted score can also be calculated for all the parameter readings taken at a particular time. If you disagree with the values for each score please give suggested values that you think are suitable for the South African context.
Please answer all the questions. Cross only one response for each question.

1. 0 = normal value; 1 (upper or lower) = early sign of deterioration; 2 (upper or lower) = serious sign of deterioration; and 3 = critical condition requiring urgent attention. You will notice that there are no values for certain scores for some of the parameters.
2. In the shaded section indicate whether you **agree or disagree** with the validated scores for EACH of the following variables:
3. If you disagree **give a suggested value**.

B1 **RESPIRATORY RATE** MEWS score**:**

3	2	1	0	1	2	3
	9 or less		9-14	15-20	21-29	30 or more

ANSWER:

B1.1 Agree ☐ **Disagree** ☐

B1.2 Suggested values:

3	2	1	0	1	2	3

Section C – comparison of attributes and layout of the research MEWS chart and the existing chart (Appendix 3.2).

SECTION C: Research 'Observation Chart' (attached)

Please answer all the questions. Cross only one response for each question:

Indicate if you Strongly Agree (SA), Agree (A), are Undecided (U), Disagree (D) or Strongly Disagree (SD) with each of the following statements:	**SA**	**A**	**U**	**D**	**SD**
C1. The chart is very useful for the identification of **physiological** deterioration					

C5. OPTIONAL OPEN-ENDED QUESTIONS:

C5.1 The research chart has the following **limitations compared to the current observation chart** (attached):

C5.2 The research chart has the following strength**s compared to the current observation chart**:

- Section D –Callout algorithm.

SECTION D: ALGORITHM FOR CALLOUT CRITERIA

Items D1.1-.7 below serve as a 'Physiological Track and Trigger System' to provide a threshold at which mandatory assistance is summoned.
You are asked to indicate the ONE most appropriate category of professional you think should be called for each of the following situations in which a ward nurse is concerned about a change in a patients' condition.
Please answer all the questions. Cross only one response for each question:

D1. If: Call the following person:

ITEM	Most senior Sister (Professional Nurse)	Intern (MO) responsible for the patient	Registrar	Consultant
D1.1 the nurse is worried about the patient				
D1.2 Change in respiratory rate: D1.2.1 to less than 9/min				

- Section E – Demographics

SECTION E: DEMOGRAPHICS
Cross the box that applies to you/insert information in blank spaces where applicable. Please answer all the questions.

E1.	What is your highest professional qualification?	
E2.	How long have you practised with this qualification?	☐ Years ☐ Months

Respondents' demographic data were requested for descriptive purposes.

Strengths and limitations of the research MEWS chart were indicated using a 5-point Likert-scale with ordinal level of measurement[199] (1 = strongly disagree to 5 = strongly agree with a neutral point of 3 = undecided). A neutral category has the potential for increasing a tendency towards central response bias. The scale was not included on the questionnaire. Twenty-three (23) pre-coded items depicting a range of disturbed physiological parameter readings for a callout algorithm were allocated a 4-point rating scale (1 = professional nurse; 2 = medical officer; 3 = registrar; 4 = consultant) and respondents had to identify who would be most appropriate to call.[164]

Phase 3. To establish the content and construct validity of the questionnaire a 3-part 61-item checklist (Appendix 3.3) was constructed guided by the literature on Index of Content Validity (CVI).[164] Three experts (Table 3-1) established the CVI for internal validation of the questionnaire. The questionnaire incorporated a written explanation of the MEWS.

Part 1 (Sections A - E) of the CVI checklist relates to the same five constructs described above: ranking of physiological and clinical variables, agreement with published MEWS, agreement with the preliminary MEWS observation chart ,callout algorithm and demographics as shown in the following excerpts.

Expert opinion on index of content validity (CVI) of EACH ITEM on the questionnaire:

SECTION A: VARIABLES

Index of content validity (CVI)				
Item (number corresponds with questionnaire)	1 = irrelevant	2 = unable to assess relevance without item revision or item is in need of such revision that it would no longer be relevant	3 = relevant but needs minor alteration	4 = extremely relevant
Item A1.1				

SECTION B: Modified Early Warning Scores (MEWS)

Index of content validity (CVI)				
Item (number corresponds with questionnaire)	1 = irrelevant	2 = unable to assess relevance without item revision or item is in need of such revision that it would no longer be relevant	3 = relevant but needs minor alteration	4 = extremely relevant
Item B1.1				

SECTION C: Research 'Observation Chart' (attached)

Index of content validity (CVI)				
Item(number corresponds with questionnaire)	1 = irrelevant	2 = unable to assess relevance without item revision or item is in need of such revision that it would no longer be relevant	3 = relevant but needs minor alteration	4 = extremely relevant
Item C1.1				
Item A1.2				

SECTION D: ALGORITHM FOR CALLOUT CRITERIA

Index of content validity (CVI)				
Item (number corresponds with questionnaire)	1 = irrelevant	2 = unable to assess relevance without item revision or item is in need of such revision that it would no longer be relevant	3 = relevant but needs minor alteration	4 = extremely relevant
Item D1.1				

SECTION E: DEMOGRAPHICS

Index of content validity (CVI)				
Item (number corresponds with questionnaire)	1 = irrelevant	2 = unable to assess relevance without item revision or item is in need of such revision that it would no longer be relevant	3 = relevant but needs minor alteration	4 = extremely relevant
Item E1.1				

Part 2 of the checklist relates to the questionnaire in its entirety as shown in the following excerpt:

Index of content validity (CVI) OF ENTIRE QUESTIONNAIRE

Check only one box:

1 = irrelevant	2 = unable to assess relevance without item revision or item is in need of such revision that it would no longer be relevant	3 = relevant but needs minor alteration	4 = extremely relevant

Part 3 of the checklist relates to the construction of the questionnaire as shown in the following excerpt:

Evaluation of CONSTRUCT VALIDITY
Please check one box for each statement relating to the questionnaire.

	Very skilful	Satisfactory	Needs improvement	Unacceptable
Layout				
Format				

Each of the sections had an optional open-ended question for omissions and/or comments. A 4-point ordinal rating scale was allocated to 53 items (1 = irrelevant; 2 = unable to assess relevance without item revision or item is in need of such revision that it would no longer be relevant; 3 = relevant but needs minor alteration; 4 = extremely relevant). Criteria for the 4-point ordinal rating scale for the remaining 8 items relating to construction were different: 4 = very skilful; 3 = satisfactory; 2 = needs improvement; 1 = unacceptable.

- *Validation results for Index of Content Validity (CVI) of the questionnaire*

Overall, the questionnaire had a high CVI (Table 3-5) with all respondents agreeing that every item on physiological signs of deterioration was either extremely relevant or relevant but needed minor alteration. With regard to the clinical signs of deterioration, the majority of respondents regarded the items as being relevant but in each of the items on pain score, pain relief, wound/plugs and girth measurement there was one dissenting respondent who regarded the item as irrelevant or unable to assess relevance without item revision.

Table 3-5: Three Experts' ratings for index of content validity (CVI) for all questionnaire items

CVI for Items relating to	1 irrelevant	2 unable to assess relevance without item revision or item is in need of such revision that it would no longer be relevant	3 relevant but needs minor alteration	4 extremely relevant
PHYSIOLOGICAL VARIABLES:				
Item A1.1 Respiratory Rate				3 (100.0%)
Item A1.2 Heart rate				3
Item A1.3 S_aO_2				3
Item A1.4 Systolic BP			1 (33.3%)	2 (66.7%)
Item A1.5 Temp			1	2
Item A1.6 Neuro AVPU				3
Item A1.7 Urine			1	2
CLINICAL VARIABLES:				
Item A2.1 Perfusion				3
Item A2.2 Skin colour				3
Item A2.3 Pain score		1 (33.3%)		2
Item A2.4 Sweating				3
Item A2.5 Pain relief	1 (33.3%)			2
Item A2.6 Wound/plugs		1		2
Item A2.7 Girth measurement		1	1	1 (33.3%)
Item A2.8 Finger prick Hb				3
Item A2.9 Looks unwell				3
MEWS values/cut points				3
Research Observation Chart: usefulness and limitations				3
REFERRAL/CALLOUT ALGORITHM				
… the nurse is worried about the patient			1 (33.3%)	2 (66.7%)
…change in respiratory rate			1	2
…change in heart rate			1	2
…change in systolic BP			1	2
…change in pulse oximetry saturation			1	2
… change in conscious state			1	2
… change in urine output			1	2
Respondent demographics				3 (100.0%)
Entire questionnaire			1	2

EVALUATION OF CONSTRUCT VALIDITY	Unacceptable 1	Needs improvement 2	Satisfactory 3	Very skilful 4
Layout			3 (100.0%)	
Format			1 (33.3%)	2 (66.7%)
Quality of printing			1	2
Length of the questionnaire			2 (66.7%)	1 (33.3%)
The response scale of 1-4			2	1
If visually easy to read			1	2
If visually easy to comprehend		1 (33.3%)	1	1
If instructions at the beginning of the questionnaire are clear and easy to understand		1	1	1

Most importantly, on a scale of 1-4 the questionnaire had a high CVI (a rating of 3-4) related to selection of physiological variables and MEWS cut points (thresholds) for each variable with corresponding weighted trigger points (0, upper and lower 1 to 3). Likewise, to the item on the usefulness and limitations of the research observation chart with all respondents agreeing that every item was extremely relevant. Experts suggested additional clinical and biochemical parameters but with the full agreement of each expert these were discarded as more suited to an intensive care unit chart than one for a general ward and not supported in the literature. The one exception was blood glucose monitoring that was added to the chart.

All respondents agreed that every item on the callout algorithm was either extremely relevant (4) or relevant but needed minor alteration (3). On the recommendation of one expert , supported by the others, the questionnaire was modified by aligning cut points and corresponding weighted trigger points (0, upper and lower 1 to 3) for each physiological parameter with four levels of consultation for callout: professional nurse, medical officer, registrar and consultant.

All experts agreed that every item related to respondent demographics was extremely relevant indicating a high CVI. Wording was changed to highest 'professional' qualification. On a scale of 1-4 the questionnaire as a whole had a high rating (3-4) for construct validity. Not one respondent found any item unacceptable.

3.4.3.3 Development of the consensus ranking sheet

A poor questionnaire response rate (section 3.5.1.7) required another method of validating the preliminary local MEWS. Consensus methods by clinical experts were explored. A consensus ranking sheet was developed in two phases.

Phase 1. The first step was a literature search of published evidence on consensus methods and appropriate research instruments. The modified nominal group technique (NGT) and Delphi method seemed feasible even though not previously used for this purpose.

Phase 2. A consensus ranking sheet (Table 3-6) was constructed with a scale of 0 "total disagreement" to 9 "total agreement"[148] using a predetermined 3-point scale to interpret participants' rankings as: low tertile (0 to 3) ranking, equivocal ranking (4 to 6) and as high tertile (7 to 9) ranking as shown below:

0 1 2 3 Low tertile agreement	4 5 6	7 8 9 High tertile agreement
Total disagreement	Equivocal	Total agreement

Published studies accepted consensus as agreement at ≥70%[152] at a high tertile and this was adopted by consensus for the study. The question to consider was how to apply the agreed predetermined cut point, so for Round 1 each MEWS value for each parameter had a ranking. The next question was how to enforce this agreement. Published consensus studies reported having 'strict' rules (all ratings are within a predefined 3 point region (1-3, 4-6, 7-9) and 'relaxed' rules (ratings fall within a 3 point region but not within a predefined region. It was agreed by consensus that the strict rule would apply for rankings between 7-9 at 70% agreement. During the final Round 5 face-to-face conference participants accepted agreement at lower percentage but still within the high tertile (7-9) for certain MEWS (sections 3.5.2.5).

Experts had a choice of ranking either the published MEWS or questionnaire derived MEWS. Alternatively, a new range of cut points and weighted trigger points for each variable could be generated (Table 3-6). Having three choices and having to rank each MEWS (3, 2, etc.) for each parameter complicated the ranking and consensus process for Round 1. The ranking sheet required private ranking.

Table 3-6: Round 1 consensus ranking sheet (using Respiratory Rate (RR) as example)

Instruction 1:

1.1 From the published values for **each** MEWS (3, 2 etc.) below or the results of the QUESTIONNAIRE for **each** MEWS select the ONE value you prefer by making a tick √ in that box [i.e. either a published value **or** questionnaire result value].

1.2 Indicate the extent to which you agree or disagree with your selection by circling the appropriate number (0 = total disagreement and 9 = total agreement) for each box.

RESPIRATORY RATE MEWS score**:** [Questionnaire 12/14; 85.7% agreement]

MEWS	3	2	1	0	1	2	3
RR value (published)	Blank	9 or less	Blank	9-14	15-20	21-29	30 or more
Questionnaire	***<9***	***9 or less***	***10-12***	***12-14***	***15-20***	***21-29***	***30 or more***
	0 1 2 3 4 5 6 7 8 9	0 1 2 3 4 5 6 7 8 9	0 1 2 3 4 5 6 7 8 9	0 1 2 3 4 5 6 7 8 9	0 1 2 3 4 5 6 7 8 9	0 1 2 3 4 5 6 7 8 9	0 1 2 3 4 5 6 7 8 9
Instruction 2:	**Change the values for each MEWS if necessary**						
Instruction 3:	**Tick the values requiring callout for assistance**						
Instruction 4:	**Indicate the category of professional to call in each instance (PN, MO, Registrar (R), Consultant (C))**						

(Adapted from Jones & Hunter, 1995:378)

After pilot Round 1 the complexity of the ranking process was reduced by modifying the ranking sheet so that for subsequent rounds ranking (0-9) was done for only one full set of values for each variable (Table 3-7) and not for each score as in the example above.

Table 3-7: Modified consensus ranking sheet

RESPIRATORY RATE							
MEWS weighted values	**3**	**2**	**1**	**0**	**1**	**2**	**3**
RR cut points (published)	Blank	9 or less	Blank	9-14	15-20	21-29	30 or more
Questionnaire cut points	***<9***	***9 or less***	***10-12***	***12-14***	***15-20***	***21-29***	***30 or more***
	0 1 2 3 4 5 6 7 8 9						

3.4.4 Procedure

3.4.4.1 Gaining access

Before obtaining ethical approval for the study the researcher had exploratory discussions with the Deputy-Director of Nursing and the Head of the Department of Surgery at the Hospital about recruiting staff for voluntary participation. Both indicated a willingness to inform staff of their support for the study after ethical approval had been obtained.

A summary of procedures is presented in Table 3-8.

Table 3-8: Outline of procedures for the four research activities in Study One

Research activity	Procedure
Establish internal validity (construct and content validity) of the questionnaire before distribution (Described under Instrumentation section)	• A researcher-designed checklist for the index of content validity (CVI) (Appendix 3.3) to ensure a uniform evaluation of the questionnaire was hand delivered to and collected from each assessor. • The CVI of each item and of the questionnaire as a whole was established using a 4-point ordinal rating scale, [164] a 5-point Likert-scale and open-ended questions. • A rating of 3 or 4 indicated a high CVI. • To establish construct validity, the checklist asked about layout, format, quality of printing, if visually easy to read and comprehend and if instructions at the beginning of the questionnaire were clear and easy to understand.[162] • Results were analysed and the questionnaire was modified.
Self-administration of validated semi-structured questionnaire in a descriptive survey	**For the nurses:** • The researcher personally recruited trained CCNs on day and night duty and distributed the questionnaire and consent form in self-addressed envelopes. • A marked research box in the Assistant Manager's office was an option to internal mailing or electronic mailing. **For medical staff:** • The Head of Surgery offered to recruit medical staff in the research wards at a clinical meeting and to distribute the questionnaires and consent form. • Labelled boxes for completed questionnaires and separate boxes for consent form were placed at strategic places in the 6 research wards and emptied daily by the researcher.
Consensus development of the MEWS cut points and weighted trigger points and of the callout algorithm	**Pilot Round 1: Face-to-face group meeting** • Personal invitations by e-mail and/or interview prior to meeting • Literature provided on: consensus development, nominal group technique and EWS/MEWS • At the meeting: an overview of the study was presented • Private ranking: participants were given a ranking sheet and had three options: o to indicate the extent to which they agreed or disagreed with the published MEWS for **each** of seven physiological parameters by circling the appropriate number from 0-9 below each MEWS (0 = total disagreement; 9 = total agreement) [7-9 indicated a high tertile of agreement; 1-3 the lowest tertile] (see Table 3-6); or, if they disagreed strongly they could o do the ranking for baseline MEWS data that emerged from the questionnaire; or if none of the above values were acceptable, they could o generate a new range of MEWS values for each variable on the sheet. **Round 2: electronic or postal Delphi: Re-ranking results from Round 1** • Rules of agreement were defined: a MEWS value for each variable would be accepted if there was a 70% rating by all participants in the 'high agreement' tertile of scores (7-9). **Round 3: electronic or postal Delphi: Re-ranking results from Round 2** **Round 4: electronic or postal Delphi: Re-ranking results from Round 3**
	Round 5: Face-to-face modified NGT: Final ranking, presentation of results and consensus • Participants provided with a summary of Round 4 results and their own results • MEWS ranges and outlay of the chart were approved by consensus.
Pilot testing final version of MEWS observation chart	The MEWS observation chart was tested (on a ward not involved in the study) for: • percentage correct charting by nurses where accuracy meant: writing (ascribing and transcribing) the value of the physiological parameter in the correct box on the chart (using parameter cut points as the reference ('gold' standard)).

3.4.4.2 Descriptive survey

The questionnaire and two copies of the consent form (one to be retained by respondents) were distributed on 2 September 2009 and collected weekly until 18 September as follows:

- After providing a full explanation about the study and a request for voluntary participation, the researcher distributed hard copies to 25 ICU Nurse Operational Managers and ICU/CCN (terms are used interchangeably) registered professional nurses (RPNs) and one ICU trained nurse researcher who were available during this period. A completed questionnaire unaccompanied by a signed consent form was regarded as assenting to participate in the study.
- The Head of Surgery and the Head of the Division of Neurosurgery assisted with the distribution of the questionnaire and consent form to surgeons who met inclusion criteria. The researcher collected completed questionnaires from four central points.
- A specialist in emergency medicine who had participated in a cited study [27] introducing a MEWS for triage in emergency departments in Cape Town agreed to participate.

The survey was followed by further validation of the local MEWS by employing Delphi[27] and modified nominal group consensus methodology.[146]

3.4.4.3 Consensus development and validation of the Cape Town Ward MEWS

• Pilot Round 1: Face-to-face consensus meeting

The researcher invited 14 participants (Table 3-9) by e-mail and/or interview to a one-hour face-to-face consensus development workshop in the Hospital's conference facilities. Prior to the meeting, participants were sent literature on MEWS systems (Appendix 3.4), consensus methods for problem solving in health care (Appendix 3.5), and a copy of the questionnaire derived MEWS cut points and weighted trigger points on a ranking sheet (Appendix 3.6). At the meeting a consent form (Appendix 3.7) was provided. A facilitator experienced in group work (PM) assisted with the process. A combination of both the Delphi and Modified Nominal Group Technique was

employed to measure the appropriateness of parameters of EWS of clinical and physiological deterioration, hitherto not used in this context.

The aim of the first consensus meeting was three-fold: firstly, to determine the extent to which nursing and medical experts in vital sign monitoring agreed on the most appropriate cut points and corresponding MEWS weighted trigger points (0, upper and lower 1 to 3) for each physiological parameter. Secondly, alternatively to generate new cut points and scores to serve as the 'gold standard'; and thirdly, to reach consensus on 'calling criteria. The attempt to establish calling criteria was abandoned after the pilot round as the MEWS exercise was difficult and time consuming but it was completed during round 5. The ranking sheet was modified after the pilot round and is reported on in the results section (3.5.2).

- *Delphi Rounds (2-4)*

A Delphi is an economical use of participants' time and was employed for the subsequent three rounds. Those nurses who did not have e-mail access had meetings with the researcher to clarify the ranking process, either in pairs or individually as preferred. The mix of participants varied for each consensus round (Table 3-9) and when compared to those sampled (Table 3-14).

Table 3-9: Participants (n) for consensus methods

Consensus method	Participants
Pilot Round 1: face-to-face modified nominal group technique	n=11/14 (78.6%) • 1 PhD-prepared specialist anaesthesiologist (from the previous sample who had validated the questionnaire); • 1 PhD-prepared emergency medicine specialist with experience in implementing a triage early warning system (TEWS) in Cape Town[193 192 106] (from the previous sample who had validated the questionnaire); • 2 Master's-prepared CCNs/lecturers (one was from the previous sample who had validated the questionnaire and the other was from the previous sample who had participated in the survey); • 4 head nurses from the 6 research wards; • *1 enrolled nurse representing a head nurse (leaving 1 ward not represented) • 2 surgical nurse operational managers. *had difficulty understanding the MEWS and the ranking process - subsequently re-ranked by the head nurse of the ward *Non-participants (n=3/14, 21.4%):* *1 specialist general surgeon (invited)* *1 specialist neurosurgeon (invited)* *1 head nurse (invited)*
Round 2: Delphi	12 Ranking sheets distributed: 11 to Round 1 participants and 1 to the absent head nurse. n=10 Completed ranking sheets *excluding 1 surgical nurse operational manager and 1 head nurse*
Round 3: Delphi	n=10 participants from Round 2 who returned completed sheets and did so again
Round 4: Delphi	n=10 participants from Round 3 who did so again
Round 5: face-to-face modified nominal group	n=8 (7/10 from round 4 and a specialist neurosurgeon participant from the survey) Non-participants from round 4: 1 emergency medicine specialist; 1 Master's-prepared CCN/lecture; 1 head nurse

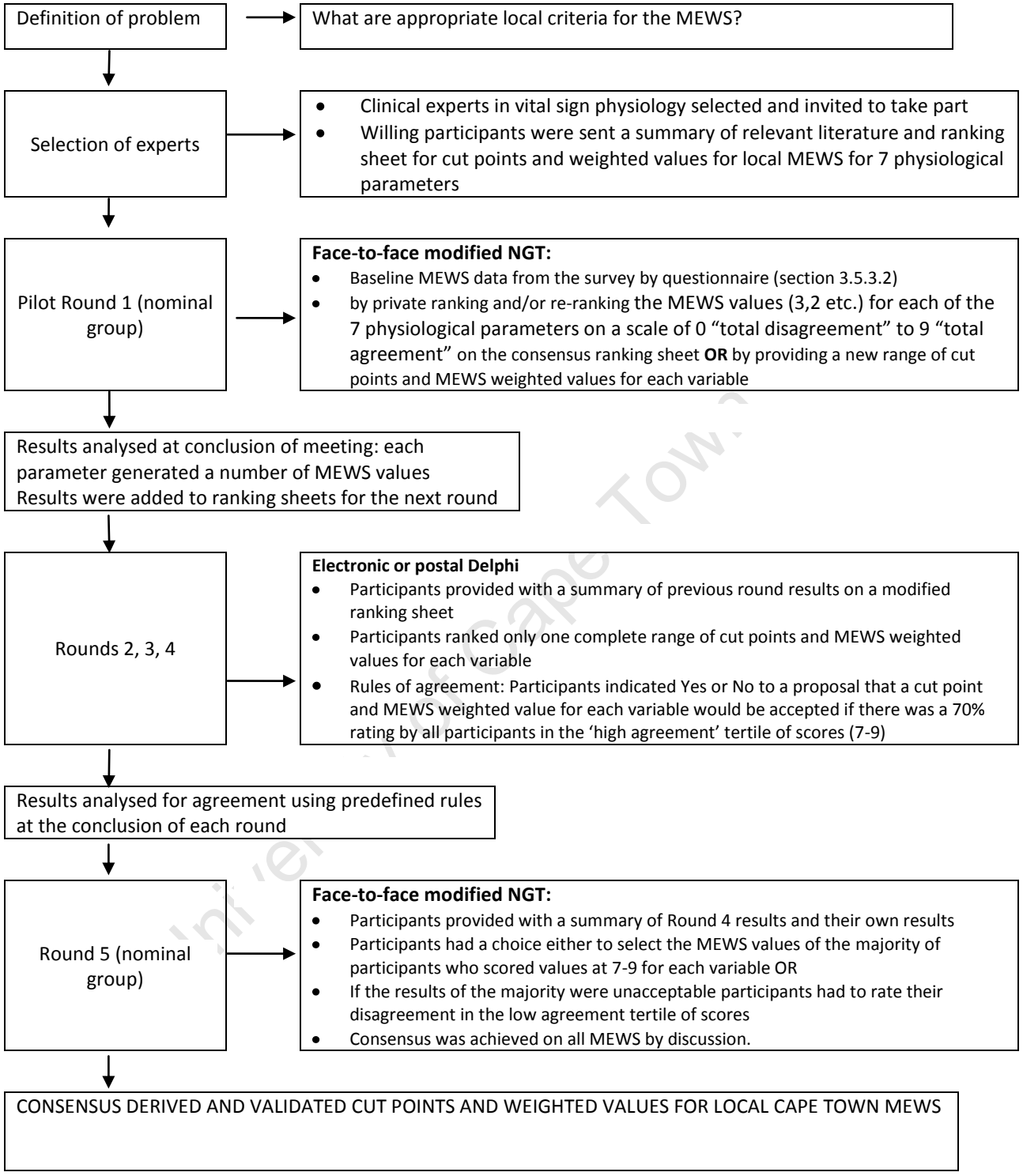
• *Round 5 (face-to-face consensus meeting)*

A Microsoft Office PowerPoint (2007)® presentation covered the MEWS process to that point and provisional objectives were presented and modified by the group. The four-fold aim of the one hour final face-to-face consensus meeting (round 5) was reached by consensus: first, to establish agreement on pre-determined MEWS cut points and weighted trigger points (0, upper and lower 1 to 3) for respiratory rate, oxygen saturation (SpO_2), temperature and urine output from Round 4 as concerns were raised by the neurosurgeon. Secondly, to establish a callout algorithm[iii] (incorporated in the preliminary MEWS chart Figure 3-2) as this was not included in the preliminary tool (section 3.4.3.1). Thirdly, to make final changes to the layout of MEWS observation chart; and finally, to reach consensus on separate 'calling criteria' derived from the

[iii] Scoring (tracking) indicates a level of urgency for triggering a response. A single parameter can trigger as well as a total (aggregate) MEWS of all parameters.

MEWS cut points and weighted trigger points. Evaluation of calling criteria would not form part of the present study. A redesigned ranking sheet was provided and shows the final ranking from Round 5 (Appendix 3.8).

The procedures employed for consensus development of the Cape Town MEWS are summarized in Figure 3-3.



(adapted from Jones & Hunter, 1995)[148]

Figure 3-3: Processes involved in consensus methods for developing the Cape Town MEWS

Results of all consensus rounds are reported in section 3.5.2. Consensus derived MEWS values were incorporated into the final research MEWS observation chart (

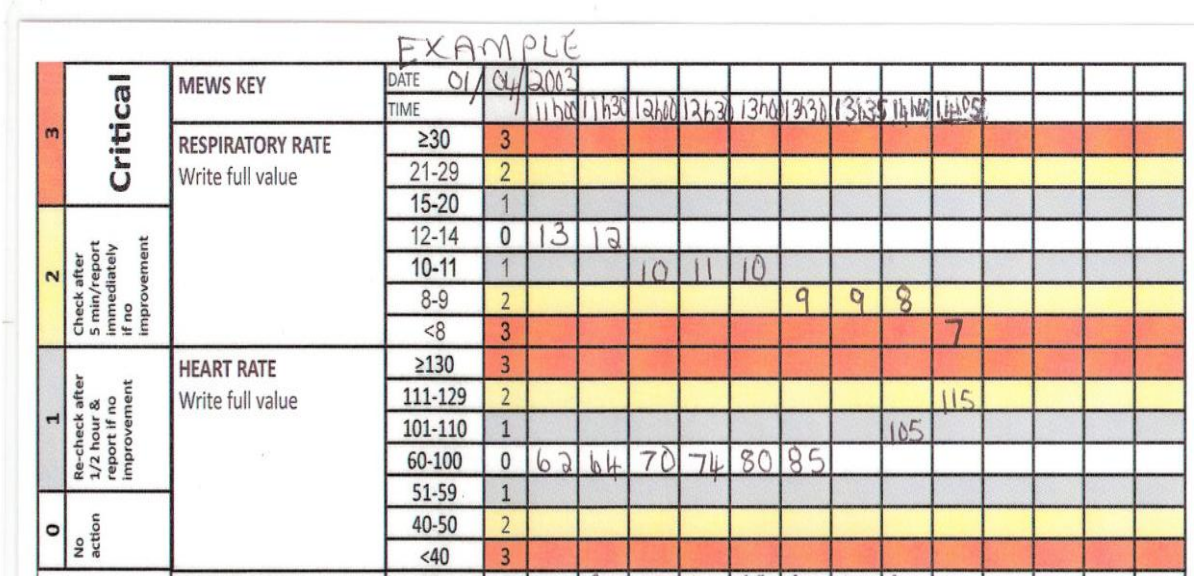
Figure **3-4**) in preparation for the final step: pilot testing the chart.

3.4.4.4 Pilot testing the Cape Town Ward MEWS chart for accuracy (percent correctness) of charting

The MEWS chart was designed to alert nurses to a patient's deteriorating condition by triggering for a single abnormal physiological reading (weighted trigger point, that is, an upper or lower 1 to 3) and for a total MEWS score and this is described as a 'combination' system.

Accurate charting involves three processes (section 2.3.3.2): first, ascribing the correct MEWS cut point (threshold) (Table 3-10) to a reading of a physiological parameter (this serves as the 'gold standard') (for example a respiratory rate of 15 falls within the cut point range of 15-20). Secondly, transcribing this value onto the correct partition on the chart (in this case having a weighted trigger point of 1); and finally, calculating a total score for the MEWS for all physiological parameters. If respiratory rate has a weighted trigger point of 1, if heart rate is ascribed a 2 and all other parameters are ascribed 0, the aggregated MEWS (total score) is 3.

Table 3-10: Physiological parameter MEWS cut points (threshold) and weighted trigger points (0, upper and lower 1 to 3)



• *Accuracy (percent correctness) of charting*[iv]

A measure of correctness of recording on a MEWS chart where the parameter cut points serve as the 'gold standard' is established by percent correctness and binomial 95% confidence intervals, minimally acceptable levels of which should be set *a priori* (personal communication – Landon Myer, epidemiologist). These measures were employed to establish correctness of transcribing each physiological parameter reading onto the final version of the MEWS observation chart.

A surgical ward not included in the study was selected. Verbal consent was obtained from ward nurses who were instructed in the use of the chart. Verbal consent was obtained from five patients able to give informed consent who were invited to participate the day before the scheduled surgery, in accordance with REC approval.

The percentage of correct recording of five predetermined vital signs for a minimum of three observation time-points by two nurses (observers) on five patients was established. Observers were the researcher and a registered professional nurse or staff nurse. Recording was accurate if the physiological reading was charted (transcribed) in the correct place on the chart described in section 3.4.4.4 and Table 3-10. Vital sign measurements were taken in the routine manner for that ward (Table 3-11).

Table 3-11: Method of measuring vital signs for pilot testing the MEWS observation chart

MEWS variable	Method of measurement	Frequency
Respiratory rate	Counted	½ hourly
Heart rate	Dinamap - electronic	½ hourly
Systolic BP	Dinamap - electronic	½ hourly
Temperature	Digital	1 hourly
Neurological status/conscious level	Clinical assessment	½ hourly

[iv] In Study One accuracy testing was limited to correct recording on the MEWS chart (tracking) and did not include trigger responses, that is, nurses' clinical responses and patient outcomes (sensitivity and specificity of the MEWS) which are established in Study Two.

Respiratory rate and conscious level were the only physiological parameters not measured with an electronic device and therefore more likely to achieve different results by two observers. Results are reported in section 3.5.4.

3.4.5 Data management and Statistical analysis

3.4.5.1 Questionnaire

Raw data from the questionnaires were captured on Excel spreadsheets (Microsoft Office Excel 2007) and secured by password protected access by the researcher alone. Data (anonymised) were duplicated on an external drive for safekeeping for three years. To ensure that data were correctly entered a 10% sample (2/15) of the questionnaires was randomly selected by an independent observer[v] (nurse with a PhD), drawing sealed lots.[200] Spreadsheet data were checked for accuracy against questionnaire data. There was 100% agreement.

Statistics were generated using SPSS (version 18) and EpiCalc 2000. Likert scales generate ordinal level data; therefore, medians, ranges and proportions[199] were reported for the survey by questionnaire. Descriptive statistics were used to establish frequency and proportions of responses of nurses (n=8) and doctors (n=7). Mean rankings and standard deviations were calculated.

A threshold of 90% of respondents agreeing with the MEWS for each of the seven physiological variables and with the usefulness of the research observation chart for identifying physiological and clinical deterioration was regarded as satisfactory. Agreement with published MEWS amongst professionals was established statistically by proportions, probability values and 95% confidence intervals (Table 3-17).

Data generated by optional open-ended questions were analysed inductively to a limited extent for content analysis. Open-ended questions gave respondents the opportunity to compare limitations and strengths of the research chart and the current observation chart (section 3.5.1.6).

[v] A nurse with a PhD.

3.4.5.2 Consensus methods

Consensus ranking sheets for agreement were used for face-to-face consensus conferences and Delphi rounds by predefined rules for analysis as described in section 3.4.3.3 that dealt with the construction and interpretation of the ranking sheet.

3.4.5.3 Pilot study

Descriptive statistics were generated using SPSS (version 18) and JavaStat[201] for proportion of charted values entered correctly, plus the binomial 95% confidence intervals, separately for two raters.

3.4.6 Ethical considerations

3.4.6.1 Autonomy, beneficence and respect of persons

Organizational aspects of assuring protection of respondents invited to participate in this study included first, the submission of a Research Proposal to the University of Cape Town, Faculty of Health Sciences' Research Ethics Committee for approval. Secondly, once approved (REC REF 192/2009, Appendix 3.9), a proposal quoting the UCT ethics reference number was submitted to the Provincial Government of the Western Cape and written consent was given to conduct the study at the selected research setting (Appendix 3.10). At institutional level approval for access to the research setting was given by the Chief Medical Superintendent responsible for institutional research (Appendix 3.11) and the Deputy Director of Nursing (DDN) (Appendix 3.12). Respondents were recruited by the researcher and written consent was obtained from each participant for the survey by questionnaire.

The consent form incorporated an Information Sheet (Appendix 3.13). After disclosure of the nature of the study, and the commitment required of respondents, written consent was requested (two copies – one to retain; optional return of the other.

Respondents known to the researcher during distribution of the questionnaire were not anonymous, others were. Nevertheless, identification was only by a unique code for professional category and confidentiality of data was protected by not having respondents' names. The

research site will not be named in the publication of findings. Participants of the nominal groups and Delphi agreed that their presence at the consensus meetings and their participation in the consensus processes was proof of their consent.

3.4.6.2 Justice

Improving patient safety in hospitals is a moral imperative. One such endeavour is to improve the vital signs chart so that it has sensitivity and specificity to 'track' physiological deterioration and 'trigger' a rapid response to save a life. Respondents, who were service providers, were given a fair and just opportunity to contribute to the design of such a chart in this way upholding the ethical principle of justice.

3.4.6.3 Risks and benefits

There were no known or anticipated risks for study respondents. Benefits of the study for respondents include the development of an observation chart to improve 'tracking' early clinical and physiological deterioration in a patient and 'triggering' an appropriate response. Benefits of the study for patients may include a reduction in-hospital SAEs and improved safety. For patients not meeting inclusion criteria who may have experienced critical illness, posters listing calling criteria were prepared for the three intervention wards. Results describing the development of the new chart follow.

3.5 Results of Study One

The results are presented in the following order: the preliminary MEWS table and prototype MEWS observation chart constructed from the literature, consensus validated MEWS cut points for physiological parameters with corresponding weighted trigger points (0, upper and lower 1 to 3) and the final MEWS observation chart incorporating a callout algorithm. 'Calling criteria' were extrapolated from the MEWS by consensus in Round 5 as a separate chart but were not evaluated in the study.

A comparison of variables on the observation chart in use at the Hospital at the time of undertaking the study (Appendix 3.2) and those on the preliminary research MEWS chart (Figure 3-2) is shown in Table 3-12.

Table 3-12: A comparison of variables on the current chart* and research observation chart

VARIABLE	CURRENT OBSERVATION CHART No cut points for variables No weighted values (trigger scores)	RESEARCH OBSERVATION CHART MEWS cut points present MEWS weighted values (trigger scores) present
Patient's Identification & Hospital Number	-	✓
Date	✓	✓
Time	✓	✓
Postoperative day	-	✓
Operation/procedure	✓	-
Temperature	✓	✓ MEWS
Respiratory rate	**-**	✓ MEWS
Pulse	✓	✓ Heart rate MEWS
Blood pressure	✓	✓ Systolic BP MEWS
O_2 saturations	-	✓ MEWS
Oxygen	✓	✓ Inspired O_2
Hb	✓	✓
Wound	✓	✓ oozing
Plugs	✓	-
Blood loss	✓	-
Urinary output	✓	✓MEWS
Circulation	✓	✓ Perfusion/capillary refill
Skin colour – pale/cyanotic	-	✓
Girth measurement	✓	✓
Pedal pulses	✓	✓
Jaw wired	✓	✓
Blood glucose	-	✓
Intravenous therapy	✓	✓
Urinary catheter	✓	✓ MEWS
Neurological observations: GCS: Eyes; Best verbal response; Best motor response	✓	✓ AVPU & GCS MEWS
Pupil size	✓	✓
Pupil reaction	✓	✓
Instructions: Hourly BP, Pulse, Pad + Wound checks for …….. hours	✓	-
Instructions: Fluid balance	✓	-
Instructions: Empty catheter bag … hourly	✓	-
Instructions: Diet	✓	-
Instructions: Analgesia	✓	✓ Pain medication &pain score
Instructions: Other	✓	-
Sweating	-	✓
LOOKS UNWELL	-	✓
Signature	✓ for giving instructions	✓ for each time observations are taken

NOTE on Table: *At least three variations of observation charts were in use in the wards at the Hospital.

The existing chart (Appendix 3.2), when compared to the research chart (Figure 3-2), did not include: patient identification, number of postoperative days, respiratory rate, oxygen saturation levels, skin colour (pale/cyanotic), blood glucose, sweating and 'looks unwell'. When compared to the current chart the research chart did not include: operation/procedure performed, plugs, blood loss, instructions as these could be written under 'Other'.

The preliminary prototype 'observation chart' was designed to track early warning signs of deterioration by:

- triggering for abnormal single parameters
- scoring seven physiological parameters to trigger action at an agreed threshold; and
- by listing clinical signs of deterioration.

3.5.1 Objective: Derivation of provisional Cape Town Ward MEWS by questionnaire

The return rate of questionnaires was poor and is summarized in Table 3-13. Limitations are addressed in section 3.6.5.1.

Table 3-13: Data for questionnaire return rate

Potential respondents (N = 98*)	Questionnaires distributed to clinical areas	Return rate n (%)
	27: CCNs	8 (29.6%)
An additional 25 questionnaires for collection by medical staff from departmental secretary were returned undelivered and were excluded	25: Medical staff	7 (28%)
	TOTAL: 52	15 (28.8%)

Legend: CCN = critical care nurse

3.5.1.1 Demographic profile of survey respondents

Descriptive statistics were used to establish frequency and proportions of responses of nurses (n=8) and doctors (n=7). The demographic profile of respondents included highest professional qualification, years of experience thereafter, period of time working at the Hospital and in the ward/department and attendance at a course on early identification of signs of clinical and physiological deterioration (Table 3-14).

Table 3-14: Demographic profile of survey respondents (N=15)

Professional category	Highest professional qualification (n)	Median number of years of experience after qualification (Range)	Median number of years working at the Hospital (Range)	Median number of years working in the ward/department (Range)	Frequency of EWS courses attended (n)
Doctor	PhD (1)	13.6 (1-38)	17.2 (5yr 8months-38)	13.8 (5-38)	No (13)
Doctor	FCS (4)				Yes (2 nurses)
Doctor	FCA (1)				
Doctor	M Med (1)				
Nurse	MSc Nurs (2)				
Nurse	ICU Nurs (6)				

Note on table: Doctor: a medical practitioner; FCS: Fellow of the College of Surgeons; FCA: Fellow of the College of Anaesthetists; M Med: Master of Medicine; MSc: Master of Science in Nursing; ICU: Diploma in Intensive Care Nursing.

Five of the seven medical practitioners had specialist qualifications in their field and two had a PhD and Master's degree respectively. The majority (n=6) of the eight nurses had a qualification in intensive care nursing and two nurses had a Master's degree. Respondents were experienced specialist clinicians having a median number of 13.6 years of experience after completing a specialist qualification and they worked for a similar number of years (median = 13.8) in their current department. The majority (13/15, 86.7%) of respondents had not attended an EWS course and this confirmed the emphasis that hospital in-service education programmes place on late rescue techniques such as cardiopulmonary resuscitation (CPR) rather than early identification of deterioration.

3.5.1.2 Ranking the relevance of physiological variables for early identification of deterioration

Mean rankings and standard deviations were calculated. Data in Table 3-15 indicate that heart and respiratory rate were deemed the most important variables to monitor and temperature was ranked the least important.

Table 3-15: Ranking of the relevance of physiological variables for early identification of deterioration (n=15, with three missing responses)

	n	Minimum	Maximum	Mean Ranking	Std. Deviation of mean rank	Median rank
Heart rate	12	1	4	1.5	1.1	1
Respiratory rate	12	0	4	1.9	1.2	2
SATS	12	1	6	3.0	2.0	3
Systolic BP	12	1	5	3.0	2.0	4
Neurological status	12	1	7	3.2	2.4	4
Urine output	12	3	7	4.8	2.7	6
Temperature	12	5	7	5.1	2.7	6

NOTE on Table: 1 = most important; 7 = least important

The current observation chart in use at the research setting did not include monitoring of respiratory rate or oxygen saturation so the high ranking of these parameters over systolic blood pressure that is monitored routinely may have expressed respondents' views of the ideal situation. Whereas temperature is also recorded routinely on the current chart it was relegated to the lowest ranked position. Urine output is recorded on a separate fluid balance sheet.

3.5.1.3 Ranking the relevance of clinical variables for early identification of deterioration

Data in Table 3-16 show that skin colour and looking unwell were ranked as being the most important clinical signs.

Table 3-16: Ranked relevance of clinical variables for early identification of deterioration (n=15, with three missing responses)

	n	Minimum	Maximum	Mean Ranking	Std. Deviation of mean rank	Median rank
Looks unwell	12	1	8	2.33	2.5	1
Skin colour	12	1	6	2.07	1.8	2
Sweating	12	0	5	2.67	1.7	3
Perfusion	12	1	9	3.20	2.9	3
Pain severity	12	2	8	3.60	2.4	4
Response to medication	12	4	10	6.20	3.8	6
Blood glucose	12	1	9	4.93	3.2	6
Hb	12	5	9	5.60	3.1	7
Wound	12	3	10	5.87	3.5	7
Girth measurement	12	7	10	7.53	4.0	10

1 = most important; 10 = least important.

Respondents who did not rank the variables indicated that these were all equally important which was surprising for experienced clinicians.

3.5.1.4 Percentage of agreement with the published MEWS

Likert scales generate ordinal level data; therefore, medians, ranges and proportions were reported for the survey by questionnaire. A threshold of 90% of respondents agreeing with the MEWS for each of the seven physiological variables and with the usefulness of the research observation chart for identifying physiological and clinical deterioration was regarded as satisfactory. Agreement with published MEWS amongst professionals was established statistically by proportions, probability values and 95% confidence intervals (Table 3-17).

Due to low numbers, and the number of comparisons (7) results were interpreted cautiously. There were few differences between the two professions. However, significantly more doctors than nurses agreed with published MEWS for systolic BP (Table 3-17).

Table 3-17: Comparison of proportion of Agreement amongst nurses (N=8) and doctors (N=7) concerning published MEWS (N=15, some responses missing*)

Agreement with published MEWS scores	Nurses n (%)	Doctors n (%)	*P*	95% Confidence Interval (CI)
Respiratory rate	7*=1 missing value (100.0)	6 (85.7)	1.0	0.9-1.6
Heart rate	4 (50.0)	5 (71.4)	1.0	0.4-1.8
Saturation (SaO_2)	5*=1 missing value (71.4)	4 (57.1)	1.0	0.6-2.8
Systolic BP	1 (12.5)	5 (71.4)	0.04	0.03-1.2
Temperature	3 (37.5)	4 (57.1)	1.0	0.2-2.3
Neurological status (LOC)	6*=2 missing values (100.0)	6 (85.7)	1.0	0.9-1.6
Urine output	6 (75.0)	7 (100.0)	0.5	0.5-1.1

P = Fisher's exact, 2-sided

As stated, the predetermined level of acceptance for agreement with published cut points and corresponding MEWS weighted trigger points (0, upper and lower 1 to 3) for physiological parameters was ≥90%. The highest percentage of agreement was 92.8% (13/14) for respiratory rate (Table 3-17) and 92.3% (12/13) for conscious level, but 86.7% (13/15) for urine output, 62.3% (9/14) for oxygen saturation,60.0% (9/15) for heart rate and 46.7% (7/15) for temperature. The lowest percentage of agreement was 40.0% (6/15) for systolic BP which was statistically significant (*p*=0.04).

The percentage of agreement that the research MEWS chart would be useful for detecting physiological deterioration was 80% (12/15) and for detecting clinical deterioration it was 86.7% (13/15).

3.5.1.5 Percentage of agreement on the callout algorithm

Results from the questionnaire concerning the category of professional to call when a patient's condition deteriorates, are shown in Table 3-18.

Table 3-18: Percentage of agreement on a callout algorithm concerning the most appropriate staff member to call for assistance (N=15)

ITEM (physiological cut points and MEWS weighted values (0 to 3: upper +; lower -)	RPN n	% [95% Confidence Interval (CI)]	MO n	% [95% Confidence Interval (CI)]	Registrar n	% [95% Confidence Interval (CI)]	Consultant n	% [95% Confidence Interval (CI)]	Missing values*
1.1 the nurse is **worried about** the patient	12*	92.3 [62.1-99.6]	0	0.0 [0.7-28.3]	1*	7.7 [0.4-37.9]	0	0.0 [0.7-28.3]	2
1.2 Change in **respiratory rate:** 1.2.1 to <9/min (2-)	4	26.7 [8.9-55.2]	6	40.0 [17.5-67.1]	4	26.7 [8.9-55.2]	0	0.0 [0.61-25.4]	0
1.2.2 to 15-20/min (1+)	10*	83.3 [50.9-97.1]	2*	16.7 [2.9-49.1]	0	0.0 [0.6-25.3)]	0	0.0 [0.6-25.3]	3
1.2.3 to 21-29 (2+)	7*	53.8 [26.1-79.6]	6*	46.1 [20.4-73.9]	0	0.0 [0.7-28.3]	0	0.0 [0.7-28.3]	2
1.2.4 to >30/min (3+)	3	20.0 [5.3-48.6]	10	66.7 [38.7-87.0]	2	13.3 [2.3-41.6]	0	0.0 [0.6-25.3]	0
1.3 Change in **heart rate:** 1.3.1 to ≤40 bpm (2-)	3	20.0 [5.3-48.6]	6	40.0 [17.5-67.1]	6	40.0 [17.5-67.1]	0	0.0 [0.6-25.4]	0
1.3.2 to 41-50 bpm (1-)	7	46.7 [22.3-72.6]	5	33.3 [13.0-61.3]	3	20.0 [5.3-8.6]	0	0.0 [0.6-25.4]	0
1.3.3 to 101-110 (1+)	10*	76.9 [46.0-93.8]	3*	23.1 [6.2-54.0]	0	0.0 [0.7-28.3]	0	0.0 [0.7-28.3]	2
1.3.4 to 111-129 (2+)	9	60.0 [32.9-82.5]	4	26.7 [8.9-55.2]	2	13.3 [2.3-41.6]	0	0.0 [0.6-25.4]	0
1.3.5 to ≥130 (3+)	4	26.7 [8.9-55.2]	8	53.3 [27.4-77.7]	3	20.0 [5.3-48.6]	0	0.0 [0.6-25.4]	0
1.4 Change in **systolic BP:** 1.4.1 to 81-100 mmHg (1-)	11	73.3 [44.8-91.1]	3	20.0 [5.3-48.6]	1	6.7 [0.35-34.0]	0	0.0 [0.6-25.4]	0
1.4.2 to 71-80 mm Hg (2-)	3	20.0 [5.3-48.6]	10	66.7 [38.7-87.0]	2	13.3 [2.3-41.6]	0	0.0 [0.6-25.4]	0
1.4.3 to 70 mmHg or less (3-)	3	20.0 [5.3-48.6]	6	40 [17.5-67.1]	6	40 [17.5-67.1]	0	0.0 [0.6-25.4]	0
1.4.4 to ≥200 mmHg (2+)	5	33.3 [13.0-61.3]	6	40 [17.5-67.1]	4	26.7 [8.9-55.2]	0	0.0 [0.6-25.4]	0
1.5 Change in **pulse oximetry saturation:** 1.5.1 to 90-92% (1)	14	93.3 [66.0-99.6]	0	0.0 [0.6-25.4]	1	6.7 [0.4-34.0]	0	0.0 [0.6-25.4]	0
1.5.2 to 85-89% despite O_2 administration (2)	2	13.3 [2.3-41.6]	11	73.3 [44.8-91.1]	2	13.3 [2.3-41.6]	0	0.0 [0.6-25.4]	0
1.5.3 to ≤85% despite O_2 administration (3)	2	13.3 [2.3-41.6]	6	40 [17.5-67.1]	7	46.7 [22.3-72.6]	0	0.0 (0.6-25.4)	0
1.6 Change in **conscious state:** 1.6.1 to Reacting to Voice (GCS 14) (1)	12	80.0 [51.4-94.7]	1	6.7 [0.35-34.0]	2	13.3 (2.3-41.6)	0	00.0 (0.6-25.4)	0
1.6.2 to Reacting to Pain (GCS 13-9) (2)	4	26.7 [8.9-55.2]	8	53.3 [27.4-77.7]	3	20.0 (5.3-48.6)	0	0.0 (0.6-25.4)	0
1.6.3 to Unresponsive (GCS 8<) (3)	2	13.3 [2.3-41.6]	5	33.3 [13.0-61.3]	7	46.7 [22.3-72.6]	1	6.7 [0.35-34.0]	0
1.7 Change in **urine output:** 1.7.1 to <30 ml/hr (2-)	9	60.0 [32.9-82.5]	4	26.7 [8.9-55.2]	2	13.3 [2.3-41.6]	0	0.0 [0.6-25.4]	0
1.7.2 to <20ml/hr for 2 consecutive hrs (3-)	2	13.3 [2.3-41.6]	10	66.7 [38.7-87.0]	3	20.0 [5.3-48.6]	0	0.0 [0.6-25.4]	0
1.7.3 to >150ml/hr (1)	9	60.0 [32.9-82.5]	5	33.3 [13.0-61.3]	1	6.7 [0.35-34.0]	0	0.0 [0.6-25.4]	0

Note on table: RPN – Registered Professional Nurse, MO – Medical Officer

Of the 22 cut points for seven physiological parameters, RPNs should be called for 40.9% (9/22) of the patients for weighted trigger points 1 to 2 (mostly 1) but never for 3. Medical officers responsible for the patient should be called for 50% of the calling criteria (single parameters) with MEWS weighted trigger points ranging from 1 to 3 (mostly 2) and Registrars for 18.2% (4/22) of the time for MEWS weighted trigger points of 1 to 3 (mostly 3). A consultant should only be called for 4.5% (1/22) of the items when there is deterioration in a patient's conscious level with a MEWS weighted trigger point of 3 and the patient is unresponsive. A summary (nurse versus doctor) is shown in Table 3-19.

Table 3-19: Summary of data for percentage of agreement on a callout algorithm

Reason for calling	Who to call	%	Who to call	%
If worried about a patient	RPN	92.3		
Respiratory rate <9 breaths/minute	Doctor	66.7	RPN	26.7
Respiratory rate 15 to 29 breaths/minute	RPN	68.5	Doctor	31.4
Respiratory rates >29	Doctor	80%		
Heart rate ≤40 beats/minute	Doctor	80%		
Heart rates ≤50 beats a minute	Doctor	53.3%		
Heart rates 101 to 129	RPN	68.4%	Doctor	63.1%
Heart rates >129	Doctor	73.3%		
Systolic BP 81 to 100 mmHg	RPN	73.3%		
Systolic BP <81, >100 mmHg	Doctor	71.1%		
Oxygen saturation 90 to 92	RPN	93.3%		
Oxygen saturation <90	Doctors	86.6%		
Responds to voice	RPN	80%		
Responds to pain/unresponsive	Doctor	76.6%		
<30ml or >150ml of urine/hour	RPN	60.0%		
<20ml/hour	Doctor	86.7%		

3.5.1.6 Participants' perceptions of limitations and strengths of the MEWS chart compared to the current observation chart

Data generated by optional open-ended questions were analysed inductively. Open-ended questions gave respondents the opportunity to compare limitations and strengths of the research chart and the current chart. Limited content analysis of qualitative data on the limitations and strengths of the research chart compared to the existing chart is presented in Table 3-20.

Table 3-20: Limited content analysis of qualitative data concerning a comparison of limitations and strengths of the MEWS chart and current observation chart.

LIMITATIONS OF MEWS CHART	STRENGTHS OF MEWS CHART
Category: Layout	Category: Layout
• Increased detail • Inadequate space for aggregated score and signature • Colour coding will be lost when photocopied • Concerns about omissions: GCS, descriptions of blood loss, operation performed.	• Colour coding alerts to appropriate action • Good layout • Vital signs arranged in order of priority • more space for charting
Category: Function	Category: Function
• Increased complexity • potential for more error in charting and interpretation • staff may resist implementation • uncertainty about the meaning of the word 'value' • *Clinical deterioration cannot be reduced to a number • Staff shortage means that more less qualified nurses will use the MEWS chart	• MEWS cut points and weighted values make for easy assessment • Actual values are recorded rather than estimations using symbols (x, •) in graph format
LIMITATIONS OF CURRENT CHART	**STRENGTHS OF CURRENT CHART**
Category: Layout	Category: Layout
• Omission: respiratory rate recording • Parameter readings are indicated with dots and crosses in graph format • GCS and pupil monitoring takes up half the page • Inadequate space for writing • Space for only one signature per page	
Category: Function	Category: Function
• Parameter readings are estimated	

NOTE on table: *Researcher response: the MEWS chart distinguishes between clinical and physiological deterioration. Clinical signs, for example, looks unwell, sweating, pallor is not scored but assessed subjectively as being present or not with the exception of a subjective allocation of a pain score. Conversely, physiological parameters are scored.

3.5.1.7 Conclusion regarding questionnaire results presented above

Although the numbers were small (return rate 15/52, 28.8%), the questionnaire established that there was not agreement with published MEWS at the *a priori* 90% level. Data from the survey provided baseline local MEWS thresholds for the next stage of validation: consensus seeking by ranking.

3.5.2 Objective: Derivation of the Cape Town Ward MEWS by consensus methods

Five rounds of consensus methods produced local validation of the Cape Town MEWS. Results for each round were analysed for agreement using predefined rules[148] of 70% agreement before proceeding to the next round, unlike 90% agreement for the questionnaire data. In the absence of available published examples of consensus ranking sheets for developing physiological MEWS cut points and weighted trigger points, Round 1 was used to pilot the research consensus ranking sheet.

3.5.2.1 Results of the pilot Round 1

Round 1 generated a total of 32 MEWS value sets (Appendix 3.14) for 7 physiological variables which was unmanageable and the process had to be modified for subsequent rounds. For example, four additional cut point range sets were generated for respiratory rate; three for SpO_2 %; five for temperature; two for conscious level; and four for urine output. Seven entirely new cut points were generated for heart rate, replacing the published MEWS and this was the same for systolic BP. What is reported in Table 3-21 are the process results of pilot Round 1.

Table 3-21: Results of pilot Round 1

A. *Consensus ranking sheet*

1. The consensus ranking sheet was erroneously populated with repeat numbers (yellow highlights) for certain vital sign cut points (values) that confused participants (10-12; 12-14) in the pilot round:

RESPIRATORY RATE

MEWS weighted values	**3**	**2**	**1**	**0**	**1**	**2**	**3**
RR cut points (published)	Blank	9 or less	Blank	9-14	15-20	21-29	30 or more
Questionnaire cut points	***<9***	***9 or less***	***10-12***	***12-14***	***15-20***	***21-29***	***30 or more***

2. Thresholds for heart rate, SATS, systolic blood pressure and temperature should each have been arranged in separate rows as discrete range sets and not grouped in one row as shown in the example below for heart rate:

HEART RATE

MEWS weighted values	**3**	**2**	**1**	**0**	**1**	**2**	**3**
HR cut points (published)	<35	40 or less	41-50	51-100	101-110	111-129	130 or more
Questionnaire cut points	***<40***	***45 or less*** ***40-49*** ***35-50***	***46-55*** ***50-60*** ***51-59***	***51-100*** ***60-100*** ***56-95*** ***50-90*** ***60-90***	***96-110*** ***91-110***	***111-129***	***130 or more***

3. Two participants did not rank any values and one participant ranked only selected values (see example below) instead of one ranking for each score.

RESPIRATORY RATE

MEWS weighted values	**3**	**2**	**1**	**0**	**1**	**2**	**3**
RR cut points (published)	Blank	9 or less	Blank	9-14	15-20	21-29	30 or more
Questionnaire cut points	***<9***	***9 or less***	***10-12***	***12-14***	***15-20***	***21-29***	***30 or more***

Key: 0 = total disagreement; 9 = total agreement

0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9

4. The ranking sheet was modified so that for subsequent rounds ranking (0-9) included only one row below a set of values for each variable (see below) and not one for each score as in 3. above.

RESPIRATORY RATE

MEWS weighted values	**3**	**2**	**1**	**0**	**1**	**2**	**3**
RR cut points (published)	Blank	9 or less	Blank	9-14	15-20	21-29	30 or more
Questionnaire cut points	***<9***	***9 or less***	***10-12***	***12-14***	***15-20***	***21-29***	***30 or more***

0 1 2 3 4 5 6 7 8 9

5. The consensus group had not been asked to establish an agreement level for ranking, for example 70% and this was rectified in Round 2.

6. It was a mistake to have also added cut points for calling criteria on the consensus ranking sheet as participants unfamiliar with MEWS found this difficult enough, therefore it had to be abandoned.

These values formed the basis of consensus seeking for subsequent rounds. The level of agreement on cut points for the seven physiological variables for each of the four rounds is presented below. When a variable achieved agreement at 70% it was not carried forward to the next round.

3.5.2.2 Results of Round 2

A modified ranking sheet described in section 3.4.3.3 and shown in point 4 of Table 3-21 above is repeated below in Table 3-22 for the sake of completeness of reporting.

Table 3-22: Modified consensus ranking sheet

RESPIRATORY RATE							
MEWS weighted values	**3**	**2**	**1**	**0**	**1**	**2**	**3**
RR cut points (published)	Blank	9 or less	Blank	9-14	15-20	21-29	30 or more
Questionnaire cut points	***<9***	***9 or less***	***10-12***	***12-14***	***15-20***	***21-29***	***30 or more***

0 1 2 3 4 5 6 7 8 9

Round 2 raw data for the seven physiological variables are summarized in Appendix 3.15. A further round by Delphi was undertaken to clarify rankings for 'conscious level' values only. Only eight members responded, deriving two range sets with the highest achieving 62.5% which included the GCS equivalent. This cut point range was accepted by consensus at this level (instead of the *a priori* 70% level) after a follow-up e-mail and/or personal interview. Including the GCS equivalent would, it was believed, facilitate the transition from using the GCS to the AVPU for ward staff.

Ranked results for one of a number of sets of respiratory rate cut points are presented in Table 3-23 below, as an example. Results reflect the range set that achieved the highest number of rankings (2+2 in yellow highlights = 4/10; 40.0%) within high tertile scores of 7-9, albeit at less than the agreed level of ≥70% agreement. This result went to the next round. Agreement scores are shown as a number and percentage of rankings. MEWS range sets for each parameter not selected in Round 2 were excluded from subsequent rounds. There were still too many range sets

for each physiological variable and at the conclusion of Round 2 not one variable achieved a ranking of ≥70%.

Table 3-23: Results of round 2 ranking portraying 40.0% agreement on Respiratory Rate cut points with corresponding MEWS weighted trigger points (0 to 3)

Respiratory Rate MEWS weighted values	**3**	**2**	**1**	**0**	**1**	**2**	**3**
Parameter cut points	<8	≤9	10-11	12-14	15-20	21-29	≥30

Total disagreement with the range: 0 1 2 3 4 5 6 7 8 9 Total agreement
Number of votes in high tertile scores 2 2 = 4/10 (40.0%)

3.5.2.3 Results of Round 3

In this round participants were provided with a collapsed MEWS range for each variable having the highest ranking from the previous round as well as a summary of their private rankings of each variable. In this way all possible permutations could be ranked. If a participant's ranking was the same as that of the majority this was clearly indicated on the ranking sheet. If different, the instruction was to either change their selection to that of the majority, or in the case of a tie between ranges, to select one of the range sets within the tie, or if they did not wish to change their selection, they were asked to indicate on a scale of 0 (totally disagree) to 9 (totally agree) how strongly they disagreed with changing. Round 3 raw data for the variables are summarized in Appendix 3.16.

Results for respiratory rate values are presented in Table 3-24 below, as an example and show an improvement on the ranking for the previous round. Results reflect the range set for respiratory rate MEWS cut points and weighted trigger points that achieved the highest frequency of rankings (9/10; 90.0%) within the high tertile scores of 7-9. Agreement scores are shown as a number and percentage of rankings. Agreement scores increased with each subsequent round.

Both heart rate MEWS and SpO_2 % MEWS achieved only a 50% ranking in Round 3 but this increased to 100.0% and 90.0% respectively in Round 4.

Table 3-24: Round 3 results for a specific range of respiratory rate MEWS values achieving the highest votes.

Ranking:	0 1 2 3 4 5 6 7 8 9 *3 6 = 9/10*						
Respiratory Rate MEWS weighted valued	**3**	**2**	**1**	**0**	**1**	**2**	**3**
Parameter cut points	<8	≤9	10-11	12-14	15-20	21-29	≥30

Total disagreement with the range: 0 1 2 3 4 5 6 7 8 9 Total agreement
Number of votes in high tertile scores 3 6 = 9/10 (90.0%)

At the conclusion of Round 3 respiratory rate, systolic BP, temperature and urine output achieved a higher percentage agreement (90-100%) than the *a priori* 70% level within the high tertile scores of 7-9. Conscious level received a 62.5% agreement from Round 2 (confirmed by Round 3). It was felt that an exception should be made in this case as the radical change from the Glasgow Coma Scale (GCS) to the AVPU system would require an adjustment by all staff including the experts. Ranking for heart rate and oxygen saturation (SpO_2) went to Round 4.

3.5.2.4 Results of Round 4

Heart rate and SpO_2 MEWS achieved a higher percentage agreement (90-100%) than the *a priori* 70% level within high tertile scores of 7-9 and the results are portrayed within the full set of results derived from Delphi rounds in Table 3-25 below in the order arranged on the MEWS chart. Agreement scores are shown as a number and percentage indicating that the MEWS for heart rate, systolic BP and temperature received the highest rankings.

Table 3-25: Round 4 results highlighted within the full set of Delphi derived physiological MEWS cut points and corresponding weighted trigger points (0, upper and lower 1 to 3).

Agreement: 90.0%	0 1 2 3 4 5 6 7 8 9 *3 6 = 9/10*						
Respiratory Rate MEWS weighted values	**3**	**2**	**1**	**0**	**1**	**2**	**3**
Parameter cut points	<8	≤9	10-11	12-14	15-20	21-29	≥30

Agreement: 90.0%	0 1 2 3 4 5 6 7 8 9 *2 3 4 = 9/10*						
SpO_2 % MEWS weighted values	**3**	**2**	**1**	**0**	**1**	**2**	**3**
Parameter cut points	<85%	85-89%	90-93%	94%+			

Agreement: 100.0%	0 1 2 3 4 5 6 7 8 9 *1 5 4 = 10/10*						
Heart Rate MEWS weighted values	**3**	**2**	**1**	**0**	**1**	**2**	**3**
Parameter cut points	<40	40-50	51-59	60-100	101-110	111-129	≥130

Agreement: 100.0%	0 1 2 3 4 5 6 7 8 9 *5 5 = 10/10*						
Systolic BP MEWS weighted values	**3**	**2**	**1**	**0**	**1**	**2**	**3**
Parameter cut points	≤70	71-80	81-100	101-149	150-169	170-179	>180

Agreement: 100.0%	0 1 2 3 4 5 6 7 8 9 *3 7 = 10/10*						
Temperature MEWS weighted values	**3**	**2**	**1**	**0**	**1**	**2**	**3**
Parameter cut points	<33^{0}C	33-35^{0}C	35.1-35.9^{0}C	36-37.7^{0}C	37.8-38.5^{0}C	38.6-39.5^{0}C	>39.6^{0}C

Agreement: 62.5%	0 1 2 3 4 5 6 7 8 9 *1 1 3= 5/8*						
Conscious level MEWS weighted values	**3**	**2**	**1**	**0**	**1**	**2**	**3**
Parameter cut points				Alert (GCS 15)	Reacts to voice (GCS 14)	Reacts to pain (GCS 13-9)	Unresponsive (GCS 8<)

Agreement: 90.0%	0 1 2 3 4 5 6 7 8 9 *1 4 4 = 9/10*						
Urine output MEWS weighted values	**3**	**2**	**1**	**0**	**1**	**2**	**3**
Parameter cut points	<20 ml/hr	≤30 ml/hr	≤50 ml/hr	60 ml/hr If normally anuric score 0	≥150 ml/hr		

In each round each prognostic variable was partitioned by identifying cut points and weighted values (0 to 3) by consensus.

3.5.2.5 Results of Round 5 from face-to-face consensus meeting

Results of the final face-to-face consensus meeting are presented in Table 3-26.

Table 3-26: Round 5 MEWS cut points and weighted trigger points (0, upper and lower 1 to 3) for 5 physiological variables finalised by a face-to-face consensus meeting.

Agreement: 100.0%	0 1 2 3 4 5 6 7 8 9 *6 2 = 8/8*						
Respiratory Rate MEWS weighted trigger points	**3**	**2**	**1**	**0**	**1**	**2**	**3**
Parameter cut points	<8	8-9 (from ≤9)	10-11	12-14	15-20	21-29	≥30

Agreement: *50.0%	0 1 2 3 4 5 6 7 8 9 *1 3 = 4/8*						
SpO_2 % MEWS weighted trigger points	**3**	**2**	**1**	**0**	**1**	**2**	**3**
Parameter cut points	<85%	85-89%	90-94% (from 90-93%)	95%+ (from 94%+)			

Agreement: 100.0%	0 1 2 3 4 5 6 7 8 9 *6 2 = 8/8*						
Temperature MEWS weighted trigger points	**3**	**2**	**1**	**0**	**1**	**2**	**3**
Parameter cut points	<34^{0}C (from <33^{0}C)	34-35^{0}C (from 33-35^{0}C)	35.1-35.9^{0}C	36-37.7^{0}C	37.8-38.5^{0}C	38.6-39.5^{0}C	>39.6^{0}C

Agreement: *62.5%	0 1 2 3 4 5 6 7 8 9 *1 1 3= 5/8*						
Conscious level MEWS weighted trigger points	**3**	**2**	**1**	**0**	**1**	**2**	**3**
Parameter cut points				Alert (GCS 15)	Reacts to voice (GCS 14)	Reacts to pain (GCS 13-9)	Unresponsive (GCS 8<)

Agreement: 100.0%	0 1 2 3 4 5 6 7 8 9 *7 1 = 8/8*						
Urine output MEWS weighted trigger points	**3**	**2**	**1**	**0**	**1**	**2**	**3**
Parameter cut points	<20 ml/hr	≤30 ml/hr	≤50 ml/hr	60 ml/hr If normally anuric score 0	≥150 ml/hr was deleted		>300 ml/hr for 2 hrs inserted

* SpO_2 of 90-94% with a MEWS weighted value of 1 rather than the previous 90-93% at this level was accepted at a 50.0% ranking as it has a higher potential sensitivity of tracking patients at risk. A 62.5% agreement for implementing the AVPU system for assessing 'conscious level' was acceptable as it is a drastic departure from the GCS in use at the time of the study and there was bound to be ambivalence within the consensus group.

from Round 2 and confirmed by Round 3). Although 'conscious level' was not re-ranked, the neurosurgeon expressed concern about the AVPU system replacing the existing Glasgow Coma Scale (GCS) on general wards but it was agreed that the AVPU would not be appropriate for a specialist neurosurgical ward and was not intended for this purpose. It was felt that an exception should be made in this case as the radical change from the GCS to the AVPU system would require an adjustment by all staff including the experts.

Changes were made to one MEWS cut point for respiratory rate (100% agreement), to two MEWS cut points for oxygen saturation requiring earlier callouts (higher sensitivity) (hence consensus at 50% agreement), to two MEWS cut points for temperature (100% agreement) and to one MEWS cut point for urine output (100% agreement).

The MEWS chart was modified as depicted in Table 3-27.

Table 3-27: Refinement of the MEWS observation chart

Prototype MEWS Chart	Refinement
'heart rate' – replaced with	pulse rate – a more familiar term as 'pulse' appears on the current chart
'aggregated score' - replaced with	'total score' – a more familiar term
'neurological status' - replaced with	'level of consciousness' a more familiar term
font size -	increased wherever space allowed for improved visualisation
blank spaces -	blocked out to prevent nurses writing in incorrect spaces
the scale of MEWS values repeated on the right hand side of the prototype chart -	removed to make the chart less 'busy' thereby also increasing column width for charting
'jaw wired' and 'abdominal girth' - replaced with	'Other' for customised instructions
A space for a patient identification sticker placed in a horizontal position - replaced with	a space in a vertical position on the left side to create more space for charting

Note on table: These changes are reflected in the final version of the chart (Figure 3-4).

Furthermore, during Round 5 there was 100.0% agreement on the inclusion of a callout algorithm on the MEWS chart representing decision rules that determine the urgency level (Table 3-28).[17]

- *Callout algorithm*

Table 3-28: Callout algorithm

0 = no action 1 = re-check after ½ hour and report if no improvement 2 = check after 5 minutes/report immediately if no improvement 3 = critical REPORT IMMEDIATELY

A trigger point of an upper 3 for a respiratory rate of >30 for example is critical, requiring immediate review of the patient by an experienced professional nurse or doctor. Similarly, a total score of 3 for the MEWS is critical. A score of 2 requires reassessment of the patient within 5 minutes, whereas reassessment could be delayed for half an hour for a score of 1. No action is required for a score of 0.

Consensus members confirmed that the 'combined' MEWS system would be implemented, that is, nurses would call for assistance not only for an aggregated MEWS of 3[i], but also for abnormal physiology of a single parameter.

- *'Calling criteria' for an emergency response*

Questionnaire data indicated that RPNs and medical officers should be called more often than registrars or consultants in the event of critical illness (Table 3-18) for published MEWS. Finally, at the conclusion of Round 5, guided by the results in Table 3-18, calling criteria (Table 3-29) were extrapolated from the final Cape Town MEWS at lower and upper 2 level trigger points for each

[i] Calculated by arithmetic addition of MEWS weighted trigger points for all physiological parameters.

physiological parameter to trigger an urgent response in the event of acute deterioration in a patient not included in the study.[ii]

Table 3-29: Calling Criteria (white font on red background) adapted from MEWS values

CALLING CRITERIA FOR INITIATION OF AN EMERGENCY RESPONSE

if any one of these is present call the Sister, if not available, the Medical Officer:

- Staff member is worried about the patient
- Acute change in heart rate to <50 or >120 beats/min
- Acute change in systolic blood pressure to <80 or >170 mmHg
- Acute change in respiratory rate to <10 or >20 breaths/min
- Acute change in pulse oximetry saturation to <90%, despite oxygen administration
- Acute deterioration in conscious state
- Acute change in urine output to <30ml/hr or >300ml/hour for 2 hours

Finalised at Consensus NGT workshop 11 February 2010
Una Kyriacos, UCT Division of Nursing & Midwifery Telephone 021-4066410

3.5.3 Objective: Locally validated observation chart incorporating the Cape Town Ward MEWS

The final version of the consensus derived Cape Town Ward MEWS chart (Figure 3-4) differed in every respect from the chart currently in use at the Hospital: layout, content (physiological and clinical parameters to be monitored), method of charting and function.

[ii] Explained in the discussion section 3.5.2.5.

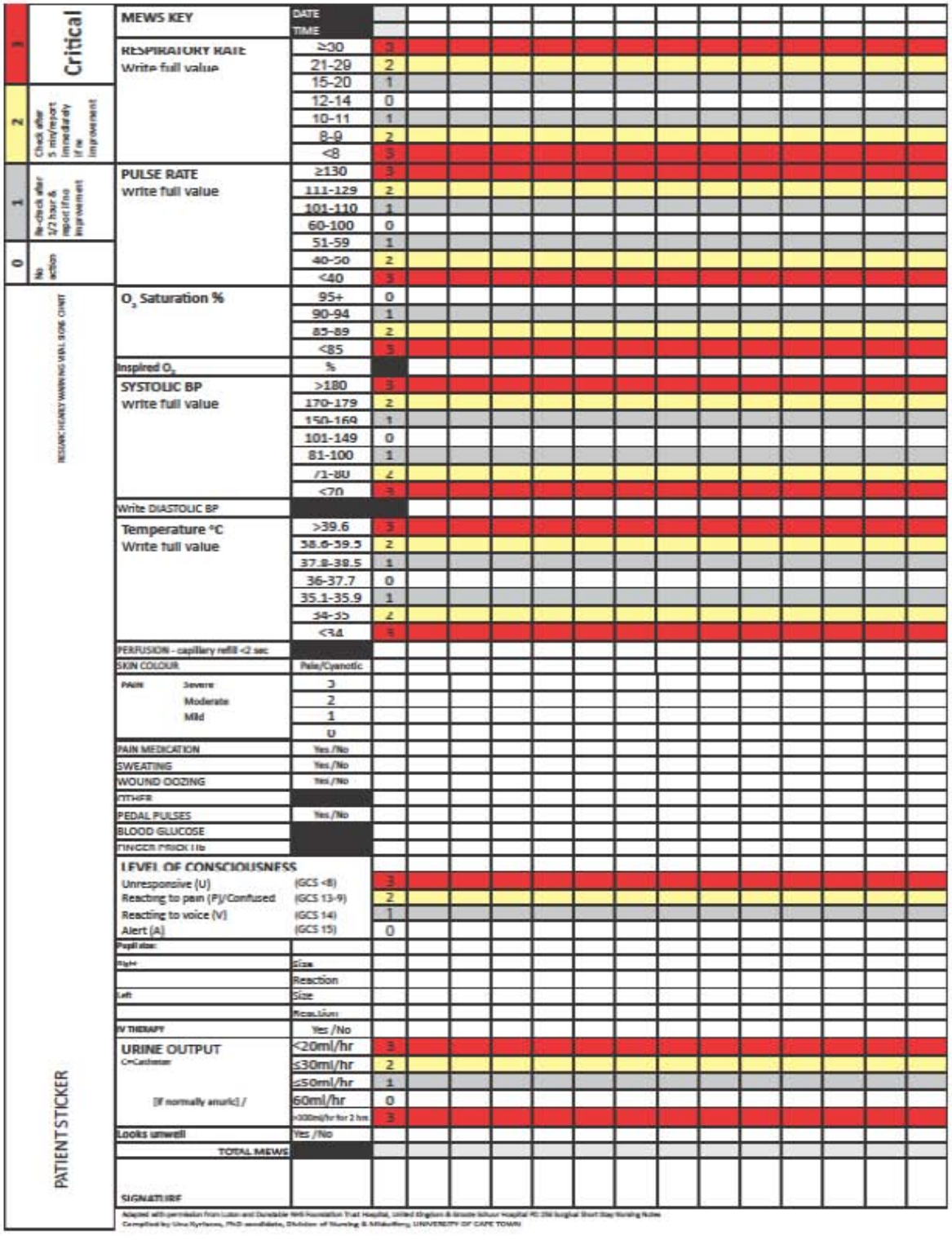


Figure 3-4: The consensus derived and validated Cape Town Ward MEWS observation chart with callout algorithm

Red shading in the chart (Figure 3-4) depicted critical scores of 3 (upper and lower) requiring immediate callout.[iii] Scores of 2, coded yellow[iv] required review of the patient after 5 minutes and scores of 1 were shaded grey indicating review of the patient after half an hour. Arbitrary 'normal' values had a score of 0, no colour coding and required no intervention. The Glasgow Coma Scale (GCS) was integral to one existing ward chart at the Hospital (Appendix 3.2) at the time the study was undertaken for short stay patients but was absent on the chart used for most postoperative patients. Although pupil size and reaction were retained on the MEWS chart, the AVPU scale (Alert/Reacting to Voice/Reacting to Pain/Unresponsive (U)) replaced the GCS but with the equivalent GCS scale in brackets (GCS 15 = A; GCS 14 = V; GCS 13—9 = P; GCS≤8 = U) to prevent confusion.[133]

Permission was obtained from colleagues in the UK for inclusion of clinical indicators and aesthetic attributes of their charts for example 'looks unwell' (with permission, Dr Fiona McIlveney UK NHS Forth Valley)[131] that were not scored but required a brief description and not present on the existing chart.

The Cape Town Ward MEWS chart unlike the existing chart includes: patient identification, respiratory rate, oxygen saturation levels, skin colour (pale/cyanotic), blood glucose and sweating but it does not include: operation/procedure performed, plugs, blood loss, instructions (as these will be written under 'Other').

The final consensus derived MEWS observation chart was subjected to pilot testing for accuracy of charting.

[iii] Neurological status and urine output only had lower 3 weighted trigger points.
[iv] Consent was obtained from the Clinical Risk, Emergency Planning and information Governance Manager and team of the Luton and Dunstable NHS Foundation Trust Hospital in the UK.

3.5.4 Objective: Results of pilot testing the Cape Town Ward MEWS observation chart for accuracy (percent correctness) of charting

There were a maximum of 21 responses for each parameter and a minimum of 17. The raw data are presented in Table 3-30.

Table 3-30: Raw data for multiple recordings of MEWS parameters for five patients by two observers (A & B) for pilot test

Subject No.	(Counted) Respiratory rate (RR) A	MEWS category	RR B	MEWS category	(Automatic/ Dinamap) Heart rate (HR) A	MEWS category	HR B	MEWS category	(Dinamap) Systolic BP A	MEWS category	Systolic BP B	MEWS category	(Digital) Temp °C A	MEWS category	Temp °C B	MEWS category	Conscious Level A	MEWS category	Conscious Level B	MEWS category
1	23	2	14	1	89	0	89	0	79	2	79	2	36.7		36.7		Alert	0	Alert	0
1	21	2	18	1	104	0*	104	1	89	1	89	1					Alert	0	missing	
1	21	2	20	1	100	0	87	0	94	1	94	1	36.1		36.1		Alert	0	Alert	0
1	18	2*	20	1	106	1	104	1	80	2	80	2	36.7		36.7		Alert	0	Alert	0
1	22	2	21	2	97	0	95	0	82	1	82	1					Alert	0	Alert	0
2	18	1	18	1	80	0	80	0	166	1	166	1	36.8		36.8		Alert	0	Alert	0
2	15	1	16	1	76	0	76	0	147	0	147	0					Alert	0	Alert	0
2	15	1	14	1*	84	0	84	0	166	1	166	1	36.9		36.9		Alert	0	Alert	0
2	17	1	16	1	86	0	86	0	174	1*	174	2					Alert	0	Alert	0
2	14	1*	15	1	82	0	84	0	170	2	170	2	37.4	0	37.4	0	Alert	0	Alert	0
3	10	1	14	0	70	0	70	0	103	0	103	0	36.6	0	36.6	0	Alert	0	Alert	0
3	11	1	10	1	64	0	64	0	97	1	97	1					Alert	0	Alert	0
3	12	0	12	0	67	0	67	0	100	1	100	1	36.5	0	36.5	0	Alert	0	Alert	0
3	11	1	12	0	70	0	70	0	94	1	94	1					Alert	0	Alert	0
3	12	0	10	0*	67	0	67	0	96	1	96	1	36.3	0	36.3	0	Alert	0	Alert	0
4	28	2	26	2	72	0	72	0	121	0	121	0	36.8	0	36.8	0	Reacts to voice	1	Reacts to voice	1
4	23	2	20	1	76	0	76	0	121	0	121	0					Reacts to voice	1	Reacts to voice	1
4	24	2	22	2	83	0	83	0	124	0	124	0	37.8	0*	37.8	0*	Reacts to voice	1	Reacts to voice	1
5	14	0	14	0	81	0	81	0	114	0	114	0	35.4	1	35.4	1	Alert	0	Alert	0
5	15	1	10	1	75	0	75	0	120	0	120	0					Alert	0	Alert	0
5	15	0*	12	0	78	0	78	0	127	0	127	0	35.7	1	35.7	1	Alert	0	Alert	0

Note on table:
*Denotes raw value in incorrect partition (therefore incorrect MEWS cut point category).

The proportion correct transcription and the binomial 95% confidence intervals for Observer A and B are depicted in Table 3-31.

Table 3-31: Data for pilot testing the MEWS observation chart for percentage correctness of transcribing values (N=17, N=21) for Observer A (the constant) and B.

Parameter	N	OBSERVER A n (% correct)	[95% CI]	OBSERVER B n (% correct)	[95% CI]
Respiratory rate	21	17 (81.0)	[58.1-94.5]	19 (90.5)	[69.6-98.8]
Heart rate	21	21 (100.0)	[83.9-100.0]	21 (100.0)	[83.9-100.0]
Systolic BP	21	20 (95.2)	[76.2-99.9]	21 (100.0)	[83.9-100.0]
Temperature	17	16 (94.1)	[71.3-99.8]	16 (94.1)	[71.3-99.8]
Consciousness	21	21 (100.0)	[83.9-100.0]	20 (95.2)	[76.2-99.9]

The sample size was small and this resulted in wide CIs, which in one case was as low as 58.1% for Observer A and 69.6% for Observer B. Nevertheless, the proportion correct was satisfactory and met the *a priori* cut point of 90% with the exception of respiratory rate at 81.0% for Observer A. No further testing was undertaken as the literature[14, 105] described recording of respiratory rate as the most inaccurate of all vital signs.

3.6 Discussion

The aim of Study One was to develop, validate and test an EWS[i] observation chart for bedside monitoring of a patient's condition on general wards, based on best practice from available published evidence and local criteria using expert opinion (survey by questionnaire) and consensus methods (Delphi and modified nominal group technique).

[i] Early warning scoring

3.6.1 Summary of results

The main findings of Study One are summarized.

- Questionnaire respondents (N=15) (Table 3-14) were experienced specialist clinicians but few had attended an EWS course. The limited survey established that only respiratory rate and conscious level achieved agreement with published MEWS (Table 3-17) above the *a priori* 90% level. The lowest percentage of agreement was for systolic BP which was statistically significant and more doctors than nurses agreed with the published MEWS.
- The final consensus derived MEWS chart (
- Figure 3-4), incorporated seven physiological parameters, each having partitioned cut points (thresholds) with corresponding colour-coded weighted trigger points (0, upper and lower 1 to 3) (Table 3-32).[ii] Consensus was achieved by applying the *a priori* strict rule of >70% agreement within the high tertile region of 7-9 (section 3.5.5.2) to five of the seven parameters:
    - respiratory rate (100.0% agreement; 4/7 cut points were unchanged from published MEWS)
    - pulse rate (100.0% agreement; 3/7 cut points were unchanged)
    - systolic BP (100.0% agreement; 3/7 cut points were unchanged)
    - temperature (100.0% agreement; all seven cut points were new)
    - urine output (100.0% agreement; 1/5 cut points remained unchanged).
- Consensus processes concerning the remaining two parameters:
    - conscious level (62.5% by applying a relaxed rule of <70% agreement; all four remained 100.0% unchanged)
    - oxygen saturation (50.0% agreement by applying a relaxed rule; 2/4 were unchanged).
- A response algorithm (Table 3-28) represents decision rules that determine the urgency level.
- The final chart was pilot tested for accuracy of charting:

[ii] Clinical variables were included for completeness but frequency of recording was considered to be outside the remit of this study.

- *Accuracy of charting*[iii] (Table 3-31):
  was satisfactory and met the *a priori* cut point of 90% except for respiratory rate (81.0%).

3.6.2 Generalisability of results

Conducting the study within a single research centre may limit external validity of results. A poor response rate for the questionnaire mitigates against generalizing findings to all populations but the subsequent consensus methods employed the recommended number of participants and processes, in this way generating valid data. Nevertheless, validity and reliability of formal consensus development methods are uncertain and this has limited its use but consensus methods have been demonstrated in specific clinical areas[160] such as the validation of a MEWS. Pilot testing the MEWS chart for accuracy of charting on one purposively sampled non-research ward and convenience sampling of nurses on this way may limit external validity of results.

3.6.3 Study results compared to existing literature and in wider context

Study objectives 1-3 resulted in the construction of a preliminary MEWS observation chart for bedside monitoring on a general ward for the detection of early signs of deterioration[166] based on published literature on validated track and trigger interventions from the developed countries (UK, Australasia, USA) as there was a paucity from poorly resourced countries. Although opinion is divided, the five most important prognostic variables for catastrophic physiological deterioration included in the prototype MEWS chart were respiratory rate (the best discriminator for clinical outcomes),[185] systolic BP, pulse, temperature and conscious level. Urine output was included as an early indicator of vascular compromise[99, 100] and oxygen saturation (SPO_2) as it is associated with in-hospital death[5, 8, 22, 101, 102] and is included in published MEWS (Table 3-3).

[iii] Refers to the proportion correct for accuracy of two nurses in ascribing the correct cut point range for each physiological parameter reading and then correctly transcribing actual parameter readings (prospective patient datasets) onto the chart.

- A comparison between the consensus derived Cape Town Ward MEWS values and published values

The consensus derived Cape Town Ward MEWS is presented as a comparative table (Table 3-32) against the published MEWS from the developed countries presented at the start of the study in Table 3-3.

Table 3-32: A comparison of the consensus derived and validated Cape Town Modified Early Warning Scoring System (MEWS) and the published MEWS

	3	2	1	0	1	2	3
Respiratory rate/min	<8 *9 or less*	8-9	10-11	12-14 *9-14*	15-20 *15-20*	21-29 *21-29*	≥30 *30 or more*
SpO_2 %	<85 *<85*	85-89 *85-89*	90-94 *90-92*	95+ *93+*			
Heart rate/min	<40	40-50 *40 or less*	51-59 *41-50*	60-100 *51-100*	101-110 *101-110*	111-129 *111-129*	≥130 *130 or more*
BP systolic	≤70 *70 or less*	71-80 *71-80*	81-100 *81-100*	101-149 *101-179*	150-169 *180-200*	170-179 *200 or more*	>180 *>200*
Temperature ^{o}C	<34	34-35 *35 or less*	35.1-35.9	36-37.7 *35-38.4*	37.8-38.5	38.6-39.5 *38.5 or more*	>39.6
AVPU NEUROLOGICAL STATUS *				Alert *Alert* *(GCS 15)*	Reacting to voice *Reacting to voice* *(GCS 14)*	Reacting to pain *Reacting to pain* *(GCS 13-9)*	Unresponsive *Unresponsive* (GCS 8<)
**Urine ml/hr	<20 *NIL*	≤30 *<30*	≤50 *<60*	60 If normally anuric score 0	*>150*		>300ml for 2 hrs
Aggregated score =							
Interpretation: Aggregated MEWS: 3 = critical score							

Note on Table: Italicised published MEWS are from the developed countries.

For the Cape Town MEWS system, severity of illness is indicated by the value of the MEWS[175] where a MEWS of 3 (for a single parameter or a total MEWS) is regarded as critical, requiring

immediate summoning of skilled assistance, whereas this was 4[5, 168] or higher for a total MEWS in the reported literature. A triggering level of 4 for total EWS reportedly is not sensitive enough for the Intensive Care Society (ICS) Classification of Levels of Care.[187] An EWS of ≥5 was associated with increased risk of death and results were confirmed a year later.[185] A significant relationship was shown between increasing MEWS score and worse outcome across a range of specialities (medical and surgical).[177] The preliminary tool did not include a callout algorithm.

A comparison of Study One findings to existing literature for a local set of MEWS including reasons for differences/similarities and for including each is presented in Table 3-33.

Table 3-33: Comparison of Study One local MEWS with existing literature

Study One findings	Comparison with existing literature	Reasons for differences/similarities and for including parameter
○ respiratory rate	4/7 cut points remained unchanged from published MEWS (Subbe, Kruger, Rutherford & Gemmel, 2001).[8]	Consensus (100.0% agreement) Measured in all the studies on reliability and validity testing listed in the table in Kyriacos et al., 2011.[84] Measured in all six papers included in a systematic review.[22] Measured in nine studies listed in Kyriacos et al., 2011[84] on performance of MEWS and was found to be the best discriminator of clinical outcomes.[185]
○ pulse rate	3/7 cut points remained unchanged (Subbe, Kruger, Rutherford & Gemmel, 2001).[8]	Consensus (100.0% agreement) Measured in all the studies on reliability and validity listed in Kyriacos et al., 2011.[84] Measured in all six papers included in a systematic review.[22] Measured in eight studies on performance of MEWS listed in Kyriacos et al., 2011.[84]
○ systolic blood pressure	3/7 cut points remained unchanged (Subbe, Kruger, Rutherford & Gemmel, 2001).[8]	Consensus (100.0% agreement) A systolic blood pressure of 80-100 mmHg is reportedly an early sign frequently associated with SAEs.[188] Measured in five studies for reliability and validity listed in Kyriacos et al., 2011.[84] Measured in all six papers included in a systematic review.[22] Measured in eight studies on performance of MEWS listed in Kyriacos et al., 2011.[84]

Study One findings	Comparison with existing literature	Reasons for differences/similarities and for including parameter
○ temperature	All seven cut points were new.	Consensus (100.0% agreement) The top two most effective aggregate weighted track and trigger systems able to discriminate between survivors and non-survivors incorporated temperature monitoring.[133] Measured in five studies on reliability and validity listed in Kyriacos et al., 2011.[84] Measured in 4/6 papers included in a systematic review.[22] Measured in seven studies on performance of MEWS listed in Kyriacos et al., 2011.[84]
○ urine output	1/5 cut points remained unchanged (http://www.glenparkhouse.co.uk/nursing/nursingposter/mews%20chart.pdf).[202] Measured in two studies on reliability and validity testing listed in Kyriacos et al., 2011.[84]	Consensus (100.0% agreement) Measured in all six papers included in a systematic review[22] but found to be missing in 97.1% of sets of observations in one of the five studies[174] listed in Kyriacos et al., 2011.[84] Measured in four studies on performance of MEWS listed in Kyriacos et al., 2011.[84]
○ conscious level	Unchanged from the published literature (Harrison, Jacques, McLaws & Kilborn, 2006).[102]	Consensus (62.5% agreement by applying a relaxed rule of <70% agreement) Alteration in mentation is reportedly an early sign frequently associated with SAEs.[188] Measured in five studies on reliability and validity listed in Kyriacos et al., 2011.[84] Measured in all six papers included in a systematic review.[22] Measured in eight studies on performance of MEWS listed in Kyriacos et al., 2011.[84]
○ oxygen saturation	2/4 remained unchanged (Subbe, Kruger, Rutherford & Gemmel, 2001).[8]	Consensus (50.0% agreement by applying a relaxed rule). Oxygen saturation of 90-95% is reportedly an early sign frequently associated with SAEs.[188] Measured in two studies on reliability and validity listed in Kyriacos et al., 2011.[84] Measured in 2/6 papers included in a systematic review.[22] Measured in three studies on performance of MEWS listed in Kyriacos et al., 2011.[84]
○ Clinical variables on the chart were not to be scored.	Not scored on published EWS charts: CEMACH obstetric early warning chart;[131] Luton & Dunstable Hospital Trusts Colour banded early warning observation chart.[132]	No differences

Results for objective 4: the final Cape Town MEWS observation chart was validated by questionnaire survey, supplemented by consensus methods (nominal group and Delphi). Introducing an EWS/MEWS system, shown to significantly improve detection of parameters previously not recognized[45], is complex.[203] The complexity is compounded when there is limited agreement about the MEWS cut points or aggregate scores and therefore little agreement about the best MEWS for sensitivity and specificity[105] as the ideal MEWS does not exist. For this reason consensus methods were appropriate for reaching agreement about local criteria for a MEWS.

Each parameter has a range of colour-coded[131, 132] MEWS cut points with corresponding weighted trigger points (0, upper and lower 1 to 3)[78, 182] for allocating points to disturbed physiological values to guide intervention[3, 5, 31, 32] for single parameters[16] and for aggregated MEWS[16, 22] agreed to by the consensus group. This makes the chart a 'combination' track and trigger system to improve patient safety, that is, it should trigger for abnormal single or multiple physiological parameters in combination with the aggregate weighted score,[16] as in the UK[97] and Australasia.[56, 98] The reason for the combined system is that aggregate scores may not trigger if one variable falls outside the predetermined score, even though this has not been reported as a practical problem.[172] However, single parameters with high scores may not always translate into an increased overall risk in single parameter track and trigger systems.

A callout algorithm for single parameters or a total MEWS was decided by consensus and was incorporated in the final chart representing decision rules that determine the urgency level.[17] A trigger point of 3 is critical, requiring immediate review of the patient; 2 requires reassessment of the patient within 5 minutes, whereas reassessment could be delayed for half an hour for a score of 1. No action is required for a score of 0.

In addition, clinical signs of deterioration (pallor, sweating, looking unwell[131]) were incorporated although these are not often included in MEWS observation charts and are not part of the existing observation chart. Early intervention affects patient outcomes favourably.[40] Of 23 aggregate weighted track and trigger systems, only one incorporated 'nurse concern'.[133]

Results for objective 5: Pilot test results for percentage correctness of charting met the *a priori* cut point of 90%, commonly set at >80%[204] except for respiratory rate (81.0%). Testing the tool on postoperative patients on busy surgical wards made it difficult to count respiratory rates for a full minute without interruption resulting in inaccuracy. A UK study of 2757 observation sets for respiratory rate found this to have the highest error rate in assigning of scores (264, 9.6%).[14] A reliable means of counting respiratory rate would be useful.[105]

The EWS/MEWS system is dependent on accurate recording of observations[176] yet few reported studies have tested the accuracy of EWS calculation and charting[44] but those that did, found accuracy to be lacking with serious implications for quality of care.[175] Results of the MEWS study support the limited published evidence that there is human variation in the accuracy of recording findings on observation charts.[175] Retrospective review of 189 patient records in the UK found that errors in calculation by nurses were common (571/2607 score totals, 21.9%), that only 54.4% (2036/3739) of observation sets had a correct EWS[14] and that errors occurred mainly at weekends.[105] This applies particularly to traditional pen-and-paper recordings on MEWS charts that are also limited by the frequency of clinical observation recordings whereas accuracy is improved with automated recording systems.[175, 176]

Scales that are precise, demonstrating high interobserver reliability can still be unreliable under certain circumstances.[18] Circumstances such as the unpredictability of a busy clinical setting, may influence reproducibility and accuracy of charting when implementing a complex patient safety intervention[142] to improve patient outcomes such as a MEWS observation chart.

The final MEWS observation chart thus developed, incorporates tracking of early warning signs of deterioration by consensus derived cut points for seven physiological parameters and trigger responses at an agreed threshold; and tracking of clinical signs of deterioration.

3.6.4 New knowledge generated

- This study has described the use of consensus methods for developing and validating a MEWS and particularly in the context of a developing country, neither aspect found in the published literature at the time of writing.
- A consensus ranking sheet for deriving and validating a MEWS has been developed, not found in the published literature at the time of writing.
- This study has contributed to the limited published literature on establishing the index of content validity (CVI) in the design of a questionnaire.
- The Cape Town MEWS observation chart is the first to be tested on general wards in public hospitals in the Western Cape that incorporates a track-and-trigger system for abnormal physiological parameters.

3.6.5 Critique of the validation studies

3.6.5.1 Strengths of methods to develop a locally relevant MEWS

• *Strengths: Survey by questionnaire*

The limited questionnaire survey (Table 3-13) had benefits. The validity of the data was strengthened by constructing a checklist from published evidence to establish the validity of the content of the survey questionnaire (Index of Content Validity (CVI))[164] and the validity of the construction[162] of the questionnaire so that the study could proceed to consensus seeking. Satisfactory agreement with published MEWS for respiratory rate and conscious level (Table 3-17) between nurses and doctors above the predetermined ≥90% level increased internal validity. Less than satisfactory agreement, particularly for systolic BP MEWS (40.0%) which was statistically significant (p-value=0.04) established a need for consensus methods. The layout of variables on the chart was established and remained unchanged.

• *Strengths: Consensus methods*[iv]

This may be the first study in South Africa or elsewhere, to employ consensus methods for the derivation and validation of a local MEWS system for physiological parameters for general hospital wards, appropriate for a subject about which there is clinical uncertainty.[147, 148 145 146 14] No examples of consensus ranking sheets for the derivation of a MEWS system were found in the available literature.

The features of consensus methods[148 149 150] that enhanced individual respondent agreement and agreement with each other[148] included anonymity by private ranking, iteration by repeated rounds, controlled feedback and statistical group response. In this way five parameters achieved high individual agreement and two less so but there was consensus that the low agreement level should not change. The Delphi method for data collection was inexpensive and convenient for respondents who had access to e-mail.

The modified NGT provided a structured environment in which experts were given the best available information on MEWSs.[147] Face-to-face meetings between senior nurses and doctors opened up discussion about EWS and patient safety that may not otherwise have happened.Consensus on MEWS values was obtained in an orderly manner from persons closely associated with vital sign monitoring and problems associated with inadequate monitoring and recording.[147] Having 8 to 11 experts was within the recommended number.[148] The researcher assumed the role of facilitator.[148] An independent person was briefed on the role of non-participant observer not concerned with analysis of the group process but collecting qualitative data from the discussion.[148]

The size of the Delphi group remained constant (n=10) during the three rounds, which was likely to increase stability of the responses (Table 3-9).[147] Conversely, the size of the face-to-face consensus group decreased from ten participants in Round 1 to eight in Round 5 but still within acceptable norms. By establishing local criteria for a MEWS in a single setting where the scale was developed,[17] internal validity was increased, allowing for inferences to be drawn about the source

[iv] Delphi and modified nominal group techniques (NGT).

population. Nevertheless, external validity was threatened by having small numbers for validity tests, limiting generalization of inferences beyond the source population.[27] Validity and reliability of formal consensus development methods are uncertain and this has limited its use, nevertheless consensus methods have been demonstrated in specific clinical areas[160] and in this study established cut points were changed based on consensus by a small group. The predictive validity of the MEWS is described in Study Three.

There is no evidence that the observation chart currently in use has been validated. Certain MEWS charts have been implemented in the UK without validation (Personal communication, Professor Gary Smith, Portsmouth, UK). The survey established that MEWS cut points and weighted values would make assessment easy (Table 3-20), as would the good layout, the arrangement of vital signs in order of priority and having more space for charting. Besides, colour coding would alert nurses to appropriate action as would the recording of actual values rather than estimations using symbols (x, •) in graph format.

3.6.5.2 Limitations of methods

Although single-centre locations may limit external validity, most studies in those reviewed in Chapter Two were also single-centre based.[6-8, 10, 101, 174]

- *Limitations: Survey by questionnaire*

The questionnaire was long (10 pages) and may have contributed to the low return rate. Respondents should have been instructed more clearly to rank items in order of priority as some ranked all items equally important. The survey was descriptive and there was no intention to include a comparison group to allow inferences to be drawn so the question about clinical experience and professional education could have been excluded.

- *Limitations: Consensus methods*

Unavailability of published literature on the use of consensus methodology, specifically the modified NGT for EWS systems, may have resulted in limited employment thereof and the undue influence of some members on others may never be known. Members' varying levels of

experience of the MEWS observation chart placed more responsibility on the facilitator than would otherwise have been the case.[147] Participants' clinical responsibilities limited the time to less than two hours for each conference that negatively influenced fidelity to implementing the process.[141]

Pre-conference literature[v] was distributed to participants, including an information sheet explaining the purpose of the study. At Round 1 pilot conference written consent was obtained from participants that included the information sheet. During preliminary discussions it became apparent that some members had not read the pre-conference material. The effectiveness of the pilot round may have been hampered by the Enrolled Nurse standing in for the Professional Nurse as she did not contribute to the process. Certain nurses needed encouragement to participate and lacked confidence in asking for more information about the MEWS. Because of time constraints, rankings were calculated only after the group had dispersed, preventing immediate distribution of the group's response. In retrospect, to maximise the outputs derived from using the modified NGT, more careful consideration should have been given to the number of anticipated rounds, to defining agreement criteria and the nature of the task at hand.[159] [vi] Also, participants should have been given clinical vignettes with vital sign datasets. Limitations of the outputs of further rounds may have been reduced if the two MEWS parameters that were accepted at <70% agreement levels, albeit within the high tertiles (7, 8, 9), had not been accepted.

The Delphi method is generally inferior to the NGT. Decisions arrived at during the three Delphi rounds were limited by the members and their past experience[151] of these consensus methods. Some group members did not have access to e-mail or were reluctant to participate in Delphi rounds, preferring to have individual meetings with the researcher. At these meetings the purpose of the Delphi rounds was repeated and expectations were clarified. The meetings were time and resource intensive, taking place in busy wards with many interruptions and resulting in lack of uniformity in methodology and the potential for acquiescence bias in ranking items in a

[v] on the MEWS and consensus methods

[vi] by making the task of ranking the seven physiological parameters less complicated by separating the MEWS cut point ranges and seeking a ranking of a selected set rather than grouping all cut points for each parameter.

certain way. Three of these members voluntarily withdrew their participation in the study stating workload as the reason, thereby decreasing Delphi reliability. No interobserver reliability testing of the Delphi rounds was undertaken.

Derivation and validation of the Cape Town MEWS by consensus rather than cohort methodology could invite criticism of best-guessing physiologic cut points and corresponding MEWS weighted trigger points based on clinical intuition. The ranking sheet had not been validated and may have been too complex. Furthermore, all 'at risk' patient groups were not included. To limit the possibility of best-guessing, the consensus group was presented with validated published MEWS as baseline values (33 cut points for seven physiological variables) but this may have influenced the final outcome (41 derived cut points, that is, 8 more than the published MEWS of which 24 (58.3%) remained unchanged). Clinical indicators on the MEWS chart were not pilot tested.

• *Limitations of a pilot study in an acute care hospital setting*

Undertaking the pilot study in a busy clinical setting was a severe limitation. Major organizational changes were underway during the period of study to create secondary level ward services by splitting tertiary level wards and may have influenced pilot test results for accuracy of charting.

Ward nurses shared one automated monitor for BP, pulse and oxygen saturation readings among all ward patients and few digital thermometers were available so that charting was done under pressure. Respiratory rate was counted manually for a full minute therefore time consuming and open to subjectivity. Recording was delayed as readings were memorized while disconnecting the patient from the equipment and handing the machine over to a waiting nurse.

Pilot testing excluded trigger responses by nurses and patient outcomes (sensitivity and specificity of the MEWS) which are established in Study Two. For the sake of completeness clinical indicators from published evidence were incorporated in the MEWS chart but not pilot tested.

3.6.5.3 Serendipitous outcome: utility of calling criteria

At the time the study was designed the difference in purpose and utility between calling criteria and a response algorithm had not been appreciated. An objective of the study was to establish calling criteria and these were extrapolated by consensus from the Cape Town Ward MEWS cut points. However, during the pilot study it became apparent that there would be limited use for separate calling criteria for abnormal physiology of single parameters as the MEWS chart incorporates a response algorithm for this purpose. It also became apparent that calling criteria were associated with a rapid response system such as the medical emergency team (MET) concept (which was outside the scope of the study).

Subsequently, at the final consensus meeting nurses raised concerns about patients not meeting inclusion criteria for the study being missed if they suddenly experienced critical illness. This raised an ethical issue and it was agreed that calling criteria would be used during Study Three as an adjunct to the MEWS chart for such patients.

3.6.5.4 Bias

The Cochrane 'Risk of bias' assessment tool[200] provides criteria for judging this study and is presented in Table 3-34.

Table 3-34: The Cochrane 'Risk of bias' assessment tool[200]

SEQUENCE GENERATION	
Adequate sequence generation? YES (low risk of bias)	Not applicable
NO (high risk of bias)	Purposive sampling of participants for internal validation of questionnaire, survey and consensus development and validation of the MEWS chart. Purposive sampling of non-research ward for pilot testing of MEWS chart. Convenience sampling of nurses on this ward. There was a small pool of eligible participants with knowledge and experience of track and trigger systems and therefore a potential for bias in the selection of experts. Attempts to minimize selection bias included having a mix of nurses and doctors with different specialist qualifications and experience of scoring systems. Notwithstanding, there was a potential for bias[151] but having anonymous ranking limited this to some extent. Also, having certain participants involved both in validating the questionnaire and consensus development/validation of the MEWS[vii] may have introduced selection bias. Including a new participant (neurosurgeon) in the final nominal group round may have introduced information bias.[141]
ALLOCATION CONCEALMENT	
Allocation concealment? YES (low risk of bias)	Drawing sealed lots (section 3.4.5.1) by an independent person ensured anonymity in quality assurance of data entry from the questionnaires onto the Excel spreadsheet
NO (high risk of bias)	Purposive and convenience sampling methods may have introduced participant selection bias in validation of the MEWS and pilot testing of the MEWS chart.
BLINDING OF PARTICIPANTS, PERSONNEL AND OUTCOME ASSESSORS	
Blinding? NO/YES	Blinding for nominal group consensus methods is not possible but the outcome measurement (validation of the MEWS) is not likely to be influenced by lack of blinding. Blinding was achieved during the nominal group by private ranking. Blinding for Delphi was possible.
NO	For the pilot study blinding of observers to each other's recordings was attempted but it is likely that the blinding could have been broken. Even though observers were blinded to each other's charting, blinding may have been broken when charts had to be laid down to apply the blood pressure cuff and take the temperature possibly resulting in acquiescence bias.
INCOMPLETE OUTCOME DATA	
Incomplete outcome data addressed? YES	Missing data have been imputed using appropriate methods (Table 3-17).
SELECTIVE OUTCOME REPORTING	
Free of selective reporting? YES	The study protocol is available and all of the study's pre-specified outcomes have been reported in the pre-specified way.
No	The low response rate (28.8%; 15/52) could have resulted in non-response bias[205] by only describing the sample that responded who may have been more interested in MEWS than non-responders.
OTHER POTENTIAL THREATS TO VALIDITY	
Free of other bias? YES	The study appears to be free of other sources of bias.

[vii] One PhD specialist anaesthesiologist and a CCN/lecturer who holds a Master's degree. This nurse also participated in the survey by questionnaire.

3.7 Conclusions, implications and recommendations for research

Study One provided an answer to the research question: what published MEWS is most appropriate for the South African context? The Cape Town MEWS observation chart was designed and validated by consensus methods for bedside monitoring on a general ward. It incorporates a callout algorithm to trigger for disturbed physiology of single parameters or for a total MEWS. Although clinical indicators of deterioration were incorporated these were not evaluated as this was deemed to be outside the scope of the study. Separate calling criteria were also designed for wider use but were not evaluated. The results of Study One limit discussion to the implications and recommendations for research concerning the development and validation of a MEWS observation chart.[viii]

A survey by questionnaire was the least useful method for the purpose of constructing a MEWS observation chart and is not recommended for future research. Published literature on CVI[ix] for questionnaire validation is limited and what was found is dated. Research in this area is indicated.

The combination of a modified nominal group technique and Delphi by electronic mail worked well for all aspects of the design phase and is recommended for future research on MEWS observation charts. To prevent members from being lost to the study from fatigue, Delphi rounds should be limited and more use made of consensus meetings. For the electronic Delphi technique to succeed, participants need e-mail facilities.

A Consensus Conference held over two to three days is recommended to focus attention on the task at hand without interruption and to provide an opportunity for questioning and clarification. MEWS reading material should be carefully selected and distributed to consensus members at least a month before the meeting. The consensus group leader should have experience in the design, validation and use of the MEWS observation chart and be well informed on published literature. An experienced group facilitator is recommended to ensure full

[viii] Efficacy and possible barriers to implementation of a MEWS chart will be described in Study Three.
[ix] Index of Content Validity

participation by all members. Membership of a MEWS consensus group should include clinical physiologists such as specialist anaesthesiologists and critical care nurses, in addition to senior medical staff and professional nurses from general wards and nurse managers in quality of care and safety posts.

It is essential that predetermined rules of agreement be defined at the start of the consensus conference and that the group's ranking responses are distributed to all members at the conclusion of each session. If ranking sheets are developed de novo these should be pilot tested.

Colour-coded MEWS charts are recommended for improved visualization of the weighted trigger points. Alternatively, shades of grey if resources for colour printing are limited but will have to be pilot tested for reliability. Validation of calling criteria for the initiation of a rapid response system in South African hospitals needs further research. MEWS callout algorithms and calling criteria at The Hospital will initiate ward-based emergency systems as a hospital-wide critical care outreach service had been discontinued two decades prior to the MEWS study. Research is needed into both systems for best patient outcomes at The Hospital. The Cape Town Ward MEWS should be validated across all diagnoses[167, 189] and disciplines.[38]

The MEWS values were used in Study Two for recoding physiological parameters recorded on the current observation chart. The aim of Study Two is to investigate the quality and quantity of current nursing practice of recording postoperative vital signs and responding to early warning signs of clinical and physiological deterioration in adult surgical wards in the Hospital through retrospective clinical record review.

4 STUDY TWO: INVESTIGATING CURRENT VITAL SIGN MONITORING THROUGH RETROSPECTIVE RECORD REVIEW

4.1 Introduction

Record review is one of the main methods for establishing the extent of adverse events (AEs)[206] and is not disruptive to health services.[207] AEs affect nearly one out of seven in-hospital patients in the USA and cause the death of more people annually than death from breast cancer or AIDS.[208] It is therefore not surprising that the world's largest provider of health care (Medicare) routinely reviews case-notes[207] to improve quality of care, particularly since record review has become the mainstay of quality assurance measures following the publication of the leading Harvard Medical Practice Study[122] of New York hospitals, the Colorado-Utah Study[209] and the Quality in Australian Health Care Study.[92] To find solutions to the problem of adverse events (AEs), research is needed to establish what percentage of AEs is preventable[x], where the majority of events happen and which type of event is the most frequent.[94]

4.2 Background and significance

The previous chapter described the development and validation of the Cape Town MEWS observation chart. In this chapter the local MEWS table was used to recode patients' retrospective vital signs datasets recorded on existing observation charts into a score for the purpose of interpreting severity of illness by record review. The MEWS chart also provided a callout algorithm for interpreting nurses' responses to signs of clinical deterioration in patients who died and those who did not die. What was also not known was whether cut points of any of the seven physiological parameters were associated with mortality and if so, what the sensitivity and specificity of the MEWS for these parameters might be. Examination of these attributes of the

[x] Preventable adverse events were those that would not have occurred if the patient had received ordinary standards of care appropriate for the time of the study (Michel et al. 2004:1).

MEWS chart for the purpose of evaluating the quality and quantity of nurses' recordings of seven parameters in the first eight postoperative hours was undertaken in this study. Information gained from the record review would inform the final study: implementing and evaluating two interventions (the training programme and the MEWS chart).

4.3 Selected literature review

Searches covered the period 1998 to the present but included earlier primary research articles of particular relevance and frequently referenced citations concerning medical record review (1960's, 1970's, 1980's and early 1990's). Search results are presented in Table 4-1.

Table 4-1: Data search results for medical record review

Database/search engine	Keywords	Results
MESH database	Medical record review	0
	Medical record linkage – sub-headings: instrumentation/methods AND -adverse events	1 dated 1999
	Medical record linkage AND -adverse events	6 including drug events
	Record review and adverse events	0
EBSCO CINAHL database	Medical record review AND adverse events	18 (2 relevant and used)
	Record review AND retrospective AND adverse events	193 (24 relevant/13 used)

The following themes emerged from a brief review of the literature on clinical record review for detecting in-hospital AEs and preventable AEs:

- Construction of data recording forms.
- Incidence, epidemiology and reliability estimates of AEs and preventable AEs.
- Policy and management implications of clinical record reviews.

4.3.1 Construction of data recording forms for medical record review

The layout of the form for data extraction should facilitate data recording with speed and accuracy under field conditions, coding, extraction and analysis and a statistician should be

involved at this stage.[162] Standard review forms have been redesigned in a modular format for a focused review guided by resources and purpose, suitable for prospective and retrospective reviews and pilot tested and evaluated by hospital teams from eight countries.[206] A published example of a modular format[206] for a retrospective case record review for AEs comprised five sections:

(A) Patient information and background to adverse event (AE)
(B) The injury and its effects
(C) Period of hospitalisation during which AE occurred
(D) Principal problems in the process of care
(E) Causative/contributory factors and preventability of AE.

Data tools must be valid, measuring what they are intended to measure.[27] The guiding question for establishing the validity of a measurement of quality of care is: does it measure the underlying construct (quality of care) that it is intended to?[207] The guiding question for establishing reliability of a measure of quality of care is: what is the intra- and interobserver variation?[207]

The success of record review[206] and particularly good inter-rater reliability[210] is entirely dependent on the accuracy, completeness and legibility of patient records and the absence of conflicting information. A variety of clinical record review methods have been undertaken to improve quality and safety of clinical care[207] and to influence policy and clinical governance[211] by estimating rates of AEs and preventable AEs occurring in hospitals.[212]

Table 4-2 contains a summary of studies on clinical record reviews for incidence of in-hospital adverse events.

Table 4-2: Studies on clinical record reviews for incidence of in-hospital adverse events as defined by the authors organized by purpose, type of design and date of publication

Meta-analysis for interrater reliability of clinical record review					
Authors	**Study objectives**	**Outcome measures**	**Sample size**	**Methods** **Systematic review**	**Findings**
Lilford et al. 2007[207]	To determine the inter-rater reliability of case-note audit by retrospective examination	To analyse papers reporting comparisons of two or three raters making independent judgements about the quality of care.	26 papers were analysed.	Retrospective review The National Library of Medicine (NLM) Gateway facility was used to search MEDLINE and SCISEARCH databases using Goldman's papers[213] as a benchmark resulting in identification of 54 papers. Additional papers were located using reference lists in the retrieved articles. In all, 33 eligible papers were available, including nine of the 12 original Goldman papers.	66 separate comparisons made as some papers reported more than one measurement of reliability. Mean kappa values ranged from 0.32 to 0.70, possibly inflated due to publication bias. Reliability was higher for reviews based on explicit, as opposed to implicit, criteria and for reviews that focused on outcome (including adverse effects) rather than process errors. An association was found between kappa and the prevalence of errors (poor quality care), suggesting that alternatives such as tetrachoric and polychoric correlation coefficients could be considered to assess inter-rater reliability.
de Vries et al. 2007[94]	To review papers that contained information about the degree of agreement between reviewers. The object of investigation was a set of case-notes, and the topic of study was quality of care as reflected by process, adverse event or causality.	Primary endpoints were incidence of in-hospital adverse events and percentage of preventability. Secondary endpoints were adverse event outcome and subdivision by provider of care, location and type of event.	Eight studies including a total of 74 485 patient records were selected.	Embase, Cochrane and Medline searches were performed. Studies were reviewed independently for methodology, inclusion and exclusion criteria and endpoints.	The median overall incidence of in-hospital AEs was 9.2% (median percentage of preventability = 43.5%). 56.3% of patients experienced no or minor disability and 7.4% of events were fatal. Operation- (39.6%) and medication-related (15.1%) AEs constituted the majority.

Comparative studies on record review for incidence of adverse events						
Authors	**Study objectives**	**Outcome measures**	**Sample size**	**Setting**	**Comparative study**	**Findings and statistical analysis**
Weissman et al. 2008[214]	To compare adverse events reported in postdischarge patient interviews with adverse events detected by medical record review.	By using parallel methods, physicians reviewed postdischarge interviews and medical records to classify hospital adverse events.	998 recently hospitalized patients	Massachusetts, USA	Random sample survey [retrospective]	23% had at least 1 AE detected by interview and in 11% the same proportion of AE was identified by record review. The k statistic showed relatively poor agreement between interviews and medical records for occurrence of any type of adverse event (k = 0.20 [95% CI, 0.03 to 0.27]) but somewhat better agreement between interviews and medical records for life-threatening or serious events (k = 0.33 [CI, 0.20 to 0.45]). Record review identified 11 serious, preventable events (1.1% of patients) whereas interviews identified an additional 21 serious and preventable events not documented in medical records, including 12 predischarge events and 9 postdischarge events, in which symptoms occurred post-discharge.
Michel et al. 2004[212]	To compare the effectiveness, reliability, and acceptability of estimating rates of adverse events and rates of preventable adverse events	Main outcome measures: the proportion of cases (patients with at least one adverse event) identified by each method compared with a reference list of cases confirmed by ward staff and the proportion of preventable cases (patients with at least one preventable adverse event). Secondary outcome measures: inter-rater reliability of screening and identification, perceived workload, and face validity of results.	778 patients: medical (n = 278), surgical (n = 263), and obstetric (n = 237)	37 wards in seven hospitals (three public, four private) in southwestern France	Three methods applied to one sample: cross sectional (data gathered in one day), prospective (data gathered during hospital stay), and retrospective (review of medical records)	Prospective and retrospective methods identified similar numbers of medical and surgical cases (70% and 66% of the total, respectively) but the prospective method identified more preventable cases (64% and 40%, respectively), had good reliability for identification (k=0.83), represented an acceptable workload, and had higher face validity. The cross sectional method showed a large number of false positives and identified none of the most serious adverse events. None of the methods was appropriate for obstetrics.

Retrospective record review for incidence of in-hospital adverse events						
Authors	**Study objectives**	**Outcome measures**	**Sample size**	**Setting**	**Retrospective Methods**	**Findings**
Zegers et al. 2009[86]	To determine the incidence, type, nature, preventability and impact of adverse events (AEs) among hospitalised patients and potentially preventable deaths	In-hospital AEs and potentially preventable deaths	7926 admissions: 3983 deceased patients and 3943 discharged patients	A random sample of 21 hospitals in the Netherlands (4 university, 6 tertiary teaching and 11 general hospitals).	a three-stage retrospective record review process	There were one or more AEs in 5.7% (95% CI 5.1% to 6.4%) of all admissions and a preventable AE in 2.3% (95% CI 1.9% to 2.7%). Of all AEs, 12.8% resulted in permanent disability or contributed to death. Age contributed to an increase in the proportion and impact of AEs. More than 50% of the AEs were related to surgical procedures. Of the patients who died, 10.7% (95% CI 9.8% to 11.7%) had experienced an AE. Preventable AEs that contributed to death occurred in 4.1% (95% CI 3.5% to 4.8%) of all hospital deaths. Extrapolating to a national level, between 1482 and 2032 potentially preventable deaths occurred in Dutch hospitals in 2004.
Mitchell et al. 2008[211]	To determine if a robust clinical review process can influence an organisation's response to adverse patient outcomes.	Engagement of clinicians; numbers of cases reviewed, system issues identified, recommendations made to the hospital board, and ensuing actions.	2776 (46.8%) of 5925 cases met one or more of the specified criteria for adverse events and progressed to detailed review; 342 of these (12.3%) were classed as serious or major.	An Australian university-affiliated tertiary hospital from 1 September 2002 to 30 June 2006	Retrospective analysis of the activity and outputs of the Clinical Review Committee (CRC)	881 system issues were identified, resulting in 98 specific recommendations being made to the Clinical Board and implementation of 81 practice changes (including seven hospital-wide projects) to improve patient care.

Retrospective record review for in-hospital adverse events (continued)						
Authors	**Study objectives**	**Outcome measures**	**Sample size**	**Setting**	**Retrospective Methods**	**Findings**
Griffin et al. 2008[215]	To detect adverse events among patients undergoing inpatient surgery.	The development and testing of a Trigger Tool employed by the Institute for Healthcare Improvement (IHI) during a 12-month Perioperative Safety Collaborative	854 patient' surgical inpatient records	11 hospitals in the USA	A form of retrospective record review.	138 SAEs were detected in 125 records (a rate of 16 SAEs per 100 patients or 14.6% of patients); 61 (44%) of these events contributed to increased hospital stay or readmission and 12 (8.7%) events required life-saving intervention or resulted in permanent harm or death. Most of the events identified during the Trigger Tool review process had not been detected or reported before.
Sari et al. 2008[216]	To estimate the extent, preventability and consequences of adverse clinical events in elderly and non-elderly patients.	The proportion of patients with adverse events, the proportion of preventable adverse events and the types and consequences of adverse events in patients ≥75 and under 75 years old.	A random sample of 1,006 non-psychiatric patients	A large NHS hospital in England	A two-stage structured, retrospective, patient case-note review.	45 [13.5%; 95% CI 10–17] of 332 patients ≥75 years and 42 (6.2%; 95% CI 4–8) of 674 patients <75 years had at least one AE. Increasing age added a significantly raised risk of experiencing an AE [odds ratio (OR) = 1.03 AEs per year of life, *P*<0.001]. After adjustment for potential confounders there was no statistically significant difference in preventability of adverse events or in experiencing disability or death as a result of an AE by age.

Retrospective record review for in-hospital adverse events (continued)						
Authors	**Study objectives**	**Outcome measures**	**Sample size**	**Setting**	**Retrospective Methods**	**Findings**
Brennan et al. 2004* (reprint of 1991 article)[217]	To estimate the incidence of adverse events, defined as injuries caused by medical management, and of the subgroup of such injuries that resulted from negligent or substandard care.	Population estimates of injuries and rates computed according to age and sex of patients as well as the specialties of the physicians	30 121 randomly selected records	51 randomly selected acute care, nonpsychia -tric hospitals in New York State in 1984	Retrospective review	AEs occurred in 3.7% of hospitalizations (95% CI 3.2 to 4.2), and 27.6% of AEs were due to negligence (95% CI 22.5 to 32.6). 70.5% of AEs resulted in disability lasting less than 6 months, 2.6% causing permanently disabling injuries and 13.6% led to death. More severe injuries (Wald test x2 = 21.04, p,0.0001) resulted in an increased percentage of AEs attributable to negligence. Weighted totals were used to estimate that among the 2 671 863 patients discharged from New York hospitals in 1984 there were 98 609 AEs and 27 179 AEs involving negligence. Rates of AEs rose with age (p,0.0001) and the percentage of AEs due to negligence was markedly higher among the elderly (p,0.01). There were significant differences in rates of AEs among categories of clinical specialties (p,0.0001), but no differences in the percentage due to negligence.

Retrospective record review for in-hospital adverse events (continued)						
Authors	**Study objectives**	**Outcome measures**	**Sample size**	**Setting**	**Retrospective Methods**	**Findings**
Baker at al. 2004[130]	To estimate the incidence of AEs among patients	Trained reviewers screened all eligible charts, and physicians reviewed the positively screened charts to identify AEs and determine their preventability	Random review of a sample of charts for nonpsychiatric, nonobstetric adult patients in each hospital	Canadian acute care hospitals: random selection of 1 teaching, 1 large community and 2 small community hospitals in each of 5 provinces	Retrospective review	At least 1 screening criterion was identified in 1527 (40.8%) of 3745 charts. The physician reviewers identified AEs in 255 of the charts. After adjustment for the sampling strategy, the AE rate was 7.5 per 100 hospital admissions (95% confidence interval [CI] 5.7–9.3). Among the patients with AEs, preventable events occurred in 36.9% (95% CI 32.0%–41.8%) and death in 20.8% (95% CI 7.8%–33.8%). Physician reviewers estimated that 1521 additional hospital days were associated with AEs. Men and women experienced equal rates of AEs but patients who had AEs were significantly older than those who did not (mean age [and standard deviation] 64.9 [16.7] v. 62.0 [18.4] years; p = 0.016). Interpretation: The overall incidence rate of AEs of 7.5% suggests that, of the almost 2.5 million annual hospital admissions in Canada similar to the type studied, about 185 000 are associated with an AE and close to 70 000 of these are potentially preventable.
Thomas et al. 2002[218]	To measure the reliability of medical record review for detecting adverse events and negligent adverse events.	Reliability and the effect of varying criteria for reviewer confidence in and reviewer agreement about the presence of adverse events.	500 medical records of inpatients	Utah and Colorado (USA) in 1992	Three independent retrospective medical record reviews	For agreements in judgments of AEs among the three sets of reviews, the k statistics ranged from 0.40 to 0.41 (95% CIs ranged from 0.30 to 0.51) for adverse events and from 0.19 to 0.23 (CIs, 0.05 to 0.37) for negligent adverse events. Rates for AEs and for negligent AEs varied substantially depending on the degree of agreement and the level of confidence that was required among reviewers.

Retrospective record review for in-hospital adverse events (continued)						
Authors	**Study objectives**	**Outcome measures**	**Sample size**	**Setting**	**Retrospective Methods**	**Findings**
Vincent et al. 2001[219]	To examine the feasibility of detecting adverse events through record review in British hospitals and to make preliminary estimates of the incidence and costs of adverse events.	The number of adverse events	1014 medical and nursing records	two acute hospitals in Greater London area	Retrospective review	110 (10.8%) patients experienced an AE, with an overall rate of AEs of 11.7% when multiple adverse events were included. About half of these events were judged preventable with ordinary standards of care. A third of AEs led to moderate or greater disability or death.
Prospective record review for in-hospital adverse events						
Authors	**Study objectives**	**Outcome measures**	**Sample size**	**Setting**	**Prospective Methods**	**Findings and statistical analysis**
Bellomo et al. 2002[220]	To assess the incidence and nature of postoperative serious adverse events (SAEs) among inpatients having surgery in a tertiary hospital, and to determine which subgroups of patients might be at greatest risk.	In-hospital mortality, length of hospital stay, and SAEs (myocardial infarction, pulmonary embolism, acute pulmonary oedema, unscheduled tracheostomy, respiratory failure, cardiac arrest, stroke, severe sepsis, acute renal failure, and emergency admission to intensive care unit [ICU]).	1125 subjects having inpatient surgery during the study period	a tertiary teaching hospital in Melbourne, Victoria.	Prospective observational study from 1 December 1998 – 31 March 1999.	There were 414 SAEs in 190 of the 1125 patients (16.9%); 80 patients died (7.1%). The most common AEs were emergency admission to ICU (95), respiratory failure (52) and readmission to ICU (37). In patients without SAEs, mean duration of hospital stay was 18.4 days (95% CI, 15.4–21.4), while in those with SAEs it was 38.5 days (95% CI, 35.3–41.7) ($P < 0.0001$). SAEs, including deaths, were more common after unscheduled surgery and in patients over 75 years of age. The combination of these two factors carried a 20% mortality. There were no differences in the incidence of SAEs among the major surgical specialties.

4.3.2 Incidence, epidemiology and reliability estimates of AEs and preventable AEs

Meta-analysis of 74 485 patient records in eight published papers[94] found that the median incidence of in-hospital AEs was 9.2% (almost one in 10 patients) (median percentage of preventability = 43.5%). Of these AEs, operation (39.6%) and medication-related (15.1%) events constituted the majority. The incidence of AEs reported in studies in Table 4-2 varied[11, 14, 21] from 3.7%[217] to 40.8%.[130] One study[212] reported that prospective and retrospective methods identified similar proportions (70%; 66%) of AEs. Incidence of AEs increased with age.[86, 130, 217, 220] Proportion of preventability of AEs varied greatly (2.3%,[86] 36.9%,[130] 43.5%[94] and 64%)[212] with more identified by prospective than retrospective methods.[212] Surgical procedures accounted for 50% of AEs[86] especially unscheduled surgery[220] and 14.6% of surgical patients had AEs, 8.7% of whom required life-saving interventions.[215] Proportion of AEs that were fatal varied (7.1%,[220] 7.4%,[94] 8.7%,[215] 13.6%,[217] 20.8%[130] and 27.6%[217]).

Screening criteria for the seminal Harvard Medical Practice study[217] revealed a sensitivity of 89% by reviewing 1% of reviewed records (used as the gold standard). More is published about reliability of medical record review than about validation. Review teams are described as consisting of trained and experienced nurses and doctors,[86, 212, 218, 219] only doctors[217] or only nurses.[211] Nurses seem to do the initial detection of possible AEs and doctors then confirm these.[212] The number of reviewers influences reliability. There is a higher level of agreement when a measurement is an average over several reviewers than when individual reviewers are compared and this may inflate findings.[207] For example, the Harvard Medical Practice Study[217] "averaged the rating of two reviewers and then calculated reliability between that average rating and an average (consensus) rating obtained independently from a group of 'experts'" (Lilford et al. 2007:174).[207] Independent reviews reduce observer bias.[207] For this reason Lilford et al. (2007)[207] included studies making comparisons of only two or three reviewers making independent judgements on the quality of care in their systematic review in Table 4-2.

One systematic review in Table 4-2 of 26 published papers[207] found three end points ('Focus') of review for assessing quality of care: first, measurements of process (errors of omission or

commission); second, outcome (the occurrence of AEs); and third, measures of causality of AEs. Two broad approaches to measurement of quality ('Style') emerged: explicit (algorithmic) methods using specific, detailed checklists and implicit (holistic) methods based on expert judgement, where guidance was either unstructured or structured. Mean kappa values ranged from moderate (0.32) to good (0.70) but these may have been inflated due to publication bias, that is, studies with poor reliability may not be submitted for publication.

There were higher levels of reliability for explicit as opposed to implicit criteria and for reviews that focused on outcome (including AEs) rather than process errors.[207, 210] Independent assessors of reliability used 17 to 25 predetermined criteria for identifying potential AEs.[212 211, 218, 219] Consensus methods have been employed for disagreement[86] failing which a third independent assessor[86] arbitrated. Three independent reviews of 500 medical records concluded that estimates of reported AE rates including those in the 2000 report of the Institute of Medicine on medical errors, are highly sensitive to the degree of consensus and confidence among reviewers (Table 4-2).[218]

4.3.3 Policy and management implications of clinical record review

The results of robust, multidisciplinary clinical reviews can influence an organisation's response to adverse patient outcomes[211] and it should, as a large proportion of AEs are the result of suboptimal care.[217] AE record review results can also focus patient safety research efforts.[86] Yet, inadequate recording of AEs in clinical records when these are known to patients, should encourage hospitals to add questions about AEs to postdischarge interviews.[214] Variation in policy and organizational characteristics between hospitals and countries influences incidence of AEs.[86] A substantial proportion of preventable AEs may be avoided with ordinary standards of care as defined by the authors and should be avoided as they are costly to the NHS.[219] Although AEs increase with increasing age there is insufficient evidence that AEs in older patients are more preventable.[216] Even so, epidemiological evidence suggests that patient safety efforts should focus on older patients and those having surgery.[86] The degree of consensus and confidence among reviewers greatly influence estimates of AE rates from clinical record review.[218]

The research setting is described in previous chapters (section 1.5).

4.4 Aims and Objectives

To establish a baseline prior to the intervention described in the following chapters, the aim of this study was to examine records of patients who did or did not have a SAE (unexpected death, admission to ICU or cardiac arrest) to investigate the quality and quantity of nurses' recordings of postoperative vital signs data and responses to signs of deterioration. To interpret responses the vital signs recordings were recoded into a score. A secondary aim was to explore the efficacy of these scores (the MEWS) in identifying clinical deterioration in preparation for evaluating the intervention in the next study.

To achieve the aims the following objectives were identified:

Objective 1 – examination of nurses' current practice of recording vital signs through retrospective record review

- To describe the number of physiological variables, range and proportion of times that ward nurses recorded these on existing observation charts as prescribed by medical doctors over an 8 hour period where 100% completeness will be rated Good; 95-99% Fair and <94% Poor.
- To describe the proportion of MEWS trigger points (1 to 3) that were associated with a response by converting the recorded values of the patients' single parameter vital signs into a MEWS.[i]

Objective 2 – Analysis of SAEs

- To assess the incidence of SAEs in post-operative patients on six purposively selected surgical wards;
- To explore any associations between SAEs and the parameters included in the Cape Town MEWS observation chart.

[i] Discussion of the appropriateness of the therapeutic interventions in response to abnormal scores was considered to be outside the remit of this study.

Objective 3 – sensitivity and specificity of the MEWS

- To establish the sensitivity and specificity of the Cape Town MEWS weighted trigger points (0 and upper and lower 1 to 3) of each physiological parameter where sensitivity refers to the ability of the MEWS chart to identify patients with established critical illness (SAEs) who trigger predetermined physiological thresholds and specificity means the ability of the MEWS chart not to trigger a response for inappropriate patients (without established critical illness who did not trigger).
- To establish the cut point of each parameter associated with SAEs.

4.5 Methods for record review study

4.5.1 Research design

Descriptive, analytical study using a retrospective dataset.

4.5.2 Subjects/sampling of patient records for record review

The target population included the records of all patients admitted to the 13 specialist surgical wards at the Hospital (Table 4-3). The sampling frame comprised records from six wards purposively selected for inclusion in the study and the records of all patients admitted to these six wards were eligible for review. These six wards resemble the sampling frame in a large study[221] of outcome measures for failure to rescue patients discharged from general surgical, orthopaedic and vascular surgical wards. The six wards comprised two for general surgery, three for orthopaedic surgery and one combined ward for vascular and general abdominal surgery. Purposive selection of the six research wards limited external validity inferences.[1] Generalisation to other settings depends on logical, rather than statistical inferences. Records were excluded from areas where patients are monitored closely such as trauma, high dependency and ICU wards.

Table 4-3: Target population, study sample and potential subjects (to be screened for inclusion/exclusion criteria

Target population: Records of patients from all surgical wards (N=13)	**Intended sample: Records from purposively selected wards (n=6)**	**Estimated actual subjects** for a 3-month period who had a general anaesthetic (GA) (1 May- 31 July 2009) (section 4.4.2.2)
2 general surgical wards	2 general surgery wards including gastrointestinal surgery	
3 orthopaedic wards	3 orthopaedic wards	
1 combined vascular and general abdominal surgery ward	1 combined vascular and general abdominal surgery ward	
1 ophthalmology ward		
1 spinal ward		
2 gynaecology wards		
1 combined urology and reconstructive surgery ward		
1 neurosurgery ward		
1 ear, nose and throat ward		

(Adapted from Hulley et al., 2007:28)[1]

4.5.2.1 Screening

Records of all patients 14 years of age[188] and older who had a general anaesthetic and were admitted to one of the six research wards during 1 May – 31 July 2009 were eligible for inclusion.

The completeness of clinical records for the purposes of the screening process was assessed[92] for having nursing progress notes including an initial assessment of vital signs, anaesthetic record including time of leaving the recovery room and destination ward, entry in nursing progress notes of the time and condition of patients on return to the ward and date and condition on discharge, half- and 4-hourly observation charts and doctor's prescription sheet for vital sign monitoring.

- *Exclusion criteria for records:*

Incomplete or unavailable records.

Patients who were defined as having experienced an SAE met the following criteria:

- *Inclusion criteria for the SAE group:*

Recording of one, two or all of the following SAEs in the patient's record: unexpected death in the ward after anaesthetic, unanticipated admission to ICU after anaesthetic, or cardiac arrest without a pre-existing not-for-resuscitation (NFR) order in the ward after anaesthetic.

- *Exclusion criteria for the SAE group:*

No SAE after anaesthetic.

- *Inclusion criteria for the control group (4 records for each SAE):*

No SAE in the ward after anaesthetic. The next chronological four records after the SAE subject were selected.

4.5.2.2 Sample size determination

To estimate the sample size required to determine the incidence of SAEs the empirical statistics reported in the Research Setting (six wards) for the previous year (1.5) were used and the following parameters were entered into StatCalc/Epi-Info version 3.5.1:

Population size = 5129 in these wards
Incidence of death = 63 in these wards; 1.2%
Margin of error of 1.0 – 1.4%
Confidence Interval = 95%
Power = 80%

The initial estimation was based on the expectation that the total number of deaths would be 1.2% of inpatient admissions to the six wards, without considering which of these patients met

inclusion criteria (for example had a general anaesthetic) because the researcher was unsure how many patients would meet the criteria. A sample of 587 was found to be necessary to establish the incidence of death. To allow for any omitted, a sample of 600 records was used, with the expectation that there would be five deaths in this sample. In the absence of data for the other two SAEs relevant to the study (cardiac arrest without a pre-existing NFR order or unanticipated admission to ICU), it was estimated that there would be a ratio of 2 such SAEs to each death. This should therefore result in a sample of approximately 5 + (5*2) = 15 patients who die or experience another SAE. In addition, for each SAE the control group consisted of the next four records drawn of a patient who did not have an SAE, until a sample of 60 (60/6 = 10 from each ward) was reached. In summary, it was estimated that 600 records would have to be screened and that the records of 15 patients with SAEs and 60 of control patients who did not experience SAEs would have to be analysed in depth.

4.5.3 Instrument construction

4.5.3.1 Designing a Criterion Record Review form

No suitable examples of record review forms were found in the available literature. The Modular Review Form For Retrospective Case Record Review[206] was too lengthy for the purpose of this study. Instead, explicit review criteria (Appendix 4.1) were guided by the research objectives and included socio-demographic variables and the seven physiological variables included in the MEWS chart (Table 4-4). As the record review form was a summary of the variables on the consensus validated MEWS observation chart, further construct and content validity testing would have repeated work completed in sections 3.4.4 and was therefore deemed unnecessary. Similarly, as the same researcher was involved in pilot testing the MEWS chart in Study One and in data gathering in Study Two, it was not deemed necessary to establish reliability a second time. Results are less likely to be biased due to differences across observers if the same observer makes measurements.[142]

Table 4-4: Explicit criteria for clinical record review form

Socio-demographic variables	**Indicator variables**
Sex	Female=1, male=0
Age	
Surgery specialty	General* Vascular Gastrointestinal* Orthopaedic
Presence of SAE	Yes=1, No=0
SAE type	Death Admission to ICU Cardiac arrest
Presence of pre-existing comorbid condition Type of pre-existing comorbid condition	Yes=1, No=0
Days in hospital	
Physiological parameter	**Indicator variables (for each physiological parameter)**
Respiratory rate	If prescribed (number and proportion) Frequency prescribed If cut points (thresholds) for a callout were prescribed Frequency recorded in first 8 post-operative hours MEWS equivalent † If MEWS triggered a callout
Oxygen saturation	
Heart rate	
Systolic BP	
Temperature	
Conscious level	
Urine output	
Other parameters eg. Hb, neurovascular compartment checks	If prescribed

Note on table:

†Nurses' recorded values for single parameters on the existing observation charts were recoded using the validated MEWS (Figure 3-4) from Study One.

* Classification on clinical folders

4.5.4 Procedure

4.5.4.1 Gaining access

Gatekeepers for gaining entry were the Provincial Government of the Western Cape (PGWC) Department of Health Ethics Committee (Appendix 3.10) and at the Hospital, the Chief Medical Superintendent for clinical research (Appendix 3.11). The two letters of authority provided access to the custodian of the medical records who gave verbal consent and allocated two research clerks to trace records. Ward clerks explained how patient folder movements were managed between wards and central records. There were no electronic records on type of anaesthesia administered so permission was obtained for a manual search of the operating room registers to trace patients from the six wards who had a general anaesthetic. The Hospital Department of Informatics provided an electronic patient dataset (CliniCom) for the study period data incorporating patient movements, clinical speciality and length of hospital stay. Data retrieval is presented in Table 4-5. The researcher did not have access to hospital computers which may have reduced the number of documents having to be accessed.

Table 4-5: Data retrieval process for clinical record review

CRITERION	DATA SYSTEM	Process
General anaesthetic	Operating room register later confirmed by anaesthetic record in patient folder	Screening undertaken in the operating room suite
Age and gender	Patient folder	Retrieved by medical records staff by pre-arrangement. Record review undertaken in that department only by hospital policy. Age calculated from date of birth on patient identification sticker as entries by health staff varied
SAE: Cardiac arrest	Patient folder	Nursing patient progress notes/medical notes
SAE: Transfer to ICU/HDU for a deteriorating condition	Patient folder	Nursing patient progress notes/medical notes
Presence and type of pre-existing comorbid condition	Patient folder	Anaesthetic record/medical notes/occasionally on nursing patient progress notes
Surgery specialty	CliniCom database	Admission specialty may have differed from discharge specialty so determined by the ward to which the patient was returned following the general anaesthetic
Days in hospital	CliniCom database	If not recorded: • the summary on the patient folder and if also blank • nursing patient progress notes
Physiological parameters prescribed: Specific parameters/Number/Frequency of monitoring/Cut points (thresholds) for a callout/Monitoring of other parameters eg. Hb	Prescription sheet completed by medical staff	If not found this was recorded as not prescribed.
Parameters and frequency of recordings postoperatively over 8 hours:		
Heart rate, systolic BP and temperature	½ hourly and 4-hourly observation charts	Nurses recorded these graphically, tending to round to multiples of five for HR and SBP and to estimated locations of 0.5 ^{o}C for temperature[14]
Respiratory rate and oxygen saturation	No parameters listed on vital signs chart for half hourly monitoring	Not recorded – but occasionally documented in the nursing patient progress notes
Conscious level (responsiveness)	Nursing patient progress notes	Only a comment such as "fully awake/drowsy" on return to ward from operating room
Urine output	Fluid balance chart	Column for urine output
MEWS equivalent (cut points and corresponding weighted trigger values 0-3)	MEWS observation chart	Raw values were recoded
If MEWS triggered a callout algorithm	Nursing patient progress notes	Checked if parameter values were high or low and if nurses' recorded interventions in response to disturbed physiological parameters

Data were captured electronically on the record review form. On days that other researchers used the only available power plug in the restricted research area, data were captured manually. For patients who had multiple general anaesthetics during one admission data were analysed for the first surgical procedure.

4.5.5 Data management and statistical analysis

The researcher entered raw data onto a password-protected Excel© spreadsheet (Microsoft Office 2007) (the dataset review form).[7] Data were duplicated on an external drive for safekeeping in a secure environment for three years. Data were analysed using Microsoft Office Excel 2007, IBM SPSS Statistics version 19, DAG-Stat[222] and GraphPad Prism version 5.0d for MAC software programmes (Table 4-6).

Table 4-6: Statistical analysis

Socio-demographic variables Table 4-9	**Indicator variables**	**Data**	**Statistical analysis**
Sex	Female=1, male=0	Categorical Binary	Number, Proportion, Chi-Square, df, p-value
Age		Interval	Mean, min-max, SD, Independent t-test (mean difference, 95% CI, p-value, t-statistic, df, F-value
SAE type	Death	Categorical	Proportion
Surgery specialty	General Vascular Gastrointestinal Orthopaedic	Categorical	Proportion
Type of pre-existing comorbid condition	8 pre-listed	Categorical	Number, Proportion, Chi-square, df, p-value, OR, CI
Days in hospital		Interval	Median, min-max, IQR, Mann-Whitney U, mean rank, sum of ranks, z-value, p-value
7 Physiological parameters	**Indicator variables (for each physiological parameter)**	**Data**	**Statistical analysis**
Table 4-15	If prescribed	Numerical	Number, proportion, Mann-Whitney U, mean rank, sum of ranks, z-value, p-value
Table 4-15	If cut points (thresholds) for a callout were prescribed	Numerical	Number, proportion, Mann-Whitney U, mean rank, sum of ranks, z-value, p-value
Table 4-12	Number of patients with parameter recordings on admission	Numerical	Number, Median†, min-max, Mann-Whitney U, mean rank, sum of ranks, Z-value, p-value
Table 4-13	Number of patients with postoperative parameter recordings	Numerical Binary 1=Done; 0=Not done	Chi-Square, p-value, OR, 95% CI Number, Proportion
Table 4-14	Number of recorded parameters in first 8 postoperative hours	Numerical	Number, Median†, min-max, Mann-Whitney U, mean rank, sum of ranks, Z-value, p-value
Table 4-11	Total MEWS	Numerical	Arithmetic addition, Number
Table 4-16	If MEWS triggered a callout	Binary 1=Yes, 0=No	Number, Proportion
Figure 4-2, **Figure 4-3**, **Figure 4-4**, **Figure 4-5**	Sensitivity and specificity of MEWS categories Age	Numerical Interval	Receiver operating characteristic (ROC) ROC
Table 4-17	Associations between SAEs and MEWS for each parameter: comormidities, systolic BP on admission, postoperative: heart rate, systolic BP, urine output	Numerical	Univariate analysis: OR, probability, CI; ROC for sensitivity and specificity

Note on table: Abbreviations denote: ROC=receiver operating characteristic; SD=standard deviation; IQR=interquartile range; df=degrees of freedom; P-value=probability; CI=confidence interval; OR=odds ratio.

†Due to asymmetry of data the median was recorded and not a mean[101] (a varying number of parameters was prescribed and recorded for each patients during the 8-hour period).

The dataset was summarized by patient identity number to produce summary statistics for each patient. Descriptive analysis of quantitative data established patients' demographic profile, compliance with medical staff instructions, incidence and type of SAEs, the median number of measurements recorded, MEWS equivalence of parameter readings and whether abnormal physiology triggered a response by the nursing staff.

For normally distributed data, results are given as means and standard deviations (SD).[185] For non-parametric data, medians and interquartile ranges (IQR) are given. Unpaired t-tests were used to compare mean variables in SAE and No SAE groups and the Mann-Whitney U-test to compare medians in nonparametric variables. The Chi-squared test and Fisher's exact test were used to compare categorical variables. A p-value of less than 0.05 was considered significant.

As the presence or absence of a SAE is a binary variable, univariate analysis using the SPSS version 19 software was used to establish the odds ratios of such events taking place in the presence of the different physiological variables.

Patients' vital signs data on admission were recoded into a MEWS format (0, upper and lower 1 to 3 weighted trigger points). Actual values *only* for admission parameters were captured on the record review form (for example a heart rate of 92=MEWS of 0) so a *total* MEWS could be calculated for each patient (Table 4-7) *on admission only.* It would be too time and labour intensive to record actual readings for seven parameters for eight hours for each patient.

The proportion of completeness of recordings reported here should be interpreted as the number of patients for whom the single parameter was recorded and not the frequency of recordings of each parameter. The reason is that there are no clinical guidelines for the optimum number of vital signs that ought to be monitored in the postoperative period or the frequency of monitoring required to ensure the best patient outcomes. Each observation time-point for the 8-

hour period for each patient was examined and the parameters that were recorded for each time-point were tallied on the review form.

Having established the number of *recordings* of patients' vital signs data for the first eight postoperative hours (Table 4-14) the data were then examined for nurses' responses to signs of disturbed physiology. No hospital guidelines for callout criteria were available. For this purpose the postoperative vital sign data were recoded into a MEWS format (as for admission data) to establish the point at which a callout should have been triggered[ii] (Table 4-7). Recoding was achieved by converting each recorded value (for example HR 50) for each observation time-point into a MEWS and reporting it as a low or high score of 1-3 on the review form. Patients' progress notes were then searched for the nurses' reponse to the trigger (yes/no).

Table 4-7: Example of vital sign data recoded into a MEWS format on the record review form

Code Number	Heart rate number of post-op recordings first 8 hrs	Post-op MEWS Heart Rate high No=0 101-110=1 111-129=2 ≥130=3	Post-op MEWS Heart Rate low No=0 51-59=1 40-50=2 <40=3	Heart Rate Triggered response 1=YES 0=NO 2=N/A
16	11	0	2	0

As groups were predefined as patients having SAEs and patients without SAEs, univariate analysis was used to assess and directly compare single variables and locally validated scoring systems in their ability to discriminate between the groups via receiver operating characteristic (ROC) curves using GraphPad Prism version 5.0d for MAC, GraphPad Software, San Diego California USA, www.graphpad.com. A variable able to differentiate between two groups with high sensitivity and specificity will have an associated ROC curve where the area under that curve will approach one.[101] After initial cleaning of the data the variable urine output was deemed unreliable due to the large amount of missing data but as low urine output was found to be

[ii] See section 3.5.2.5. 0=requiring no action, upper and lower 1=re-check after half an hour and report if no improvement, upper and lower 2=serious - check after 5 minutes and report immediately if no improvement, upper and lower 3=critical requiring immediate action.

significantly associated with mortality (SAE) on univariate analysis, it was not excluded from the ROC analysis for the sake of completeness.

4.5.6 Ethical considerations

The study complies with the principles enshrined in the 2008 version of the Declaration of Helsinki[223] despite its vulnerability to criticism since claiming 'ethical primacy'[224] and to the International Council of Nurses' Code of Ethics for Nurses.[225]

4.5.6.1 Autonomy: Confidentiality, anonymity and respect for persons

The most important ethical considerations in record review for adverse events include the confidential nature of patient information, protection of anonymity and consent. In terms of South African legislation (Section 16 (2)) a health care provider may examine a user's health records for the purposes of research without authorization if the research will not obtain information relating to the identity of the user.[226] The Mayo Clinic has a long tradition of patient record review to improve patient care.[227] Debates concerning the waiving of patient consent for quality-improvement research initiatives in hospitals, provided stringent conditions are met, are well documented[228] [229]and if these studies are not done, may well be more harmful than helpful.[230] In certain American states legislation restricts access to medical records for research purposes but there are practical consequences particularly as medical-records studies are important to monitor the health of the population, to identify populations at risk for disease, to determine the effectiveness of treatment, to quantify prognosis, to assess the usefulness of diagnostic tests and screening programmes, to influence policy through cost-effectiveness analysis, to support administrative functions and, to monitor the adequacy of care.[227]

This anonymised reporting of retrospective record review is of patients who will have been discharged so patient consent will not be required. There was no hospital policy concerning pre-admission patient consent for access to records for research purposes, particularly to monitor the outcomes of care.

Although reporting is anonymous, patients were not, therefore all research assistants signed a confidentiality clause. To ensure anonymity outside of the study, a unique identification code was assigned to each patient dataset and patients' identity was known only to the researcher and research assistants. Confidentiality of data was protected by not linking participants' names to data and there will be no disclosure of personal information in reporting on the study. The name of the research site will not be reported by name in the publication of findings.

4.5.6.2 Beneficence and Nonmaleficence

No harm was done to patients or nurses in name or person. Although, in the opinion of the researcher, the record review revealed evidence of inappropriate clinical decisions, there was no disclosure of personnel's personal information.

All attempts were made to safeguard human rights during the study. Results will be reported to relevant authorities.

4.6 Results of Study Two

4.6.1 Baseline data: sampling process for incidence of SAEs

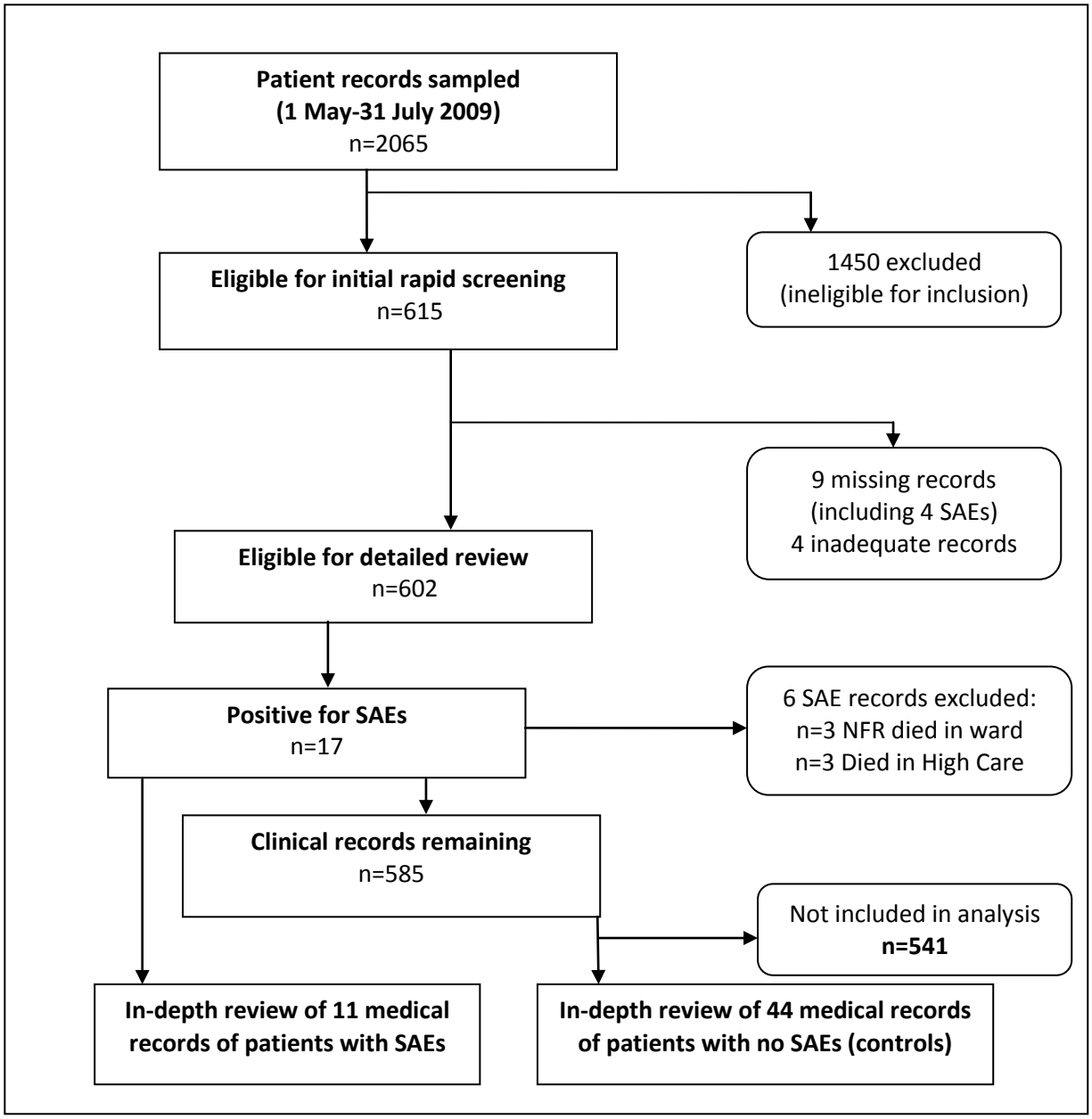
There were 2065 admissions to the six wards for the period of study (Figure 4-1) recorded in the CliniCom database. Operating room registers identified 615 (29.8%) patients who had a general anaesthetic. Using the CliniCom database, 21 deaths (3.4%) of the 615 patients were identified. Four missing SAE records (for medico-legal review) were excluded leaving 17 deaths. Three patients died in a high dependency unit (HDU) after routine short-stay admission for specialized care following certain surgical procedures and were excluded. The fourteen remaining deaths occurred on the six wards. Three of these patients were not for resuscitation (NFR), therefore excluded (4.4.2.1) leaving 11 deaths in the sample. No other SAEs were recorded on the database.

On initial rapid screening of the remaining 615 clinical records no further deaths were identified but 9 records were missing leaving 602 records for detailed review. No patient who had a cardiac arrest was referred to ICU before they died. No patient with abnormal physiology who did not die was referred to ICU. Record screening for patient transfers to ICUs and High Care Units established that, although none of these patients were transferred for a deteriorating condition, they were routinely admitted to these high surveillance areas postoperatively following certain high risk surgical procedures and did not meet inclusion criteria.

Records of the 11 (n=602, 1.8%) patients who died fulfilled specified criteria for SAE and progressed to detailed review. Of the remaining 585 patients (Figure 4-1), 44 (7.5%) control subjects (4:1 SAE) who fulfilled specified criteria for inclusion were selected consecutively and were then examined in detail to find other SAEs. The results therefore relate to 11 patients with SAEs and 44 control patients. An eventual sample of 55 records (n=602, 9.1%) was reviewed to meet the objectives.

4.6.1.1 Review process

The review process and eventual sample is shown in Figure 4-1.



(Adapted from Wilson, Runciman, Gibberd, Harrison, Newby & Hamilton, 1995).[92]

Figure 4-1: Flow chart of record review process and outcome of record selection

Note on Figure: All records were sampled from the six research wards.

4.6.1.2 Quality control of record review process

A 10% random sample (6/55) of anonymized[7] reviewed records was independently coded by a nurse assessor [iii] to evaluate the quality of the clinical record review process.[92] The duplicate reviews were then searched for agreement in 61 explicit checklist criteria for six patients. There was no disagreement for demographic and comorbidity criteria or for frequency of parameters prescribed by medical staff or recoding of recorded vital signs into a MEWS. The overall agreement for criteria was 91.8% (56/61). Disagreement (9.8%, 6/61) related to the number of observations recorded (n=4) for oxygen saturation, heart rate, BP and temperature; volume of urine output (n=1) and whether an abnormal reading for BP had triggered a response by nurses (n=1). Resolution was achieved by review of these records by both assessors and disagreement was reconciled by discussion and agreement. Nurses recorded vital signs on 3 charts (1/2-hourly and 4-hourly observation charts and on patient progress notes) and these recordings were often duplicated. In a few cases legibility of symbols on graph charts was poor especially when heart rate (indicated with a dot) coincided with the BP symbol (X).

4.6.1.3 Demographic and clinical characteristics of the SAE and control group

An in-depth review of the records of the 11 patients who died found that four were preceded by cardio-respiratory arrest (Table 4-8). The third criterion for classification as an SAE, unexpected admission to ICU, was not recorded in any patient.

[iii] Surgical clinical nurse instructor who holds a degree in nursing education and management and is currently undertaking a Master's degree.

Table 4-8: Mortality by age, comorbidity, surgical procedure, time and associated cause of death

SAE (n=11)	Age	Comorbidity	Surgical procedure	Postoperative period of death	Cause/associated cause of death
1	72	Non-insulin dependent Diabetes Mellitus, Hypertension, orthopnoea	Angiogram, right iliac artery stenting and femoral-popliteal bypass graft	Peri-arrest: 15 hours 15 minutes; death: 19 hours 40 minutes – unsuccessful CPR	Myocardial infarction
2	62	Chronic obstructive airways disease, Diabetes Mellitus II Amoebic liver abscess	Right hemicolectomy & stoma	52 hours (2 days) (monitored then late decision of NFR)	Cardiac arrest
3	67	Peripheral vascular disease, Hypertension, Diabetes Mellitus II	Right groin exploration; angiogram; femoral-femoral crossover; right through knee amputation; Left fasciotomy & toectomy	11 hours Apnoea 1 hour prior to death – no reporting; Intern attended – unsuccessful CPR	Hyperkalaemia
4	55	Diabetes Mellitus	Relook: Left above knee amputation	2 days (monitored – late decision of NFR)	Septic shock, renal failure, liver failure
5	70	Diabetes Mellitus II, Hypertension, Renal impairment, Limb ischaemia	Right trans-malleolar amputation for foot sepsis	42 hours – unsuccessful CPR	Myocardial infarction
6	63	Ulcerative colitis	Laparascopic incisional hernia repair proceed to laparotomy for incisional hernia repair & insertion of MESH	6 days – unsuccessful CPR	Aspiration of vomitus
7	37	Ingestion of battery acid 8 years previously - adhesions	Laparotomy for adhesiolysis & release of bowel obstruction	3 hours 20 minutes – declared dead by doctor (no CPR)	Cardiorespiratory arrest, Massive aspiration due to bowel obstruction
8	64	Gastric carcinoma	Laparotomy for total gastrectomy	3 hours – unsuccessful CPR	Cardiorespiratory arrest
9	70	Angina, dyspnoea, paroxysmal nocturnal dyspnoea	Sigmoid colectomy	4 days – unsuccessful CPR	Aspiration
10	76	Bleeding peptic ulcer	Gastroscopy under GA for bleeding gastric ulcer & injection with adrenaline	11 hours – unsuccessful CPR	Cardiac arrest, Hypovolaemic shock
11	62	Schizophrenia; alcohol abuse	Debridement right shoulder; fractured right femur - intramedullary nail	7 days – unsuccessful CPR	Acute renal failure secondary to septic compound fracture right humerus; respiratory distress

Two patients, including a 37-year old, died within three hours of having surgery, three within 11-19 hours and six within two to seven days. It was not possible to establish the proportion of preventable deaths. Myocardial infarction was associated with two deaths and both patients had a history of Diabetes Mellitus and hypertension.

Cardio-pulmonary resuscitation (CPR) was unsuccessful in all eight of the 11 patients for whom it was attempted. This included a 67-year old patient who had major vascular surgery and amputation and a recorded apnoeic attack one hour preceding death that was not reported. The 37-year old patient was declared dead by the attending doctor one hour after being summoned following massive aspiration after surgery for severe bowel adhesions. A late 'Not for Active Resuscitation' decision was made for two patients: a 62-year old with chronic obstructive airways disease and Diabetes Mellitus and a 55-year old with Diabetes Mellitus following above knee amputation and the development of multiple organ failure.

Data in (Table 4-9**)** portray differences in demographic and clinical characteristics between patients who died (SAE group n=11/55, 20.0%) and those who did not die (n=44/55, 80.0%).

Table 4-9: Mortality by demographic and clinical characteristics (no SAE group is the reference and = 1 for calculation of the OR)

Characteristic	**SAE[1] (n=11)**	**No SAE (n=44)**		
Categorical Variables	Number (%)	Number (%)	χ^2 (df)	p-value
Sex: Female	4 (36.4)	29 (65.9)	3.201 (1)	0.074
Type of surgery:	**n=11**	**n=44**		
General	5 (45.5)	28 (63.6)		
Vascular	3 (27.3)	3 (6.8)		
Gastrointestinal	2 (18.2)	9 (20.5)		
Orthopaedic	1 (9.1)	4 (9.1)		

Pre-existing comorbid conditions:[2]

	SAE (n=11) Number	**No SAE (n=44)** Number	**Proportion of Sample (N=55)**	**χ^2 (df=1)**	**p-value**
Myocardial infarction	1	1	2 (3.6)	Fisher's	0.363
Renal	2	1	3 (5.5)	Fisher's	0.099
Diabetes Mellitus	5	7	12 (21.8)	4.503	0.034
Carcinoma	1	10	11 (20.0)	1.023	0.312
Respiratory	3	6	9 (16.4)	Fisher's	0.362
CVA/ Hypercholesterolaemia	0	5	5 (9.1)	Fisher's	0.571
Hypertension	3	15	18 (32.7)	.186	0.666
Other (eg. pancreatitis, schizophrenia)	9	7	16 (29.1)	18.532	0.000

Interval Variables

Patients' age in years:

	Mean*/ median†	**min-max**	**SD**	**IQR**	**Independent t-test**			
					Mean difference [95% CI]	**p-value**	**t-statistic (df)**	**F-value**
SAE (n=11)	63.5*	37-76	10.5		16.57 [6.0-27.1]	0.003	3.147 (53) Equal variances assumed	F=3.840, p=0.055
No SAE (n=44)	46.9*	17-81	16.5 8					

Hospital stay (days):

					Mann-Whitney U-test				
					Mean Rank	**Sum of Ranks**	**U-value**	**Z-value**	**p-value**
SAE	5.0†	1-24		7	29.07	1279.00	195.00	-.994	0.328
No SAE	7.0†	2-53		9	23.73	261.00			

Notes on table:

1. SAE denotes serious adverse event.
2. Some patients had more than 1 comorbid condition recorded (see Table 4-10).

As indicated in (Table 4-9) there were significantly more patients with pre-existing diabetes in the control group (Chi-Square 4.50, df=1, p=0.034) and more patients with 'other' comorbidities (Chi-Square 18.53, df=1, p<0.001) in the SAE group. The mean age of the SAE group was significantly greater than the control group (mean difference 16.6, t=3.15, df=53, p=0.003), otherwise the two groups were equivalent.

Most patients in both groups had a co-morbid condition but patients who died all had at least one and in some cases three or more (Table 4-10).

Table 4-10: Number of pre-existing comorbid conditions

	Comorbid conditions					
	0	1	2	3	4	Total
SAE (n=11)	19	25	0	0	0	44
No SAE (n=44)	0	6	1	3	1	11
Total	19	31	1	3	1	55

Having three or more comorbid conditions when undergoing long and complicated surgical procedures at this public specialist referral hospital already compromised patient outcomes.

Pre-intervention nursing practice of recording postoperative vital sign data on existing charts and responding to early warning signs of clinical and physiological deterioration was then investigated.

4.6.1.4 Patients with recordings of vital sign data on admission

Four parameters were recorded on admission: respiratory rate, pulse, blood pressure and temperature. An example of a calculation of a total MEWS from vital sign data on admission is shown in Table 4-11. A total MEWS of 3 was predetermined (section 3.5.2.5) to trigger a callout response.

Table 4-11: Example of a calculation of a total MEWS for recoded vital sign recordings on admission for one patient (0=normal, +=upper value, -=lower value)

	Respiratory rate	MEWS	Heart rate	MEWS	Systolic blood pressure	MEWS	Temperature ^{o}C	MEWS	Total MEWS
SAE n=11									
Patient 1	20	+1	70	0	206	+3	36.6	0	4

Analysis of recorded parameters on admission was not a study objective therefore data are presented in Appendix 4.2. In summary, record review showed that not all patients had recordings of all four parameters on admission. Two patients who died and one from the comparator group had no recordings. On admission 10.9% (6/55) of patients should have triggered the call-out algorithm by scoring 3 on the MEWS for systolic BP, three of whom died following surgery. The median total MEWS for both groups was 1 (SAE=range 0-4; No SAE=range 0-5).

The number of patients with recordings of respiratory rate, heart rate, blood pressure and temperature on admission and data are reported in Table 4-12.

Table 4-12: Patients with parameters recorded on admission

				Mann-Whitney U test				
Parameter	**Number of patients**			**Mean rank**	**Sum of Ranks**	**U statistic**	**Z-value**	**p-value**
	Number	Median	Min-max					
RESPIRATORY RATE								
SAE group (N=11)	4	0	0-1	26.50	291.50	225.500	-.406	0.685
No SAE group (N=44)	19	0	0-1	28.38	1248.50			
HEART RATE								
SAE group (N=11)	8	1	0-1	23.50	258.50	192.500	-1.929	0.054
No SAE group (N=44)	41	1	0-1	29.13	1281.50			
SYSTOLIC BLOOD PRESSURE								
SAE group (N=11)	8	1	0-1	23.50	258.50	192.500	-1.929	0.054
No SAE group (N=44)	41	1	0-1	29.13	1281.50			
TEMPERATURE								
SAE group (N=11)	8	1	0-1	23.50	258.50	192.500	-1.929	0.054
No SAE group (N=44)	41	1	0-1	29.13	1281.50			

For respiratory rate recordings (Table 4-12) the mean rank of scores in the no SAE group was higher (28.38) than that of the SAE group (26.50) but this did not reach statistical significance (Z=-.406, p=0.685). For heart rate, BP and temperature recordings the mean rank of scores in the no SAE group was higher (29.13) than that of the SAE group (23.50) and this reached statistical significance (p=0.054).

Record review showed that not all patients had recordings of all four parameters on admission. Two patients who died following surgery and one from the control group had no recordings. On admission the majority of patients in both groups scored 0 ('normal') on the MEWS for single parameters (systolic BP, heart rate and temperature). However, six (N=55, 10.9%) patients should have triggered the callout algorithm by scoring 3 on the MEWS for systolic BP, three of whom died following surgery. All patients had a rapid respiratory rate (15-29, MEWS upper 1 and 2). Eight patients had seriously disturbed physiology (MEWS of 2 for single

parameters) but none died. The median[iv] total MEWS score for the SAE group was 1 (range 0-4) and for the control group it was 1 (range 0-5).

4.6.2 Objective 1: Examination of nurses' current practice of vital signs recording through retrospective record review

4.6.2.1 Patients with recordings within the first 8 hours following surgery

The number of patients who died (n=11) and those who did not die (n=44) with vital sign recordings [binary Done/Not done] within the first 8 hours following surgery is shown in Table 4-13**.**

[iv] Due to asymmetry of data the median was calculated as nurses performed a variable number of observations on patients in an 8-hour period.

Table 4-13: Patients[1] with postoperative parameter recordings by group

Parameter	SAE N=11 patients	No SAE N=44 patients	x^2	p-value	OR (df=1)	95% CI
	Number (%)	Number (%)				
Respiratory rate recorded	0 (0.0)	1 (2.3)	Fisher's Exact	p=1.000	Not computed	
Respiratory rate not recorded	11 (100.0)	43 (97.7)				
Heart rate recorded	11 (100.0)	43 (97.7)	Fisher's Exact	p=1.000	Not computed	
Heart rate not recorded	0 (0.0)	1 (2.3)				
Oxygen saturation[2] recorded	6 (54.5)	3 (6.8)	Fisher's Exact	p=0.001	16.40	3.09-86.96
Oxygen saturation not recorded	5 (45.5)	41 (93.2)				
Systolic blood pressure recorded	11 (100.0)	44 (100.0)	Not computed			
Systolic blood pressure not recorded	0 (0.0)	0 (0.0)				
Temperature recorded	11 (100.0)	42 (95.5)	Fisher's Exact	p=1.000	Not computed	
Temperature not recorded	0 (0.0)	2 (4.5)				
Conscious level[3] recorded	4 (36.4)	30 (68.2)	3.775	p=0.052	.267	.067-1.063
Conscious level not recorded	7 (63.6)	14 (31.8)				
Urine output recorded	9 (81.8)	42 (95.5)	Fisher's Exact	p=0.175	.214	.027-1.729
Urine output not recorded	2 (18.2)	2 (4.5)				
All parameters recorded	0	0	Not computed			
Incomplete recording of all parameters	11	44				

Note on table:

1. Not all patients survived for 8 hours.
2. Oxygen saturation was measured by pulse oximetry.
3. Conscious level denotes the patients' state of wakefulness and not Glasgow Coma Scale assessment.

Not one patient in either group had recordings for all parameters (Table 4-13). The proportion of completeness of recordings[v] within the first 8 postoperative hours was:

- Good for BP and met the *a priori* level of 100% coverage for both groups (N=55);
- Good (100%) for heart rate and temperature for the SAE group (N=11);
- Fair for heart rate (98%), temperature and urine output (96%) for patients who did not die (N=44);
- Poor for oxygen saturation but there were significantly ($p<0.001$) more patients in the SAE group (55%) than in the no SAE group (7%);
- Poor for conscious level for the SAE (36%) and no SAE group (68%) and for urine output for the SAE group (82%);
- zero for respiratory rate in patients who died and for one patient (2%) who did not die.

[v] Criteria for proportion of completeness of recording should be interpreted as coverage, i.e. each patient having at least one recording of a parameter: Good=100%; Fair=95-99%; and Poor=<94% coverage.

4.6.2.2 Recordings of vital sign data within the first 8 hours following surgery

The number of recordings of each parameter by group is shown in Table 4-14.

Table 4-14: Number of postoperative vital sign recordings (for 8 hours)

				Mann-Whitney U test				
Parameter	**Number of recordings**			**Mean rank**	**Sum of Ranks**	**U statistic**	**Z-value**	**p-value**
RESPIRATORY RATE	Total number[1]	Median	Min-max					
SAE group (n=11)	0	0	0-0	27.50	302.50	236.500	-.500	p=0.617
No SAE group (n=44)	1	0	0-1	28.13	1237.50			
HEART RATE								
SAE group (n=11)	80	7	2-13	33.32	366.50	183.500	-1.237	p=0.216
No SAE group (n=44)	272	6	0-14	26.67	1173.50			
OXYGEN SATURATION								
SAE group (n=11)	13	1	0-3	38.59	424.50	125.500	-3.807	p<0.001
No SAE group (n=44)	7	0	0-5	25.35	1115.50			
SYSTOLIC BLOOD PRESSURE								
SAE group (n=11)	92	9	3-15	33.86	372.50	177.500	-1.364	p=0.172
No SAE group (n=44)	305	7	2-14	26.53	1167.50			
TEMPERATURE								
SAE group (n=11)	19	2	1-3	24.27	267.00	201.000	-.927	p=0.354
No SAE group (n=44)	94	2	0-5	28.93	1273.00			
CONSCIOUS LEVEL[2]								
SAE group (n=11)	5	0	0-2	22.36	246.00	180.000	-1.528	p=0.126
No SAE group (n=44)	30	1	0-1	29.41	1294.00			
URINE OUTPUT								
SAE group (n=11)	25	2	0-8	32.59	358.50	191.500	-1.133	p=0.257
No SAE group (n=44)	72	1	0-7	26.85	1181.50			

Note on table: Total number of observations = all observation time-points.

1. State of wakefulness recorded in patient progress notes and not on the observation chart.

There were more patients in the control (No SAE) group (n=44) than in the SAE group and this was reflected in the higher distribution of recordings in the control group for all other parameters. However, there were more recordings for oxygen saturation in the SAE group than in the control group and this reached statistical significance (Z=-3.807, p<0.001) (Table 4-14) meaning that nurses might have been concerned about a deteriorating clinical condition in these patients.

The frequency of prescribed vital signs is shown in (Table 4-15).

Table 4-15: Number of patients (N=55) with prescribed vital signs in the SAE group (n=11) and no SAE group (n=44)

Number of patients with prescribed vital signs (%)		Mann-Whitney U				
		Mean rank	Sum of Ranks	U statistic	Z-value	p-value
Respiratory rate						
SAE group	7 (63.6)	29.00	319.00	231.000	-.273	.785
No SAE group	26 (59.1)	27.75	1221.00			
Oxygen saturation						
SAE group	1 (9.1)	28.50	313.50	236.500	-.257	.797
No SAE group	3 (6.8)	27.88	1226.50			
Heart rate						
SAE group	7 (63.6)	35.00	385.00	165.000	-1.925	.054
No SAE group	14 (31.8)	26.25	1155.00			
Blood pressure						
SAE group	7 (63.6)	29.00	319.00	231.000	-.273	.785
No SAE group	26 (59.1)	27.75	1221.00			
Temperature						
SAE group	7 (63.6)	25.00	275.00	209.000	-.920	.357
No SAE group	34 (77.3)	28.75	1265.00			
Conscious level						
SAE group	0	28.00	308.00	242.000	.000	1.000
No SAE group	0	28.00	1232.00			
Urine output						
SAE group	0	28.00	308.00	242.000	.000	1.000
No SAE group	0	28.00	1232.00			
Specific cut points for parameters						
SAE group	1 (9.1)	29.50	324.50	225.500	-1.071	.284
No SAE group	1 (2.3)	27.63	1215.50			
Specific parameters						
SAE group	3 (27.3)	29.00	319.00	231.000	-.314	.753
No SAE group	10 (22.7)	27.75	1221.00			

Observations were monitored for more patients than had prescriptions[vi] (Table 4-15). Overall, doctors prescribed monitoring of nonspecific 'regular' observations for 60.0% (33/55) of patients (7/11, 63.6% who died; 26/44, 59.1% who did not die). There were specific prescriptions for 23.6% of patients (13/55). Monitoring of oxygen saturation was prescribed for one patient in the SAE group and for three patients (6.8%) in the No SAE group. There were no prescriptions for monitoring conscious level and urine output. The only statistically significant difference in prescribed parameters between the two groups was for heart rate (Z=-1.925, p=0.054). Cut points

[vi] Prescriptions worded 'regular observations/vitals' were interpreted by ward nurses as half hourly monitoring of respiratory rate, heart rate and BP and one hourly for temperature for four hours.

for vital signs were prescribed for one patient in each group respectively, meaning that for the majority of patients nurses were required to use clinical judgement in deciding to call for more skilled assistance.

4.6.2.3 Nurses' responses to high and low threshold vital sign recordings

Data were then examined for nurses' responses to signs of disturbed physiology (a high or low MEWS) and by reviewing patient progress notes for recorded interventions (Table 4-5). Single parameters were analysed and no attempt was made to recode for calculating a total MEWS for each patient. To obtain a total MEWS would require calculating an aggregate for each patient's recorded episodes of vital sign monitoring for 8 hours from four existing charts which was resource intensive and was not a study objective. Vital sign data are presented as MEWS trigger points in Table 4-16 (which ought to trigger a callout algorithm). The number of nurses' responses to abnormal single parameter MEWS is presented for both groups.

Table 4-16: Summary of nurses' responses to disturbed physiology (upper and lower MEWS 1 to 3† that should have triggered a callout) in the first 8 postoperative hours

PARAMETER	Number of MEWS trigger points	SAE Group response (N=11)		Number of MEWS trigger points	No SAE Group response (N=44)	
		YES	NO		YES	NO
Respiratory rate MEWS						
1	0	0	0	0	0	0
2	0	0	0	0	0	0
3	0	0	0	0	0	0
Heart rate MEWS						
1	6	2	4	13	0	13
2	4	1	3	10	0	10
3	4	1	3	0	0	0
Oxygen saturation MEWS						
1	2	1	1	0	0	0
2	1	0	1	0	0	0
3	2	2	0	0	0	0
Systolic BP MEWS						
1	5	2	3	18	1	17
2	2	1	1	3	0	3
3	1	1	0	6	4	2
Temperature MEWS						
1	0	0	0	17	1	16
2	1	0	1	4	2	2
3	0	0	0	0	0	0
Conscious level MEWS						
1	1	1	0	14	0	14
2	1	1	0	0	0	0
3	0	0	0	0	0	0
Urine output MEWS						
1	5	0	5	14	0	14
2	13	0	13	4	0	4
3	0	0	0	3	0	3

Note on table: †No distinction is made between lower and upper MEWS trigger points.

Data in Tables 4-13 to 4-16 are summarized below:

- Heart rate: In the SAE group 14/80 recordings for 11 patients should have triggered a callout and nurses responded to four but not to three callouts for a critical score of 3.

In the control group 23/272 recordings for 43 patients should have triggered a callout but nurses did not respond to any.

- Oxygen saturation: In the SAE group 5/13 recordings for six patients should have triggered a callout and nurses responded to three, including two callouts at a critical score of 3.
- Blood pressure: All patients in both groups had recordings. In the SAE group 8/92 recordings should have triggered a callout and there were four responses which included one for a critical score of 3. In the control group 27/305 recordings should have triggered a callout and there were five responses including four to six callouts for a critical score of 3.
- Temperature: All patients in the SAE group had recordings and 1/19 should have triggered a callout but there were no responses. In the control group 21/94 recordings for 42 patients should have triggered a callout and nurses responded to three callouts.
- Conscious level: In the SAE group 2/5 recordings for four patients should have triggered a callout and nurses responded to both. In the control group 14/30 recordings for 30 patients should have triggered a callout but nurses did not respond to any.
- Urine output: In the SAE group 18/25 recordings for nine patients should have triggered callouts but nurses did not respond to any. In the control group 21/72 recordings for 42 patients should have triggered callouts but nurses responded to none.

Record review revealed few recordings of action taken for scores that should have triggered (SAE group: 9/48, 18.8% = 81.2% non-response; control group 8/106, 7.6% = 92.4% non-response). Most patients who died had a fast heart rate (9/11, 81.1%), a low systolic BP (8/11, 72.7%) and oliguria (6/11, 54.6%), with no evidence of external haemorrhage. The association between these parameters and mortality for this study is presented next.

4.6.3 Objective 2: Analysis of SAEs

4.6.3.1 Univariate analysis: variables associated with mortality (SAEs)

Univariate analysis was performed to calculate the odds ratio (OR) for SAEs (mortality) for the different variables (vital sign parameters on the observation chart, demographic variables and clinical characteristics). As there were several analyses in which one value was 0, Haldane's estimator[vii] was used to calculate OR as this circumvents 0s in cells by adding ½ to each cell.

Receiver operating characteristic (ROC) analysis indicated that 61 years of age was the most sensitive (the true-positive rate) and specific (the false-positive rate) age to differentiate between patients with SAEs (mortality) and those without SAEs. The association between age and mortality is portrayed in Figure 4-2. Age was therefore dichotomized into 61 or older and 60 or younger.

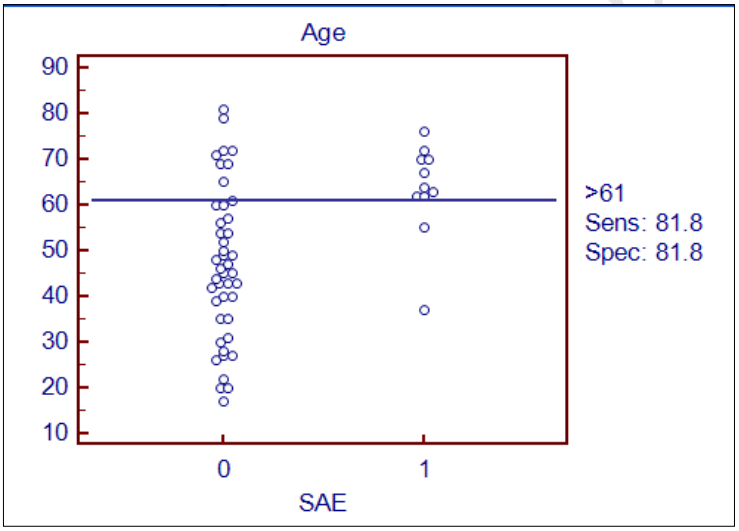


Figure 4-2: Graphic representation of the association between age and SAE (mortality)

Note on figure: 0 denotes no SAE; 1 denotes mortality.

[vii] Haldane's estimator is used when cells have a very small or zero value. It calculates the OR as follows: ((TP+0.5)/(FN+0.5))/((FP+0.5)/(TN+0.5)):TP=true positive; FP=false positive (Mackinnon, 2000; Agresti 1990).

The calculation of the OR for all variables associated with mortality is shown in Table 4-17.

Table 4-17: The odds ratio (OR) for variables associated with SAEs (mortality) (no SAE group is the reference and = 1 for calculation of the OR)

Variable	**SAE**	No SAE	Association (Probability)	Odds ratio	Confidence Interval (CI)
Age category:	N=11	N=44	Fisher's Exact=p<0.001	14.2†	95% 3.0-68.0†
61 years and older	9	9			
60 years and younger	2	35			
Comorbid conditions:	N=11	N=44	Fisher's Exact=p<0.001	75.3†	95% CI 3.7-1527.4†#
One or less	6	44			
Two or more	5	0			
Systolic BP on admission:	N=8 (3 missing values)	N=41 (3 missing values)	Fisher's Exact p=0.015	7.2†	95% CI 1.5-34.2†
High/Low systolic BP	5	7			
No High/Low systolic BP	3	34			
Heart rate 8 hours postoperatively:	N=11	N=44	Fisher's Exact p=0.018	6.6†	95% CI 1.4-30.0
Fast heart rate (MEWS 1 to 3)	9	16			
No fast heart rate	2	28			
Systolic BP 8 hours postoperatively:	N=11	N=44	Fisher's Exact p=0.003	8.0†	95% CI 1.9-33.1†
Low systolic BP	8	10			
No low systolic BP	3	34			
Urine output 8 hours postoperatively:	N=9 (2 missing values)	N=42 (2 missing values)	Fisher's Exact p=0.053	4.1†	95% CI 1.0-17.3
Low urine output	6	13			
No low urine output	3	29			

Note on table: † Haldane's estimator[222, 231]; # denotes that there was a 0 in one group.

As indicated in Table 4-17, the variables that were associated with mortality were being ≥61 years (OR 14.2, CI 3.0 - 68.0), having two or more pre-existing comorbid conditions (OR 75.3, CI 3.7 – 1527.4), a high or low systolic BP on admission (OR 7.2, CI 1.5 – 34.2 three missing values in each group), a fast heart rate (OR 6.6, CI 1.4 – 30.0) and a low systolic BP (OR 8.0, CI 1.9 – 33.1) during the first 8 postoperative hours 6.6. The association between low urine output and SAEs approaches significance (OR 4.1, CI 1.0 – 17.3).

4.6.3.2 Univariate analysis: variables *not* associated with mortality (SAEs)

Most vital sign parameters recorded on admission were not associated with SAEs (respiratory rate p=0.55, heart rate p=0.17 and temperature p=0.58).

Postoperatively, recordings for respiratory rate and oxygen saturation (pulse oximetry) within the first eight hours were not tested due to the large number of missing responses. There were too few subjects with low heart rate to warrant analysis (two). The high (p=0.39) and low temperature MEWS (p=0.08) and conscious level (p=0.37) were not found to be associated with SAEs.

Thirteen patients without SAEs (n=13/44, 30.0%) and no patients with SAEs had a recorded high systolic BP during the first eight hours postoperatively (OR 0.1, 95% CIs 0.005-1.8[viii], Fisher's Exact p=0.04).

In summary, being 61 years of age or older, having two or more pre-existing comorbid conditions and either a high or low systolic BP on admission before surgery, was significantly associated with mortality (SAEs) postoperatively. Three of the seven vital sign parameters were significantly associated with mortality (SAE) in the postoperative period: a fast heart rate, low systolic BP and low urine output.

Small numbers and having zeros in cells made it impossible to do multivariate analysis.

[viii] Haldane's estimator.

4.6.4 Objective 3: Sensitivity and specificity of MEWS categories and cut points for variables

The three vital sign parameters that were significantly associated with mortality (SAE) in the postoperative period (fast heart rate, low systolic BP and low urine output) were analysed for sensitivity and specificity[ix] using receiver operating characteristic (ROC) statistics. Data recorded on existing charts were recoded for a MEWS so would not have triggered a callout algorithm but this analysis provided a baseline of the effectiveness of the MEWS for the intervention in the next study.

ROC analysis for *heart rate* is shown in Figure 4-3.

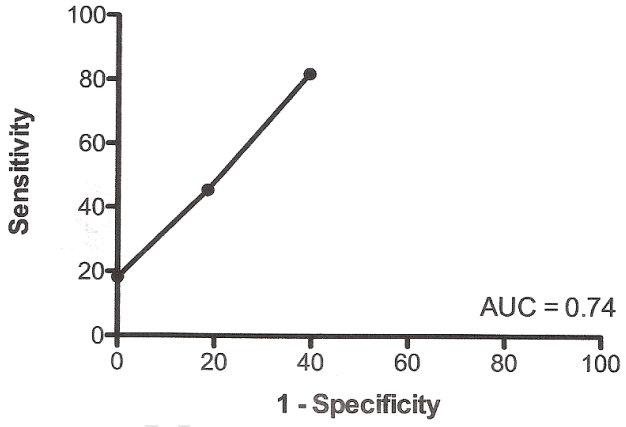


Figure 4-3: Sensitivity and specificity of fast heart rate associated with mortality (SAE)

[ix] Sensitivity refers to the ability of the MEWS chart to identify patients with established critical illness (SAEs) who trigger predetermined physiological thresholds and specificity means the ability of the MEWS chart not to trigger a response for inappropriate patients (without established critical illness who did not trigger).

MEWS	Sensitivity %	95% CI	Specificity %	95% CI	Likelihood ratio
>0.5000	81.8	48.2-97.7	60.5	44.4-75.0	2.1
>1.500	45.5	16.8-76.6	81.4	66.6-91.6	2.4
>2.500	18.2	2.3-51.8	100.0	91.8-100.0	

A MEWS of 1 for heart rate was sensitive in that 82.0% of patients with established critical illness would have been seen but it would also have triggered a callout inappropriately for 40.0% of patients. At 3 the MEWS had perfect specificity (100.0%) but at the cost of sensitivity (18.2%), that is, no patient with a score of 3 survived. For this data, an upper MEWS of 2 for heart rate (111-129 beats a minute) was the most satisfactory early warning trigger with a sensitivity of 46.0% and an inappropriate callout rate (specificity) of 19.0%.

ROC analysis for *systolic blood pressure* is shown in Figure 4-4.

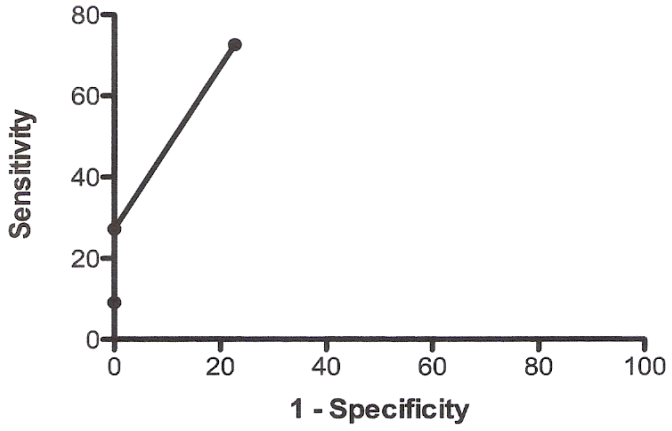


Figure 4-4: Sensitivity and specificity of low systolic blood pressure in association with mortality (SAE)

	Sensitivity %	95% CI	Specificity %	95% CI	Likelihood ratio
>0.5000	72.7	39.0-94.0	77.3	62.2-88.5	3.2
>1.500	27.3	6.0-61.0	100.0	92.0-100.0	
>2.500	9.1	0.2-41.3	100.0	92.0-100.0	

A MEWS of 2 and 3 for low systolic BP were 100.0% specific respectively, that is, no patient in these categories survived but sensitivity was low at 27.3% and 9.1% respectively. However, a MEWS of 1 was sensitive in that 73% of patients with established critical illness would have been seen with an inappropriate callout rate (specificity) of 23%. For this data, a lower MEWS of 1 for systolic BP (81-100) was the most satisfactory early warning trigger.

ROC analysis for low urine output is shown in Figure 4-5.

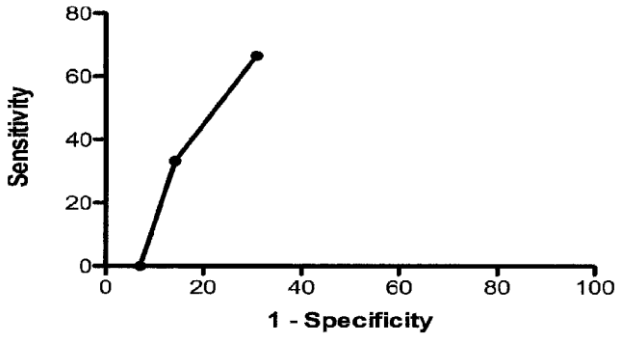


Figure 4-5: Sensitivity and specificity for low urine output in association with mortality (SAE)

	Sensitivity %	95% CI	Specificity %	95% CI	Likelihood ratio
>0.5000	66.7	29.9-92.5	69.1	52.9-82.4	2.2
>1.500	33.3	7.5-70.1	85.7	71.5-94.6	2.3
>2.500	0.0	0.0-33.6	92.9	80.5-98.5	0.0

As there were many missing values and no patients with a MEWS of 3, these results ought to be viewed with caution but were included for the sake of completeness. A MEWS of 1 was sensitive in that 67% of patients with established critical illness would have been seen but with a specificity of 69.1%, a callout algorithm would have been triggered inappropriately (specificity) for 31.0% of patients. At 2, the MEWS had a specificity of 86.0% but at the cost of sensitivity (33.3%). No further interpretation is helpful.

At a cut-off point of an upper 2, the sensitivity of the MEWS for heart rate is 45.5% (95% CI, 16.8–76.6) and the specificity is 81.4%. At a cut-off point of a lower 1, the sensitivity of the MEWS for systolic BP is 72.7% (95% CI, 39.0–94.0) and the specificity is 77.3%.

The callout algorithm established in Study One is repeated here (Table 3-28).

0 = no action 1 = re-check after ½ hour and report if no improvement 2 = check after 5 minutes/report immediately if no improvement 3 = critical REPORT IMMEDIATELY

4.7 Discussion

The aim of this study was to examine records of patients who did or did not have a SAE (unexpected death, admission to ICU or cardiac arrest) to investigate the quality and quantity of nurses' recordings of postoperative vital signs data and responses to signs of deterioration. The aim was achieved.

4.7.1 Summary of results

Baseline demographic data and clinical characteristics obtained from the records of 11 patients who died and a control sample of 44 patients who did not die, in six purposively selected wards (general surgery incorporating gastrointestinal and vascular surgery and orthopaedic surgery) were examined. Unexpected ward death was the only SAE found. When explored further, four of these deaths were preceded by cardio-respiratory arrest. There were significantly more patients with pre-existing diabetes in the control group (Chi-Square 4.50, df=1, p=0.034) and more patients with 'other' comorbidities (Chi-Square 18.53, df=1, p<0.001) in the SAE group (Table 4-9). The mean age of the SAE group was significantly greater than the control group (mean difference 16.6, t=3.15, df=53, p=0.003). Most patients in both groups had a co-morbid condition but patients who died all had at least one and in some cases three or more (Table 4-10), otherwise the two groups were equivalent.

Objective 1 – Examination of nurses' current practice of vital signs recording through retrospective record review

Analysis of baseline data showed that by recoding recordings of vital sign data on admission (Appendix 4.2) two patients who died following surgery and one from the control group had no recordings on admission. The median total MEWS for both groups was 1 (SAE=range 0-4; No SAE=range 0-5).

- ***Recordings of postoperative vital sign data within the first 8 hours and nurses' responses*:**

Doctors prescribed monitoring of nonspecific 'regular' observations for 64% (7/11) of patients who died and for 59% (26/44) of patients who did not die (Table 4-15). There were specific prescriptions for 23.6% of patients (13/55). No patient (N=55) in either group had recordings for all seven parameters (Table 4-13). Generally, recording was low (median recordings: SAE group n=2; control group n=1) (Table 4-14). The number of patients who had recordings, described as the proportion of completeness[x] of recording, was good for BP and met the *a priori* level of 100% coverage for both groups, and for heart rate and temperature for the SAE group (N=11). The proportion of completeness of recording was fair for heart rate (98%), temperature and urine output (96%) for patients who did not die (N=44) but poor for the other parameters.

The existing observation chart excluded clinical guidelines for interpreting severity of illness and for a callout algorithm. The appropriateness of the nurses' responses was therefore interpreted against the locally derived MEWS as a 'gold standard' for interpreting severity of illness and for a callout algorithm. Nurses' responses were determined from recorded entries in patient progress notes (Table 4-5). Data (Table 4-16) showed that for both groups, 16 recordings should have triggered a callout for a critical MEWS of 3 (there were eight responses, 50.0%), 43 recordings should have triggered a callout for a serious score of 2 (five responses, 11.6%) and 95 recordings should have triggered a callout for a score of 1 (eight responses, 8.4%). Responses have to be interpreted with caution as the absence of recorded interventions does not mean that there were no interventions.

[x] Coverage for all patients as Good=100%; Fair=95-99% and Poor=<94% (i.e. not number of recordings).

Objective 2 – Analysis of SAEs

Most patients who died had a high or low systolic BP on admission (OR 7.2). Univariate analysis for odds ratio showed that postoperatively, there was a significant association between tachycardia (OR 6.6) and hypotension (OR 8.0) (Table 4-17) and mortality but that the association between mortality and oliguria (OR 4.1) only approached significance. Patients' demographic data and clinical characteristics that were significantly associated with mortality included age (≥61 years, OR 14.2) and having two or more pre-existing comorbid conditions (OR 75.3).

Objective 3 – Sensitivity and specificity of the MEWS

An upper MEWS of 2 for heart rate (111-129 beats a minute) (**Figure 4-3**) and a lower MEWS of 1 for systolic BP (81-100) (**Figure 4-4**) showed the best sensitivity and specificity.

4.7.2 Generalisability of results

Purposive selection of the six research wards comprising two for general surgery, three for orthopaedic surgery and one combined ward for vascular and general abdominal surgery, resembling the sampling frame in a large study[221] limited external validity inferences.[1] Records were excluded from areas where patients are monitored closely such as trauma, high dependency and ICU wards. Generalisation to other settings depends on logical, rather than statistical inferences.

4.7.3 Study results compared to existing literature and in wider context

As was used in this study, retrospective reviews are undertaken the most frequently (Table 4-2). However, it is acknowledged that it was not possible to identify all the preventable causes of AEs and that a prospective study might have resulted in a more complete dataset.[212] The proportion of preventable deaths and deaths attributable to negligence is costly[219] and was outside the scope of this study.

Results for objectives 1 and 2: Patients' demographic data and clinical characteristics are presented first, then the quality and quantity of vital sign recordings.

Review of 585 records of patients eligible to participate in the study established that 11 (1.9%) had died on the wards. Analysis of SAEs established that unexpected death and cardio-respiratory arrest were the only SAEs found (Table 4-8). For four patients (36.4%) cardio-respiratory arrest had preceded death and if other cardiac related causes are considered such as myocardial infarction (n=2) and hyperkalaemia (n=1) that causes severe arrhythmias, this proportion increases to 63.6% (n=7). Prospective record review of 1,125 inpatients having surgery revealed that 80 patients died (n=1125, 7.1%) and respiratory failure (52/414 SAEs, 12.6%) was one of the most common AEs.[220] The six research sites are admission wards for patients needing emergency surgery. It is reported that SAEs, including deaths, are more common after unscheduled surgery particularly if patients are over 75 years of age, when this combination of factors carries a 20% mortality[220] confirmed by a later study co-authored by the same author.[232] Of 110 patients who had a cardiac arrest in four Finnish hospitals 56 (51%) occurred on the wards.[233]

The Australian study by Bellomo et al. (2002) [220]also reported 95 (22.9%) emergency admissions to ICU. There were no recorded incidents of unexpected admission to ICU after cardiac arrest in the Cape Town study. The existing policy of routine patient admission to High Care following high risk surgery seems effective in reducing SAEs. There is contradictory evidence about the benefit for some patients of being admitted to ICU due to irreversibility of pathophysiological processes, lack of physiological reserve or poor predicted outcome.[9] Conversely, it is reported that inpatients requiring cardiopulmonary resuscitation (CPR) have better outcomes in intensive care units (ICUs) than wards.[234] In the Cape Town study death occurred within 3 hours for two patients (18.2%) including a 37-year old and within 2 to 7 days for the majority (54.6%) of patients (Table 4-8). What was not recorded in the clinical notes is that some patients may have requested and received limited care.[92]

Most patients in both groups had a pre-existing co-morbid condition but all had at least one and in some cases three or more which was significantly associated with SAEs (Table 4-17). Review of 3745 charts in Canada showed that comorbidities reportedly significantly related to the probability of having an AE (p=0.10 level by univariate analyses) included congestive heart failure, deep vein thrombosis, valvular heart disease, chronic obstructive pulmonary disease, liver disease, cirrhosis, any gastrointestinal disease, acute confusional state, renal failure, dialysis, any renal disease, and blindness.[130] Interestingly, in the Cape Town study comorbidities of patients in the SAE group included all the above conditions except for heart and valve conditions, deep vein thrombosis and blindness.

As in the current study in which advancing age but not gender was associated with an increased risk of SAE, a Canadian retrospective review of 3745 patient charts[130] identified equal rates of AEs amongst males and females. However, an Australian prospective review[220] of 1,125 inpatients' records found that there was a 20% mortality in patients over the age of 75 years who had unscheduled surgery. The study found that patients with AEs were significantly older than those without AEs (mean age [and standard deviation] 64.9 [16.7] v. 62.0 [18.4] years; p = 0.016). Further supporting evidence recorded odds ratio (OR) = 1.03 adverse events per year of life(P<0.001)[216] and rates of adverse events rising significantly with age (p,0.0001).[217] Age-related AEs may be attributed to the complexity of care needed by older people.[86]

Most patients in both groups had general surgery. In a prospective study of 334 patients, those who triggered the callout algorithm by scoring 4 or more had surgery for anastomosis, bowel obstruction and malignancy[6] not too dissimilar from the Cape Town study. A large retrospective record review of 30,121 randomly selected records found that there were significant differences in rates of AEs among categories of clinical specialities (p=0.0001). However, an Australian prospective review of 1,125 inpatients' records[220] found that there were no differences in the incidence of SAEs among the major surgical specialities. The general surgical wards in the present study (incorporating vascular and gastrointestinal specialities) have a high proportion of emergency cases. A systematic review of eight studies including 74,485 patient records, reported that operation-related AEs (39.6%) (and medications) constituted the majority.[94] A retrospective

record review in a multi-centre study in Holland found that more than 50% of the AEs were related to surgical procedures.[86] Patients for whom late decisions were made not to resuscitate were nevertheless included as they provide important epidemiological information.[91]

Patients who died spent fewer days in hospital than the control group but this was not significant. Published record reviews have found that SAEs contributed to increased length of stay, [130, 215, 220] however, this would not necessarily be so if death occurred soon after operation, as was the case in this study.

Findings related to quality of care: The Cape Town study found that doctors seldom prescribed vital signs postoperatively (Table 4-15), or monitoring of specific parameters (13/55, 23.6%) or cut points for vital signs (2/55, 3.6%), leaving nurses to use clinical judgement in deciding to call for more skilled assistance. The proportion of unrecorded responses by nurses to signs of impending critical illness is assumed to be high.

The Cape Town Ward MEWS system generally has lower cut points than the published MEWS (usually associated with higher sensitivity), a desirable attribute[25] but it may therefore have lower specificity than the published MEWS, meaning that the calling triggers are activated earlier than for the published MEWS, increasing workload.[190] A balance between sensitivity and specificity would be optimal.[25] Most importantly, the response algorithm is a combined track and trigger system (TTS) involving referral for deterioration in either a single parameter triggering at 3 or for an aggregate score[16] of 3 as severely ill patients can be missed if single parameters are ignored. Equally important, single parameters with high scores may not always translate into an increased overall risk in single parameter track and trigger systems.[8] The medical team that introduced the EWS/MEWS system in 1997 cautioned that it is a screening tool not designed to predict outcome.[105] "The overall clinical course for most critically ill patients is punctuated by multiple potential confounding influences making such attempts at final outcome prediction, on the basis of early routine standard bedside observations, an unrealistic expectation".[166]

An association between vital sign parameters (fast pulse rate and low systolic BP) and mortality was established by this study (Table 4-17) and others.[22, 35, 36, 99, 100, 102] Six patients triggered a callout algorithm on admission for systolic BP by scoring 3 on the MEWS which had a significant OR=8.1, CI 1.6-42.0. The impact of low systolic BP is remarkably similar to another study of 79 medical emergency admissions in which the relative risk ratio (RR 95% CI) for patients with scores of (low) 3 for systolic BP on admission compared to patients with a score of 0 was 8.6, 0.5-139.[8] Cut points on the MEWS used in that study were similar to the Cape Town MEWS cut points for systolic BP so the results are comparable. A high incidence of recordings of disturbed physiological variables in general ward patients has been reported.[33] In the Cape Town study nurses did not always respond to early warning or even advanced signs of deterioration (Table 4-16), also found in other studies.[172]

Postoperatively in the Cape Town study heart rate, systolic BP, temperature and urine output (recorded as a volume rather than a rate) were recorded graphically on the existing chart. Graphic recording was reported for 90% of patients for 3739 observation sets for 189 patients in a UK retrospective record review study but urine output was recorded infrequently and poorly.[14] Nine Cape Town (N=55, 16.4%) patients had recordings for oxygen saturation (Table 4-13). Only one patient (of 55, 1.8%) had respiratory rate recorded which is considerably lower than UK studies reporting 73.7% (2757/3739 observation sets),[14] 50-55% recording[97] and no recordings in the previous 8 hours in 127 patients (55.5%).[115] Pulse oximetry measurements do not obviate the need for respiratory rate monitoring.[9] Failure to recognize physiological derangements of breathing and mental status over a period of 8 hours has been reported to result in cardiac arrest.[5, 34, 35]

Patients did not routinely have a neurological assessment, even after a general anaesthetic (Table 4-13). Instead, recordings in patient progress notes reported once on patients' state of wakefulness upon return to the ward (eg. 'drowsy') and were recoded for interpretation in relation to the AVPU[xi] classification. Reporting was poor and infrequent (61.8), supported in a UK study[14] in which this parameter and urine output were excluded from detailed analysis. Even so,

[xi] A=alert, V=responds to voice, P=responds to pain, U=unresponsive.

observations were monitored for more patients than had prescriptions except for respiratory rate (Table 4-15). The problems of infrequent and incomplete monitoring and recording, misinterpretation of clinical data, delays in reporting and little convincing evidence of appropriate interventions being carried out[37] were evident in the Cape Town study.

Even without a MEWS to guide practice, nurses' poor response to MEWS that should have triggered callouts (Table 4-16), particularly for a critical MEWS of 3 was disturbing. Of 110 patients who died in four Finnish hospitals, 30 (54%) had documented signs of disturbed physiology 3.8 hours before death and 13 (11.8%) patients had no intervention.[233] Delays of 1 hour have been reported for 18% of patients and up to 3 hours for 8% of patients.[235] A delay in early identification of deterioration in a patient's condition and slow transfer to ICU is associated with a 60% increase in hospitalisation costs.[117]

4.7.4 New knowledge generated

This appears to be the only South African study to examine records of adult patients on surgical wards to investigate the quality and quantity of nurses' recordings of postoperative vital signs data of patients who did or did not have a SAE[xii] and nurses' responses to signs of deterioration. Uniquely too, vital sign recordings were recoded into a MEWS format to explore the efficacy of this scoring system in identifying these events within the first eight postoperative hours. A summary of what this study adds:

- the design and utility of an explicit, criterion-based patient record review form (Appendix 4.1) for quantifying three specific serious adverse events (SAEs) occurring on public hospital surgical wards: unexpected admission to ICU, cardiac arrest and death within the first 8 postoperative hours;
- that there was a low incidence of 1.9% (n=11) of ward deaths in a sample of 585 postoperative patients: finding no unexpected admission to ICU possibly attributable to hospital policy requiring patients having specific high-risk orthopaedic and general surgical procedures to be admitted to high care units postoperatively;

[xii] unexpected death, admission to ICU or cardiac arrest

- that medical doctors prescribed monitoring of 'regular' observations rather than specific parameters (Table 4-15) or few cut points for callouts, that there were no clinical guidelines for vital sign monitoring and no callout algorithm;
- that there was infrequent monitoring of too few vital sign parameters (Table 4-13) and scant evidence of responding to recorded disturbed physiological parameter readings in the first eight postoperative hours (Table 4-16) that is well documented to be associated with mortality;
- that a MEWS system is effective for recoding patients' vital sign data recorded on existing ward observation charts into a standard scoring format for interpretation and classification of patients according to urgency for appropriate clinical responses.

4.7.5 Critique of Study Two methods

4.7.5.1 Strengths of record review process

This retrospective review showed 91.8% (56/61) interrater agreement (section 4.4.1.2) on explicit review criteria that focused on outcome rather than implicit criteria and reviews focused on process errors, supporting the published evidence[207] from a systematic review of 26 papers on case-note audit. It is reported that consensus methods have been employed to resolve disagreement[86] as in the present study and when these methods have failed, a third independent assessor[86] arbitrated. Three independent reviews of 500 medical records concluded that estimates of reported AE rates are highly sensitive to the degree of consensus and confidence among reviewers (Table 4-2).[218]

Patient characteristics and outcomes are captured in clinical records. The layout of the criterion-based review form, based on the MEWS chart, facilitated data recording, coding, extraction and analysis with speed and accuracy under field conditions. The same researcher was involved in designing and pilot testing the MEWS chart in Study One and in data gathering in Study Two so it was not deemed necessary to establish validity and reliability of the MEWS a second time. Results are less likely to be biased due to differences across observers if the same observer makes measurements.[142] Nevertheless, a 10% random sample (6/55) of anonymized[7] reviewed

records was independently coded by a nurse assessor and found to have overall agreement for criteria of 91.8% (56/61). Resolution on disagreement (9.8%, 6/61) was achieved by review of these records by both assessors and consensus agreement on outcomes requiring best-guessing when entries were illegible. There is a higher, inflated level of agreement when a measurement is an average over several reviewers than when individual reviewers are compared.[207]

4.7.5.2 Limitations of record review

A 10% sample of records reviewed by an independent coder was not guided by published evidence and may have been inadequate thereby limiting reliability of the findings although 1% of records (used as the gold standard) were reviewed for the seminal Harvard Medical Practice study.[217] The record review form did not extract data on background to the SAE so annotations were made.[206] Preventability of AE was not explored.

The Hospital has no generally available electronic database on type of anaesthesia administered, requiring a manual search of handwritten operating room registers for patients who had a general anaesthetic. Review of patient folders revealed contradictory entries by anaesthesiologists in a few instances, requiring re-selection. The electronic database had limited data for this study, requiring data retrieval from five further documents in patient folders but most observation sets were retrieved from charts as would be expected.[105] The researcher did not have access to hospital computers which may have reduced the number of documents having to be accessed.

The success of record review[206] and particularly good inter-rater reliability[210] is entirely dependent on the accuracy, completeness and legibility of patient records and the absence of conflicting information. Incomplete and missing records (n=13) including those for four patients with SAEs were excluded, reducing availability for sampling and having implications for quality of care. Nurses' recordings of vital signs in at least four places (Table 4-5) were often duplicated. Both reviewers were nurses and it may be considered a limitation of the study that doctors did not confirm findings.[212] Interpretation of conscious level against the AVPU criteria was tenuous as

patients who were 'drowsy' from the anaesthetic scored 1 (reacting to voice) but being 'asleep' scored 0 (alert).

A retrospective record review meant that documentation could potentially be incomplete, for example nurses reporting abnormal vital signs verbally to senior nurses and receiving verbal instructions or nurses having telephonic discussions with the doctor that were not recorded.[236] The methodology to establish the incidence of AEs for retrospective record review is reported to be subjective.[237]

In retrospect not capturing data about the number of patients admitted for unscheduled surgery limited interpretation of the data. The small sample size (wards and records) and the short duration of the study is a limitation and does not allow the findings to be compared to large studies, nevertheless, the data show trends that are similar to larger studies.

4.7.5.3 Limitations of selection methods

The small sample size was based on selection first of SAEs meeting inclusion criteria and four controls for each SAE but low cardiac arrest rate may reflect the high NFR[xiii] rate, which is not saying the DNR policy is incorrect.[236] Low prevalence of ward death could be attributable to routine admission to High Care units for high risk surgery at the research site. Limiting the focus of the study to three SAEs limited a comparison to existing literature on SAEs.

Thirty patients had multiple general anaesthetics, adding to the complexity of the selection process so a decision was made not to count the same patient twice and to analyse data for the first anaesthetic only.

4.7.5.4 Bias

The reviewer was not independent of the study. During the sampling and record review processes every effort was made to minimize bias classified by the Cochrane group[200] with evidence from the study as outlined in Table 4-18.

[xiii] Not for resuscitation.

Table 4-18: A common classification scheme for bias[200]

Type of bias	Description	Relevant domains in the Collaboration's 'Risk of bias' tool – evidence from the study
Selection bias	Systematic differences between baseline characteristics of the groups that are compared.	• Sequence generation – low risk of bias because of sequence generation: for each SAE the control group consisted of the next four records drawn of a patient who did not have an SAE. • Allocation concealment – therefore low risk of bias. • There were more deaths on general surgical and vascular surgical wards (n=8/11) than gastrointestinal or orthopaedic therefore more records were reviewed from these wards.
Performance bias	Systematic differences between groups in the care that is provided, or in exposure to factors other than the interventions of interest.	• The independent record reviewer was blinded to allocation. • The researcher as record reviewer was not blinded to allocation but there was a low risk of bias as outcome measurements were not likely to be influenced by lack of blinding. • Other potential threats to validity were minimised by training the independent reviewer.
Attrition bias	Systematic differences between groups in withdrawals from a study.	• Incomplete outcome data – low risk of bias as incomplete and unavailable records were excluded.
Detection bias	Systematic differences between groups in how outcomes are determined.	• Other potential threats to validity such as observer bias were minimised by quality assurance of the review process by an independent reviewer of 10% random sample of reviewed records. When there was disagreement about outcomes each record was reviewed by both reviewers until consensus was reached. • There was a risk of bias as only 10% of records was reviewed independently. • Although explicit criteria minimised bias, illegibility of recording required best-guessing at times.
Reporting bias	Systematic differences between reported and unreported findings.	• Selective outcome reporting – low risk of bias by using explicit review criteria.

4.8 Conclusions, implications and recommendations

Study Two provided answers to three research questions. Each question is dealt with separately.

How was the existing vital signs chart operationalised by nurses for the identification of postoperative early warning signs of clinical and physiological deterioration in patients at risk of serious adverse events (SAEs) in adult surgical wards in one public hospital in Cape Town?

Data for Study Two should be interpreted with the understanding that the existing chart had no guidelines for the detection of early warning signs of deterioration therefore data were recoded into a MEWS format on the criterion based record review form for the purpose of interpreting severity of illness. The MEWS was used as the 'gold standard'. Recording was inadequate concerning the number of patients who had recordings of parameters and the number of parameters that were monitored in the first eight postoperative hours. On admission some patients had no recordings of baseline parameters.

What was the association between the number of recorded vital signs on the current observation chart and patient outcomes in those at risk of a SAE?

There are too many confounding variables in a clinical setting to attribute SAEs to poor vital sign monitoring alone. Nevertheless, data showing inadequate monitoring of respiratory rate, oxygen saturation, conscious level and urine output is of concern particularly as there was a significant association between mortality and certain parameters. Most patients who died had a high or low systolic BP on admission and postoperatively, there was a significant association between mortality and tachycardia and hypotension (Table 4-17) . Demographic data and clinical characteristics that were significantly associated with mortality included advancing age and having two or more pre-existing comorbid conditions.

What was the association between the clinical responses of nurses to recordings on the current chart and patient outcomes in those at risk of a SAE?

An upper MEWS of 2 for heart rate (**Figure 4-3**) and a lower MEWS of 1 for systolic BP (**Figure 4-4**) showed the best sensitivity and specificity for the MEWS cut points for these parameters for predicting SAEs.

Inadequate recordings of patients' vital signs data on admission and during the first eight postoperative hours have implications for nursing practice, education and research. For practice inadequate recording implies that monitoring is also inadequate and this has implications for detection of early warning signs of clinical deterioration. RPNs should not have to rely on doctors to prescribe the monitoring of vital signs other than for exceptional cases as this is an independent function of the nurse sanctioned by statute[238] and is mandated best practice following the administration of a general anaesthetic. It is strongly recommended that the doctors prescribing postoperative orders should prescribe against the MEWS chart and also consider the MEWS recordings on Day 1 after surgery on ward rounds. That would increase awareness of the value of the chart and encourage nurses to use it more effectively for interpreting data when deciding to summon assistance.

Evidence of inappropriate responses of nurses to early and advanced signs of clinical deterioration implies that more patients are at risk of avoidable SAEs than ought to be the case. It is recommended that curricula for nurses should include assessment of competencies in bedside monitoring techniques, interpretation and prompt and appropriate response to signs of deterioration. There is published evidence that calling criteria provide important guidelines for appropriate responses when used in conjunction with emergency outreach services such as medical emergency teams and critical care outreach systems. Calling criteria and such outreach services should be included in educational programmes.

The aim of Study Three was to implement and explore the effectiveness of the MEWS observation chart and training programme.

5 STUDY THREE: MODIFIED EARLY WARNING SCORING (MEWS) SYSTEM AND TRAINING INTERVENTION VERSUS STANDARD CARE: PRAGMATIC PARALLEL GROUP CLUSTER RANDOMISED CONTROLLED TRIAL

5.1 Background and significance

The previous two studies described a consensus derived and validated local MEWS system and callout algorithm that was used for retrospective record review to recode patients' vital signs datasets into a MEWS format. The MEWS format of vital signs and the callout algorithm were used for interpreting severity of illness. Recoding also provided a 'gold standard' for establishing when disturbed physiology should have triggered a callout and therefore the appropriateness of nurses' responses. The quantity of postoperative recordings was then established. Records of patients who died and those who did not die were examined. Cut points of two parameters associated with mortality and the sensitivity and specificity of the MEWS for these two parameters were established. We therefore concluded that it would be feasible to use this tool to assess whether calls for assistance would have triggered in relation to predetermined physiological thresholds and for evaluating nursing practice, but recording of vital signs was inadequate. Patients who died had a median of two recordings for seven parameters in the first eight postoperative hours and those who did not die had one recording.

This chapter describes a cluster randomized trial to test the hypothesis that a two-fold intervention will improve recording of postoperative vital signs and nurses' responses to triggers.

An overview of concerns about nurses' practice of vital signs monitoring was presented in Chapter Two. In this chapter a selected pertinent literature review covers:

- The design of hospital-based training programmes for recognising deterioration in patients on general wards.

- Nurse-related determinants of hospital mortality.
- Systematic reviews of nursing studies on patient safety.
- Patient safety research considerations.
- The CONSORT guidelines for reporting parallel group RCTs.

5.2 Literature review

5.2.1 Hospital training programmes

Hospital courses for life support after a catastrophic event are well established.[110] One of the few examples of a training programme for early recognition and management of the adult patient with impending critical illness is the 'Acute Life-threatening Events - Recognition and Treatment' (ALERT) course that originated in Portsmouth, UK.[110] The 1-day (9-hour) joint course for doctors and nurses incorporates Clemmer's[239] five methods for nurturing cooperation (developing a shared purpose; creating an open, safe environment; including all who share a common purpose and encouraging diverse viewpoints; negotiating agreement; and insisting on fairness and equity in the application of rules). Brookfield's (1986) six principles of adult education (voluntary participation, mutual respect, collaborative facilitation, practical experience, critical reflection and self-directed learning) have proved useful.[110] There is no formal assessment. The 70-page manual serves as pre-reading material for the interactive course which covers clinical assessment, monitoring and treatment of critical illness, organizational skills, communication skills and ethics. The course is based on the assumption of pre-existing knowledge of the biosciences and an appropriate nursing curriculum but previous research[54] suggests that this background may be seriously lacking. An Australian questionnaire survey found that nurses may not always follow predetermined MET[xiv] calling criteria and may not recognize when assistance is required.

The Quality and Safety Education for Nurses (QSEN) initiative was developed in the USA in response to a report by the IOM[xv] outlining core curriculum knowledge for all health professionals

[xiv] Medical Emergency Team
[xv] Institute of Medicine

to enhance patient safety, patient-centred care, teamwork, evidence-based practice, quality improvement and informatics.[240] One university college of nursing integrated these outcomes in the assessment of eight practice competencies: assessment and intervention, communication, critical thinking, human caring relationship, teaching, management, leadership and knowledge integration.[240] Purposeful implementation of this approach requires 'mindful organizing' and recognition that nursing work environments are often complex and hazardous.[241] The reality of such an environment with little margin for human error[241] requires innovative practices for knowledge acquisition. An example cited is a Web-based reporting system for hazards and near-misses that postgraduate nursing students used during clinical placements.[242] In a 3-year period, 453 students reported 6,005 hazards (59%) and 4,200 near-misses (41%). Innovative knowledge translation practice is needed in the developing countries to reduce the "know-do gap" between what is known from research and what is done to apply knowledge.[243] 'Responsive' regulation[244] is advocated to achieve safety and quality outcomes in the increasingly complex Australian health sector. This approach considers the context, conduct and culture of personnel and includes self-regulation, using the regulatory pyramid[245] as the blue print.

Efforts to reduce the gap between best evidence and practice include educational strategies towards behaviour change and organisational and administrative interventions [246] such as knowledge translation models. "Knowledge translation is defined as the exchange, synthesis and ethically sound application of knowledge—within a complex system of interactions among researchers and users—to accelerate the capture of the benefits of research … through improved health, more effective services and products, and a strengthened health care system" (citing Schön, 1990).[246]

To enhance patient safety practices, UK nurses[247] advocate:

- short patient safety briefings during the shift to review early warning scores and concerns;
- review of handover processes to make patient safety central to the handover using early warning scores as part of patient details;
- ensuring that escalation is appropriately documented and that all staff caring for specific patients are clear about the next steps.

- Improved communication during handover of all patients using a communication tool such as SBAR (situation-background-assessment-recommendation).[248, 249]
- The use of case studies and problem-solving approaches to ensure there is understanding of the physiological processes that influence trends in the patient's vital signs.[96]
- A competency framework for recognizing and responding to acutely ill patients in hospital.[250]

Training hospital staff to recognise signs when a patient is deteriorating is recommended in a systematic review.[183] "Work in the real world involves detecting when things have gone awry; discriminating between data and artifact; discarding red herrings; knowing when to abandon approaches that will ultimately become unsuccessful; and reacting smoothly to escalating consequences. It involves recognizing that hazards are approaching; detecting and managing incipient failure; and, when failure cannot be avoided, working to recover from failure".[251] The complexity of health care is an obstacle to researchers attempting to study safety systematically so it is recommended that the 'gaps' in patient safety be pursued as a research target.[251] One such gap may be developing innovative teaching strategies that promote critical thinking skills and foster quick problem solving such as the use of algorithms to guide novice nurses in interpreting vital sign data and responding appropriately.[252]

There is a paucity of theoretical models to guide nursing practice in AE prevention, and in particular, an absence of a model for the recognition and management of early warning signs of deterioration. Some authors[252] recommend Benner's (1982, 1984) Model of Skill Acquisition (comprising five levels of proficiency: novice, advanced beginner, competent, proficient and expert) when learning a new skill such as vital sign assessment.

5.2.2 A Conceptual Framework to guide nursing practice in limiting SAEs

The relationships among theory, practice and research in nursing are portrayed as cyclical.[253] Theories constitute statements and propositions that answer critical questions generated from practice.[254] Nursing research not guided by a theoretical construct, or theory not emerging from

research was labelled 'atheoretical'[255] by nurse theorists in the twentieth century but more contemptuously in earlier years as 'excursions into the trivial' (Fawcett, 1978:49).[256] At a doctoral level of study, candidates are required to generate new theories or to test existing theories if nursing is to reach its full potential.[253]

Clinical outcome research, in nursing in particular, has been criticized for being atheoretical for failing to explain outcomes being studied in terms of hypothesized factors and mechanisms.[254] This may to some extent account for the paucity of theoretical models to guide nursing practice in AE prevention, and an absence of models for early warning vital signs monitoring in particular. A contributing factor to limited published AE prevention models may be traditional assumptions that mortality outcomes and determinants of survival fall within the domain of medical care, but there is increasing evidence that these outcomes are 'nursing sensitive' (Tourangeau et al. 2005:2).[254]

Aiken and colleagues[257] are acknowledged for their seminal hypothesis of a theoretical model of the relationships between various nurse-related hospital characteristics and mortality in the USA[135] to guide policy (personal communication, Aiken 20/09/2010). This unpublished model, using 30-day mortality as the quality outcome indicator, was tested extensively in Canada by Tourangeau and colleagues and revised in 2001.[135] They concluded that the original linear mortality model hypothesizing that certain hospital factors, in addition to patient characteristics (age, sex, comorbidity, socioeconomic status, chronicity), had a direct effect on outcome, was too simplistic. The Canadian results showed direct relationships of only three predictors with 30-day risk-adjusted mortality: nursing skill mix, years of nurse experience on the clinical unit, and nurse capacity to work.[135] The model was revised to capture complex mechanisms by which nursing and other determinants influence mortality for hospitalized patients. The determinants of mortality of both models outlined by Tourangeau et al. have been extrapolated and compared in Table 5-1.

Table 5-1: A comparison between the original USA model and a revised Canadian model of nursing and other predictors of hospital mortality

Mortality model predictors (Aiken et al. 1994[258], 1997[257] revised by Tourangeau et al. 2002[135])		
Predictors	**Aiken and colleagues' original linear model hypothesis**	**Revised model hypothesis[254] showing more complex relationships among predictors**
Nurse staffing dose	Direct relationship with mortality	Indirect effect on mortality mediated through Nurse Burnout, Nurse Satisfaction and Nurse Capacity to Work
Nursing skill mix	Direct relationship with mortality	Direct and indirect effects on mortality – a richer RN skill mix (having more RNs) results in lower mortality
Professional Role Support:	Direct relationship with mortality	Indirect effect on mortality through Condition of the Nursing Practice Environment
Nurse characteristics: • experience	Direct relationship with mortality	Indirect effect on mortality
• capacity to work	Direct relationship with mortality	Indirect effect on mortality
Nursing Practice Environment Condition	Direct relationship with mortality	Direct and indirect effects on mortality
Continuity of Registered Nurse Care Provider	Direct relationship with mortality	Indirect effects on mortality through Nurse Burnout and Condition of the Nursing Practice Environment
Nurse Burnout	Not described	Indirect predictor of mortality
Nurse Satisfaction	Not described	Indirect predictor of mortality
Patient characteristics: • age • sex • comorbidity • socioeconomic status • chronicity	Direct relationship with mortality	Direct effect on mortality
Other Determinants: • physician expertise	Direct effect on mortality	Indirect effect on mortality
• teaching hospital status	Direct effect on mortality	Indirect effect on mortality mediated through Nurse Capacity to Work, Nurse Experience and Physician Expertise
• hospital location	Direct effect on mortality	Indirect effect on mortality mediated through Nursing Skill Mix, Nurse Capacity to Work, Nurse Experience and Physician Expertise

The revised model changes include: rearranging the concepts, hypothesizing that five predictors exert indirect effects on mortality which are then mediated by and exert their effects through other model predictor variables.[254] Also, the revised model added two indirect predictors of mortality: nurse burnout and nurse satisfaction. In Aiken et al.'s (1997) conceptual framework of the comparative cost effectiveness of nursing delivery system strategies[257] (Appendix 5.1), patient characteristics affect costs and outcomes directly but it is hypothesized that nursing factors may mediate their effects. Hospital structure factors are depicted as directly affecting costs and outcomes while also influencing patient characteristics. Previous and ongoing research indicates that nursing factors have a direct effect on hospital costs and outcomes that in this case includes burnout and job satisfaction.

These nurse-related determinants of hospital mortality may provide a useful construct for establishing the factors that might be associated with the introduction of a MEWS in limiting SAEs on general wards.

- Nurse-related determinants of hospital mortality[135, 254]

Increasingly since 1994, the organizational context of hospital-based nursing practice and its effect on patient outcomes, particularly the prevention of adverse events (AEs), has been described in the published literature.[258] In the 1990s USA hospitals embarked on widespread restructuring and reengineering resulting in fewer staff being employed thereby changing the skill mix.[259] In a large study of 10,184 nurses in 168 hospitals, it was found that having specialist nurses, increased registered nurse (RN)-to-patient ratios and a richer RN skill mix (more RNs than other categories of nurses) is inversely related to hospital mortality rates[260] and to most AEs in a study of 124,204 patients.[261] These results ought to be viewed with caution as hospital characteristics vary greatly.[262]

Nevertheless, a 10% increase in the proportion of nurses holding a bachelor's degree was associated with a 5% decrease in both the likelihood of surgical patients dying within 30 days of admission and the odds of failure to rescue (odds ratio, 0.95; 95% confidence interval, 0.91-0.99 in both cases).[221] Analysis of outcome data for 18,142 discharged patients showed that the odds

ratios (95% confidence interval) of significant hospital nursing characteristics that predict 30-day mortality were as follows: 0.81 (0.68–0.96) for higher nurse education level, 0.83 (0.73–0.96) for richer nurse skill mix, 1.26 (1.09–1.47) for higher proportion of casual or temporary positions, and 0.74 (0.60–0.91) for greater nurse-physician relationships.[263]

Nineteen of 27 studies that were systematically reviewed found an association between one or more unfavourable nursing environmental attributes and higher mortality. Despite extensive variability in attribute and outcome measures, settings and research quality across studies, there is evidence that social and environmental attributes of hospital nursing practice have an effect on the outcomes of care but more research is needed to link the nursing environment to patient outcomes.[264]

5.2.3 Systematic reviews of nursing studies on patient safety

In Odell's (2009)[265] systematic review of studies investigating nursing practice in recognizing and managing deteriorating patients on general wards, 14 studies met inclusion and quality criteria but 16 studies were reviewed. A summary of each study is presented in Table 5-2. Nine studies used a qualitative design and seven were quantitative.

Table 5-2: A systematic review of studies investigating nursing practice in detecting and managing deteriorating general ward patients organized by type of study[265]

Quantitative study design	Author	Study objectives	Conclusion
Cohort study	Smith & Oakey (2006)[14]	To describe how an early warning scoring system is used in practice	Scores were recalculated from 3739 sets of primary observations and compared with those recorded in case notes. 571 (21.9%) of observations had been incorrectly calculated. Incorrect scoring meant that observations of 66 of 270 patients (24.2%) should have reached the trigger value but did not. The more abnormal observations were more likely to be mis-scored. As the degree of physiological abnormality increased scoring errors were more likely to lead to underscoring.
Quasi experimental before and after	McBride et al. (2005)[186]	The short and long-term effects of introducing a new patient vital signs chart and the MEWS which incorporates respiratory rate (RR) on the prevalence of respiratory rate recording	RR recording increased on all 6 wards from 29.5 ± 13.5% to 68.9 ± 20.9%. There was a long-term beneficial effect of introducing the MEWS system on respiratory rate recording into the general wards (91.2 ± 5.6%).
Chart review	Nurmi et al. (2005)[233]	To analyse the effectiveness of observation practice to detect abnormalities in vital signs in the 8 hours prior to cardiac arrest and to determine the need for a medical emergency team system in Finnish hospitals	Of the 110 patients suffering a cardiac arrest in 4 hospitals 56 (51%) arrests occurred on the wards. 30 (54%) of these patients had an abnormal vital sign meeting the MET criteria 3-8 hours before the arrest. 13 patients had no intervention; 8 had an intervention within 1 hour and 9 waited for more than 1 hour.
Before and after, using case-note review	Kenward et al. (2001)[116] Part of a wider study (Hodgetts et al. 2002)[236]	The effect of an educational programme on respiratory rate recording	Respiratory rate recordings increased from 27% to 89% after an educational programme.
Point prevalence survey that reviewed all ward patients during one week	Chellel et al. (2002)[115]	To establish numbers of patients at each level of care, level of observations of level 1 and above, and the nature of outreach services being offered	229 (12%) patients at level 1 and above 35 (2%) level 2 3 (<1%) level 3 Of the 229, 127 (55%) had no respiratory rate recordings.
Survey of medical records	Crispin & Daffurn (1998)[235]	To assess the responses of nurses in the presence of preset Medical Emergency Team warning signs	(MET studies are outside the scope of the study so limited reporting here): 50% of MET calls were from general wards. Delays of 1 hour were found for 18% of patients and up to 3 hours for 8% of patients. There is a need to educate health professionals to recognize the warning signs of acute severe illness and when to summon assistance.
Survey using questionnaires with 4 hypothetical clinical situations	Daffurn et al. (1994)[107]	To determine Registered Nurses' opinions, knowledge and use of medical emergency team system	See Table 2.5

Qualitative study design	Author	Study objectives	Conclusion
Exploratory, descriptive using semi-structured interviews, questionnaires and an attitude scale	Cox et al. (2006)[266]	To explore factors that influence the experiences of trained nurses caring for critically ill patients in the ward setting	Five key themes were identified: clinical environment, professional relationships, patient assessment, nurses' feelings and educational needs.
Focus group	Hogan (2006)[97]	To investigate the reasons behind the paucity in patient monitoring	Four major factors emerged: organization of nursing care activities, development of nursing observation skills, clinical decision-making processes and equipment management issues.
Ethnographic, using a 2 month participant observation period and semi-structured interviews	Wheatley (2006)[267]	To determine the practice of recording basic observations of level 1 general ward patients	Experience is important in the assessment of patients to detect deterioration. The role of taking basic observations has been devolved from the Registered Nurse to the health care assistant. There seems to be a reliance on the use of electronic monitoring equipment.
Grounded theory using interviews and observations	Andrews & Waterman (2005)[83]	To study how ward based staff use vital signs and the EWS to ensure successful referral to doctors	Nurses use 'intuitive knowing' to establish patient deterioration but to get medical attention they have to communicate this information in a credible way.
Interpretive phenomenological, using group interviews	Minick & Harvey (2003)[268]	To describe the phenomena of early problem recognition among medical surgical nurses	Three themes emerged: knowing the patient directly; knowing the patient through the family; and knowing something is not expected.
Focused ethnographic, using semi-structured interviews	Cutler (2002)[269]	To explore real life experiences of nurses caring for the critically ill in an acute ward and identify their educational needs	There was limited time to apply learning in practice. Perceived roles between doctors and nurses were complex and resulted in conflict. The incongruence between nurses' needs and educational provision results from ignorance.
Phenomenological, using interviews	Kenward & Hodgetts (2002)[270]	To identify and quantify the phenomenon of nurse concern	Four key themes emerged: the need to know the patient to detect change; the role of experience, nursing credibility; the factors that cause nurse concern. When to be concerned and quantifying the reasons for concern improves recognition of deterioration and improves multi-disciplinary communication.
Exploratory, using interviews	Cioffi (2000)[40]	To describe patient characteristics and the process nurses use to recognize patients about whom they are seriously worried	Four patient characteristics emerged through touch, observation, listening, feeling or sensing, 'knowing' and past experience: feeling 'not right'; colour; agitation; and observations
Descriptive, using interviews	Cioffi (2000)[39]	To explore the experiences of ward nurses calling the Medical Emergency Team	Nurses recognized patient deterioration by feeling that 'something was wrong', drawing on past experiences and knowing the patient, but they were unable to articulate this concern. They felt anxious and nervous about 'doing the right thing' when calling the emergency team.

South African nurses[271] are involved in global discussions about the World Health Organisation-led strategy of task shifting[272] to lesser qualified persons to deal with a global trend of demand exceeding supply of health care cadres. It seems that delegating the taking of vital signs to health care assistants[267] is not part of this strategy. The context within which deterioration is detected and reported is an important consideration that will influence the design of more effective education and support systems.[265]

5.2.4 Patient safety research – issues of methodology

Study Three is about evaluating interventions aimed at reducing an error of omission (infrequent monitoring of vital signs) occurring in the causal chain.[142] There are certain well documented constraints[273, 274] when implementing a trial in a clinical setting and therefore a pragmatic trial was utilized. The selection of a prospective pragmatic cluster randomised parallel group clinical trial of intervention[xvi] versus standard care using clinical record review was influenced by four considerations:[143]

- pragmatic constraints imposed by the nature of the patient safety problem (described in Chapter Two and the publication[84]) and the intended intervention (described in this chapter);
- a priori assessment of the probability of benefit and harm (section 5.5.10.3);
- plausible effects on end points (unexpected cardiac arrest, admission to ICU or death);
- the target audience for the results: the study intends to influence hospital ward nurses.

Although randomized trials are the most robust method of assessing most health care innovations, in research that evaluates clinical guidelines (for example the introduction of an EWS system), there is a danger that treatment given to control patients "may be contaminated by doctors' knowledge of the guidelines, leading to underestimates of the true effects of guidelines. Studies where doctors (or hospitals) are randomised are at risk of a different bias: those randomised to the guidelines group may be subject to a greater Hawthorne effect (the beneficial

[xvi] Training programme, implementation of a MEWS vital signs observation chart in three intervention wards versus non-intervention in three control wards and clinical record review.

effect on performance of taking part in research) than controls, with the result that the evaluation may overestimate the true effects of guidelines".[275] In the Hospital doctors covered all wards in their clinical speciality and this aspect will be explored further in the limitations section.

In reaction to poor reporting of RCTs a CONSORT statement of guidelines was published in 1996, revised in 2001 and updated in 2010[276, 277] to include a 25-item checklist to make RCT reports easier to interpret for relevance to clinical practice and for teaching research methods to doctoral students.[278]

5.2.5 The CONSORT 2010 Statement guidelines for reporting parallel group RCTs

Provided the design, conduct and reporting of RCTs is appropriate, these represent the gold standard for evaluating healthcare[277] and nursing interventions.[279] Yet, the quality of reporting RCTs is not optimal[276, 277] and until 2008, the quality of RCT reporting in published nursing studies had not been evaluated.[279] Quality reporting of RCTs increases the visibility of nursing research beyond professional boundaries[278] and minimizes the risk of bias by increasing internal validity.[280]

A USA study using a modified 2001 CONSORT checklist found that of 4 nursing journals with the 10 highest impact factors that had published a total of 100 RCTs between 2002-2005, none had required use of the CONSORT statement, although in 2003 the journal 'Nursing Research' had this information in their "Information for Authors" and was the only journal to show a significant improvement (23.67 to 27.0; t=-2.70, p=0.01) in the quality of reporting RCTs.[279]

The 2010 CONSORT Statement[277] focuses on the most common design type - individually randomised, two group, parallel trials and does not include extension to cluster randomised trials. However, the CONSORT website acknowledges the work of Campbell et al. (2004),[281, 282] as an 'official' extension of the 2001 CONSORT statement to cluster trials requiring additional information.

The intention of Study Three was to enhance understanding of EWS/MEWS systems through training and improved vital sign monitoring of postoperative patients by surgical nurses. The

rationale for using a pragmatic cluster randomized trial to achieve this aim was to minimize contamination[229] therefore the unit of randomization and analysis was intervention versus standard care wards as the two arms of the trial. Secondly, monitoring, recording and interpreting patients' vital signs and responding to abnormal physiology is a responsibility of the ward nursing team and evaluation of the quality of such care can best be done at a cluster level. Logistical constraints for using a cluster trial include administrative convenience in having nurses and patient case-notes in a few locations.

This was the first exposure of nurses at the Hospital to the MEWS so this trial introduced the tool on a small scale, particularly as the Helsinki declaration makes it unethical to expose people unnecessarily to the risks of research[223] described in section 5.5.10.3.

This chapter describes firstly, a training programme that was designed, implemented and evaluated. The second intervention reported here is the implementation and evaluation of the Cape Town MEWS chart.

5.3 Aim and Objectives

The aim of the study was to implement and explore the effectiveness of a local MEWS training programme and consensus derived MEWS observation chart through a prospective pragmatic cluster randomised parallel group clinical trial of intervention versus standard care. Outcomes were assessed by test scores and patient record review. Objectives were:

Objective 1 - To establish whether the MEWS training programme resulted in a significant difference in knowledge test scores:

- at group level between pre- and post-intervention knowledge test scores of nurses in the intervention and control arms;
- at individual and cluster level between pre- and post-intervention test scores of nurses in the intervention arm who received training; and

- at individual and cluster level between pre- and post-intervention knowledge test scores of nurses in the control arm who received no training.

Objective 2 - To establish whether, when intervention and control arms were compared, the MEWS training programme and observation chart resulted in a change in practice as recorded in patient records, in:

- the number of physiological variables, range and proportion of times (as prescribed by medical doctors) that ward nurses recorded these on the MEWS chart and existing observation charts over an 8 hour period;
- nurses' responses to high or low threshold vital sign recordings on the existing charts and MEWS observation chart using the MEWS as a benchmark; and
- the proportion of postoperative patients developing in-hospital SAEs in control and intervention wards respectively . It is realized that as the number of SAEs (deaths) was so small (section 5.6.1.2, Figure 5-5), this study was under-powered to detect any difference in SAE outcome. However, this information was gathered to inform sample size determination in larger future multi-site trials.

5.3.1 Main outcome measures:

The main outcome measures were to explore the effects of the MEWS training programme between intervention and control arms on:

1. pre- and post-intervention test scores of nurses' knowledge and self-reported quality of measurement by independent marking;
2. the number of physiological variables recorded on the MEWS chart in intervention wards and on existing vital signs charts in control wards.

The quality of recording in intervention wards was intended to be enhanced (see CONSORT guidelines in Table 5-36) by appointing MEWS project leaders from amongst the nurses.

5.4 Hypothesis

The following hypotheses were examined.

If nurses are trained in the use of a MEWS observation chart:

1. their knowledge of early warning signs of physiological deterioration in patients will improve;
2. the number of recordings of vital sign data will improve compared to that of nurses using the existing observation chart;
3. they will respond more frequently to patients with disturbed physiology than nurses receiving no training and using the existing observation chart.

5.5 Methods

5.5.1 Research description and design

This chapter reports a prospective pragmatic cluster randomised trial with two arms (intervention versus no intervention) using surgical wards as the unit of randomization that is, random allocation of groups of participants rather than individuals to trial arms. The first phase was random allocation of all nurses in three intervention ward clusters for a training programme and no training for nurses in the three control ward clusters, using pre-and post-intervention knowledge testing of nurses in all six wards for measurement. The second phase comprised a parallel group clinical trial of intervention (implementation of the Cape Town MEWS observation chart in three wards) versus standard care (existing observation chart in three control wards), using criterion based clinical record review for measurement. Activities in the intervention arm are shown in Figure 5-1 and in the control arm in Figure 5-2.

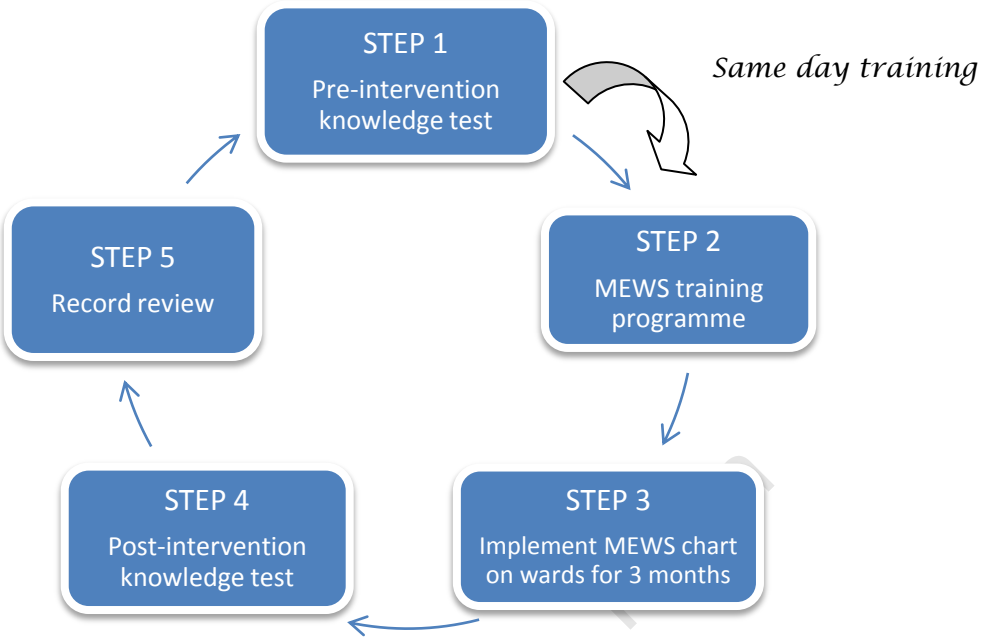


Figure 5-1: Diagram of Study Three training activities in the intervention arm

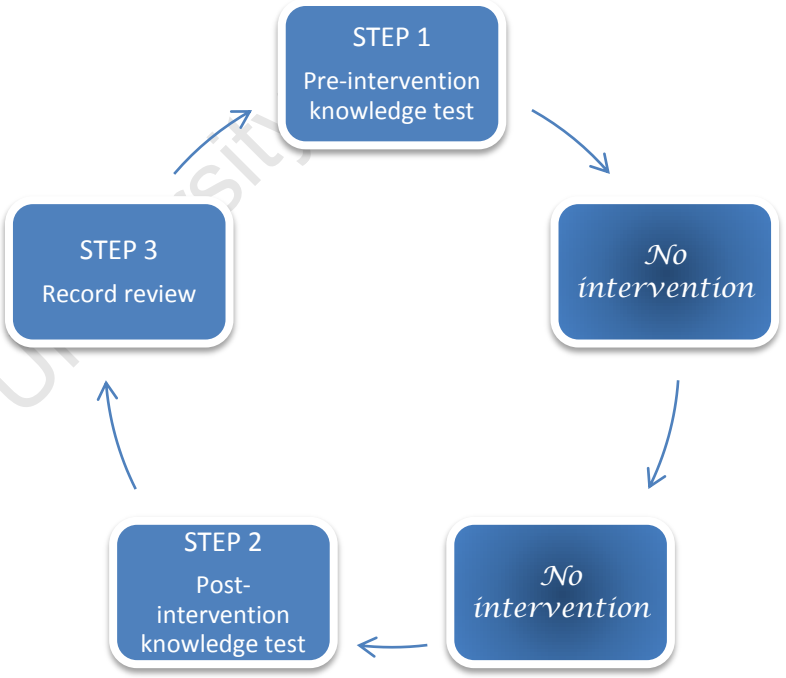


Figure 5-2: Diagram of Study Three activities in the control arm

Cluster randomised trials are increasingly used for evaluating health-care, screening or educational interventions.[283] These are an extension of randomized clinical trials (RCTs).

5.5.2 Features of pragmatic cluster randomised trials

The purpose of pragmatic trials is to inform decisions about practice[280] by adopting a pragmatic approach to key features (Table 5-3) in its design.

Table 5-3: Key features of pragmatic trials[280]

		Application to Study Three
Research question	Is about effectiveness: does the intervention work in normal practice?	Whether the MEWS observation chart is effective in detecting early signs of physiological deterioration is a most important question
Setting	Usual practice	Surgical wards in a public hospital
Participants	Little or no selection beyond the focus of the study	Nurses and patients in the intervention arm (comprising 3 cluster wards) and control arm (comprising 3 cluster wards)
Intervention	Not strictly enforced but applied flexibly as in normal practice	The MEWS chart was the preferred chart in intervention wards
Outcomes	Directly relevant to participants, funders and healthcare practitioners	The effectiveness of a MEWS training programme and a MEWS observation chart has implications for improved patient safety
Relevance to practice	Directly relevant to the setting	Nurses routinely use observation charts to monitor patient progress and to detect deterioration

The next section describes methodological issues in cluster randomized controlled trials (CRCTs).

5.5.2.1 Methodological issues in cluster randomised trials compared with individually randomised trials

Features of design, sample size, analysis and conduct of CRCTs are outlined in Table 5-4.

Table 5-4: Features of cluster randomised trials[281] as applied to the current study

	Cluster trials	Application to Study Three
Design	Random allocation of groups of participants to study groups as opposed to random allocation of individual participants to study groups	Random allocation of nurses and patients in 3 cluster wards to the intervention arm and nurses and patients in 3 cluster wards to the control arm
	More complex to design	Allocation to intervention and non-intervention arms was based on clusters
Rationale	To limit the threat of contamination In certain settings it may be the only feasible method for conducting a trial	Allocation of all nurses in respective clusters to the intervention and control arm rather than individual nurses limited the threat of contamination
Sample size	More participants are required	The number of clusters (N=6) was limited by the availability of pre-selected orthopaedic, vascular and general surgical wards based on published studies[176, 221] that guided Study Three resulting in a small sample size of: • nurse participants (n=66) in the intervention and control arm (n=63); and • patients for record review (n=57 in each arm; N=114)
Rationale	To obtain equivalent statistical power	A small sample size has limited the statistical power of Study Three. Resource limitations of the doctorate precluded a larger study.
Analysis	More complex analysis is required Two levels of inference rather than one: the cluster level and the individual level	Description of individuals and clusters within the intervention and control arms respectively and analysis at this level for knowledge test results but mainly at between-arm level for record review
Rationale	Observations on individuals in the same cluster tend to be correlated (non-independent) therefore the effective sample size is less than the total number of individual participants but this depends on average cluster size and the degree of correlation within clusters	Randomization was at cluster level. Hypothesis generation, outcome measures and intervention targeting was at the group level (intervention versus control arm)

	Cluster trials	Application to Study Three
	(intracluster/intraclass correlation coefficient (*p*)) It is important to report explicitly the level at which the interventions were targeted, hypotheses were generated, outcomes measured and randomization was done	
Conduct	Clusters are usually randomised all at once (or in batches) rather than one at a time for sequential randomization of individuals for a randomized trial	The first 3 wards randomly selected were allocated to the intervention arm as clusters and the remaining 3 wards were allocated to the control arm
Rationale	After randomization individuals in the clusters may be approached for consent to participate (raising the possibility of post-randomisation selection bias) or they may not, which raises ethical concerns	Post-randomisation, nurses in the intervention arm were recruited for voluntary participation in the training programme. Nurses in the control arm were recruited for voluntary participation in the pre- and post-intervention knowledge testing only

5.5.3 Participants

Participants were nurses (at individual and cluster level) on the six research wards (at cluster level) at the Hospital. Records of patients (at cluster level) admitted to the six wards during 1 May and 31 July 2010 constituted the sample for record review.

The same six wards described in section 1.5 and used for the record review in Study Two (section 4.5.2) were used for Study Three.

5.5.3.1 Eligibility criteria: Inclusion Criteria and Exclusion Criteria for educational intervention

All permanently employed registered nurses (Professional, Staff and Auxiliary – see section 1.1.2 for role description) on the three intervention wards including those on night duty were eligible to participate in the interventions (training programme and implementation of 'observation chart'). Those on the 3 control wards were eligible to only participate in the pre- and

post-intervention knowledge tests and received no training and the existing observation chart was retained for patient monitoring.

Overall, approximately 122 nurses excluding agency nurses (recruited from private employment agencies with no permanent status estimated to be n=7 but this number varied) were allocated to the six wards in 2010: 62 on intervention wards and 60 on control wards. These numbers were then split to cover two day shifts and night shifts (and included those on study leave, vacation, maternity leave, sick leave and absent). Nurses are typical participants for this trial as monitoring, recording, interpreting patients' vital signs and responding to abnormal physiology by either intervention or calling for more skilled assistance is a nursing responsibility. Hospital wards outside of critical care units are typical settings for this trial about bedside vital sign monitoring as published evidence shows that critically ill patients are increasingly being nursed on general wards where monitoring is infrequent and inadequate.[111, 112]

5.5.3.2 Eligibility criteria: Inclusion Criteria and Exclusion Criteria for record review

Patient case-notes (at cluster level) from intervention and control wards (at cluster level) provide demographic and clinical data and nurses' notes on vital sign monitoring and patient progress notes are typical of data required for this trial.

- *Inclusion criteria for records from intervention and control wards:*

Records of all patients 14 years of age[188] and older who had a general anaesthetic and were admitted to one of the six research wards during 1 May – 31 July 2009 were eligible for inclusion.

- *Exclusion criteria for records:*

Incomplete or unavailable records.

5.5.4 Sample size

The sample of clusters comprised three intervention and three control wards. A cluster trial should recruit a larger population of participants than is required for a RCT to increase statistical power[284] but this was not done due to the unknown clinical importance and value of the intracluster correlation coefficient and resource limitations. Calculation of the ideal sample size was done post hoc.

5.5.4.1 Sample size determination for MEWS training programme

The whole population of permanently employed nurses on the 3 intervention wards including those on night duty were eligible to participate in the interventions in Study Three (training programme and implementation of 'observation chart') at the individual and cluster level. Staff shortages resulted in approximately 18 full-time nurses being available to cover all shifts on the three intervention wards on day duty (n=81 beds) and 12 full-time nurses to cover on night duty. The proportion for control wards was the same. These are the subjects whose pre-and post training score were compared.

5.5.4.2 Sample size determination for record review

The researcher is unaware of any studies examining quality of postoperative vital signs recording on general wards or nurses' responses to high and low threshold vital sign readings using the MEWS systems as a benchmark ; this might be attributed to the relative novelty of this method of vital sign monitoring. However, the UK Health Foundation's Safer Patients Initiative (SPI) studies[285, 286] indicate that a multi-component organisational intervention increased respiratory rate monitoring frequency significantly from 40% to 69% and from 37% to 78%. A lower figure (41%) is given for detecting tachypnoea after the introduction of an early warning scoring observation chart.[196] Study Two data indicated that respiratory rate and oxygen saturation were monitored the least frequently (1.8% (1/55; 16.4% (9/55) patients) respectively. Conscious level was monitored for 61.8% (34/55) patients, urine output for 92.7% (51/55) patients, temperature for 96.4% (53/55) patients, heart rate for 98.2% (54/55) patients and BP was monitored for all patients (100%). None of the 55 patients had monitoring of all 7 vital sign

parameters. We would expect the interventions to increase this to at least 20.0%, a more cautious estimate using the studies above as a guide and results from Study Two that indicate monitoring of respiratory rate of 1.8% and oxygen saturation of 16.4%.

Sample size estimation for record review was guided by the following Study 3 objective (section 5.3): to establish whether there is a significant difference in the number of physiological variables recorded between the existing observation chart in the control wards and the MEWS chart in the intervention wards.

A sample of 114 records (57 from each trial arm (intervention and control)) was calculated to be sufficient to detect a difference of 20.0% between arms in the frequency of monitoring all MEWS parameters with 80% power and a 5% significance level.[287] No information on clustering is available in this situation or data for intercluster/intracluster correlation coefficients for number of vital signs recorded by nurses. After data analysis the intracluster correlation coefficient was calculated on the number of patients who had recordings of all seven vital sign parameters using a binary (yes/no) variable, that is, a completed respiratory rate, oxygen saturation, heart rate, BP, conscious level, temperature and urine output (section 5.5.4.2). This calculation takes no account of clustering, such as teamworking.[237] Sample size estimation (number of clusters and number of patient records in each cluster) was limited by predetermined wards used for Study Two.

TWO SAMPLE ANALYSIS:[xvii]
RESULTS for double sided:
The sample size required for group 1=n1=57. The sample size required for group 2=n1*allocation ratio=57*1=57. The total sample size required N=n1+n2=57+57=114. As there are three wards in each arm n=19*3=57 in each arm.

Patient records for prospective record review on discharge included all patients who underwent a general anaesthetic and were older than 14 years of age during 1 May to 31 July 2010.

[xvii] See Appendix 5.2 for full calculation (Uitenbroek, 1997).

5.5.5 Randomisation

Every effort was made to minimize bias tabulated in section 5.7.5.7.

5.5.5.1 Screening and Randomisation

Cluster randomization was at the level of ward selection. The total population of surgical wards (N=13) was purposively sampled to locate general surgical wards, orthopaedic wards and vascular surgical wards (n=6) and these wards were selected and randomized into two clusters.[288]

5.5.5.2 Sequence generation: wards and patient records

Sequence generation for random selection of wards was unmatched. To minimize selection bias the 'drawing of lots' method of sequence generation described as adequate by the Cochrane Collaboration Group[200] was employed. Six folded sheets of paper each of which had the name of one ward written on it were placed in a container. The first three drawn out by an independent person not associated with the study were allocated to the intervention group (Figure 5-4).

Sequence generation for record review was randomized for the intervention and control arms first, then at cluster (ward, n=3) level within each arm (Figure 5-5). To select a total of 114 records, 19 records were randomly selected for each cluster (n=3) in each arm (n=2) as follows: all deaths were first selected in each cluster (n=8 in intervention arm; n=3 in control arm= 11 deaths) on an intention to treat basis. Rapid screening of these (n=11) records revealed that five records were eligible, two of which were unavailable; the remaining six records were ineligible for analysis as three deaths occurred in High Care Units and the remaining three patients were NFR, leaving three records for analysis all of which were from cluster 3 in the intervention arm.

The remaining records (n=16) in cluster 3 were entered separately onto an Excel spreadsheet and numbered sequentially. Random numbers were generated in a separate Excel column and matched with the 16 records which were selected. Subsequently, once records were drawn, each was rapidly screened and if incomplete or unavailable (Figure 5-5), new numbers were generated and a new record corresponding with that number was selected. As there were no further deaths

to be analysed, the same process was followed for the remaining two clusters in the intervention arm and for the three clusters in the control arm but in each instance 19 random numbers were generated.

5.5.5.3 Allocation concealment

Allocation concealment was managed by an independent person (NL) being blinded to the ward names on the lots and to outcome (wards for the intervention and control trial arms), explained in section 5.5.5.6. The researcher was not blinded to outcome and implemented the interventions to the respective trial arms. Although a cluster trial is intended to minimize contamination, a control group may be contaminated by the effect of outreach[170] in an intervention ward.

5.5.5.4 Implementation

Implementation started once a ward had been allocated to the intervention or control group and all nurses on that ward were included in that group.

5.5.5.5 Recruitment of participants

'Community' consent[229] for trial entry for implementing the MEWS chart and individual consent for the nurse training programme and knowledge testing has been explained elsewhere (sections 5.5.7.1, 5.5.8.1). Having gained access to the research wards, the researcher was identifiable from a UCT identity tag. The process for recruiting participants entailed:

- inviting the Surgical Clinical Instructor (TW) to participate as a research assistant;
- a meeting with charge nurses in the six wards to disclose the allocation of their wards to either the intervention or control arm;
- an explanation of the study, particularly the institutional 'communty' consent for the implementation of the MEWS chart but also the voluntary individual participation of nurses in the training programme;

- negotiating who should recruit volunteers but for pragmatic reasons the charge nurses requested that they should do this.

The recruitment schedule is outlined in Table 5-5.

Table 5-5 : Recruitment Schedule

Recruitment activity	Commencement Date	Completion date
Random selection of wards for the intervention cluster and the control cluster	26 February 2010	26 February 2010
Recruitment of nurses from these wards for the training programme	1 March 2010	15 March 2010
Pre-intervention test	Intervention wards: March 12th, 15th, 16th, 17th, 24th Control wards: March 18th, 19th, 23rd	Same day
Training programme for Intervention wards*	March 12th, 15th, 16th, 17th, 24th	Same day as test
Revision training programme for intervention wards*	April: 19th, 20th,21st, 22nd	Same day
Implementation of the MEWS chart on intervention wards	1 May 2010	31 July 2010
Post-intervention test	Intervention wards: August 3rd, 4th,5th, 6th Control wards: August 10th, 11th, 12th, 13th	Same day

* Each nurse attended only 1 session

Training commenced on 12 March and recruitment continued for three days thereafter until all available nurses (that is, not on leave) had been invited to participate (UK, TW).

5.5.5.6 Blinding

The independent person (NL) was blinded to outcome and drew lots for ward allocation in the presence of the researcher. The researcher administered the interventions so blinding to allocation was not possible.

Nurses who participated voluntarily in the training programme and knowledge testing were not blinded to allocation as the purpose of the training was to implement the MEWS chart. The

researcher did the training so blinding to allocation was not possible. The independent assessor (JO) who marked the tests was blinded to allocation. Nurses from the control arm were not blinded to allocation.

5.5.6 Interventions

Interventions were twofold: a MEWS training programme and implementation of the Cape Town Ward MEWS observation chart (Table 5-6).

Table 5-6: Schematic representation of planned programme of intervention

Baseline		Intervention	Outcome Measure
Intervention wards	Pre-intervention knowledge test scores	Training programme	Post-intervention knowledge test scores
Control wards	Pre-intervention knowledge test scores	No training programme	Post-intervention knowledge test scores
Intervention wards	*1. Performance of the MEWS from Study Two* 2. Demographic data and clinical characteristics of patients in Study Three	Implement MEWS Observation Chart	Post-intervention criterion record review for quality and quantity of recorded vital sign data and nurses' responses to deterioration using MEWS Observation Chart
Control wards	*1. Performance of the MEWS from Study Two* 2. Demographic data and clinical characteristics of patients in Study Three	No intervention - existing observation chart used in control arm	Post-intervention criterion record review for quality and quantity of recorded vital sign data and nurses' responses to deterioration using MEWS Observation Chart

5.5.7 Instrumentation

Resources for all materials were provided by the researcher.

5.5.7.1 Design and validation of training programme

Content for the training programme was guided by published literature and validated[xviii] (see invitation letter (Appendix 5.3).

- *Validation: Index of Content Validity (CVI) and Construct Validity of the training programme*

Results are presented in Table 5-7.

[xviii] Three experts: a PhD-prepared nurse (PM) participating in national training programmes for nurses in primary health care clinics, a Master's-prepared nurse who participated in the validation processes in Study One and a BN-prepared nurse (Education and Administration) (DK) independent of the study who was a clinical instructor in the Hospital's Nursing Education Department.

Table 5-7: Index of content validity (CVI) and Contruct Validity of the training programme

CVI for the slides of the PowerPoint presentation	1 irrelevant	2 unable to assess relevance without item revision or item is in need of such revision that it would no longer be relevant	3a relevant 3b relevant but needs minor alteration	4 extremely relevant
Slide 1			3a:1 (33.3%)	2 (66.7%)
Slide 2				3 (100.0%)
Slide 3			3a:1	2
Slide 4			3a:1	2
Slide 5			3b:1	2
Slide 6			3a:2	1
Slide 7			3a:2	1
Slide 8			3a:1, 3b:1	1
Slide 9			3a:1, 3b:1	1
Slide 10			3b:2	1
Slide 11				3
Slide 12			3a:1	2
Slide 13				3
Slide 14			3a:2	1
Slide 15			3a:2	1
Slide 16			3a:1	2
Slide 17				3
Slide 18			3a:2	1
Slide 19			3a:1	2
Slide 20			3a:2	1
Slide 21			3a:2	1
Slide 22			3a:2	1
Slide 23			3a:2	1
Slide 24			3a:1, 3b:1	1
Slide 25			3a:2	1
Slide 26			3a:2	1
Slide 27			3a:1, 3b:1	1
Slide 28			3a:2	1

EVALUATION OF CONSTRUCT VALIDITY	Unacceptable 1	Needs improvement 2	Satisfactory 3	Very skilful 4
Layout			1	2
Quality			1	2
Length of the presentation		1	1	1
Are slides visually easy to read?		1	1	1
Is the style of writing clear and understandable?		1	1	1
Are slides visually easy to understand?			2	1
Are the objectives of the training programme clear?			1	2
Do the graphics clarify the content?			2	1

On a scale of 1-4 the training programme had a high *CVI* (a rating of 3-4) for all 28 slides. One expert suggested that the term MEWS should be introduced on slide one but the term early warning signs (EWS) is the broader concept to start with, followed by its modification (MEWS). Slide 5: Omnopon was changed to Morphine with suggested dosages. Concern was expressed that the chart on slide 7 may be too small but a larger printed chart was included in the training manual. The words 'ward' and 'MEWS' were added to slides 8 and 23 respectively. One expert was concerned that the level of physiology (slide 10) may not be appropriate for all nurse categories. The word 'mentation' was replaced with 'mental status' (slide 13) as the level of language was of concern. The rating was high (3-4) for 5/8 items for *construct validity* of the training programme. Items needing improvement (rated 2): length of the presentation (1/3), visual readability of the slides (1/3) and the style of writing (1/3). Not one respondent found any item unacceptable. One expert expressed concern that the level of the language may be inaccessible to English second language speakers so explanations and verbal illustrations were used liberally during the training sessions. A fourth expert, a PhD specialist anaesthesiologist gave verbal feedback, suggesting that a completed chart for the fictitious patient may re-inforce the message and this was included as a learning activity for each participant.

Each participant received a training manual containing a printout of the validated PowerPoint presentation (Appendix 5.4a) and the following documents:

- overview of the MEWS system;

- blank Cape Town MEWS chart for transcription of the vital signs of a fictitious case study;
- blank current observation chart;
- calling criteria for patients not on the MEWS chart (see ethical considerations in section 5.5.10.4; Table 3-29);
- Modified SBAR communication tool[xix] (Appendix 5.4b) although not a study objective it was deemed important;
- publication[247] on how to measure and record vital signs to ensure detection of deteriorating patients with case studies and comments (Appendix 5.4c);
- colour illustrations of the:
  - negative feedback control of blood pressure (Appendix 5.4d);
  - structure of the respiratory system (Appendix 5.4e); and
  - formation of urine (Appendix 5.4f).

5.5.7.2 Design and validation of knowledge questionnaire

- The content of the 16-item test (Appendix 5.5) is listed below:
  - eight questions for 23 marks on basic physiology and how to recognize early signs of clinical deterioration in a patient[250];
  - seven questions on clinical decision-making about calling for skilled assistance for changes in seven physiological parameters based on MEWS cut points to ascertain whether they would respond to a MEWS callout algorithm at 1, 2 or 3, showing at best, what the trend was but no right or wrong responses; and one closed (yes/no) question asked if the participant measured oxygen saturation on the ward to give an indication of category of nurse performing this test and linking it to their responses to a MEWS triggered callout algorithm for oxygen saturation levels.

[xix] Modified by the researcher but not validated. Abandoned during the first training session as there were too many new charts.

• *Validation results for Index of Content Validity (CVI) and Construct Validity of the knowledge test*

Results are presented in Table 5-8.

Table 5-8: Index of content validity (CVI) and construct validity of knowledge test items

CVI for Items relating to	1 irrelevant	2 unable to assess relevance without item revision or item is in need of such revision that it would no longer be relevant	3 relevant but needs minor alteration	4 extremely relevant
Recognising respiratory arrest				3
When to call for skilled assistance for sudden changes in respiratory rate			2	1
Recognising signs of inadequate breathing				3
Do you measure and record oxygen saturation (pulse oximetry)			1	2
When to call for skilled assistance for sudden changes in oxygen saturation levels			1	2
3 common causes of breathlessness			1	2
Recognising cardiac arrest				3
When to call for skilled assistance for sudden changes in heart rates			1	2
When to call for skilled assistance for sudden changes in systolic blood pressure levels			1	2
3 causes of low blood pressure				3
3 causes of high blood pressure				3
4 factors responsible for maintaining a normal BP			1	2
5 factors to help to assess cardiac output clinically				3
Normal body temperature			1	2
When to call for skilled assistance for sudden deterioration in conscious level			2	1
When to call for skilled assistance for changes in urine output				3
EVALUATION OF CONSTRUCT VALIDITY	**Unacceptable 1**	**Needs improvement 2**	**Satisfactory 3**	**Very skilful 4**
Layout			2	1
Quality of printing			2	1
Length of the test			2	1
Is the test visually easy to read?			2	1
Is the style of writing clear and understandable?			2	1
Is the test visually easy to understand?			2	1
Are instructions at the beginning of the test clear and easy to understand?		1	1	1
Is the purpose of the test clear?		1	1	1

On a scale of 1-4 the test had a high *CVI* (a rating of 3-4) for all 16 items. Experts suggested that a question should be added to determine the category of nurse but instead a pre-listed tick box was inserted. It was noted that, for items requiring clinical judgement (2, 5, 8, 9) in deciding when to call for skilled assistance, RPNs would first attempt to intervene and manage the situation whereas RNAs would first call for help therefore RNAs may find this question difficult. For item 6 'shortness of breath' was added for further clarification of 'breathlessness'. Pain was added to the memorandum as advised by an expert. It was suggested that the Glasgow Coma Scale equivalent of the AVPU system should be used for item 6 and this was done. The test also had a high rating (3-4) for *construct validity* for 6/8 items. Items needing improvement (rated 2): instructions for participants (1/3) and wording of the purpose of the test (1/3). Not one respondent found any item unacceptable. One expert expressed concern that the level of the language may be inaccessible to English second language speakers so explanations were added to most questions. There was concern about the abbreviation (SAT/SpO_2) so 'oxygen saturation' was added to item 5.

5.5.7.3 MEWS teaching aids for the ward

After training certain recommendations from Study One were implemented on the intervention wards such as a laminated copy of a:

- MEWS chart correctly populated with dummy data (Appendix 5.6);
- colour flowchart for the MEWS callout algorithm (Figure 5-3);
- calling criteria (Table 3-29);
- MEWS training manual (5.4).

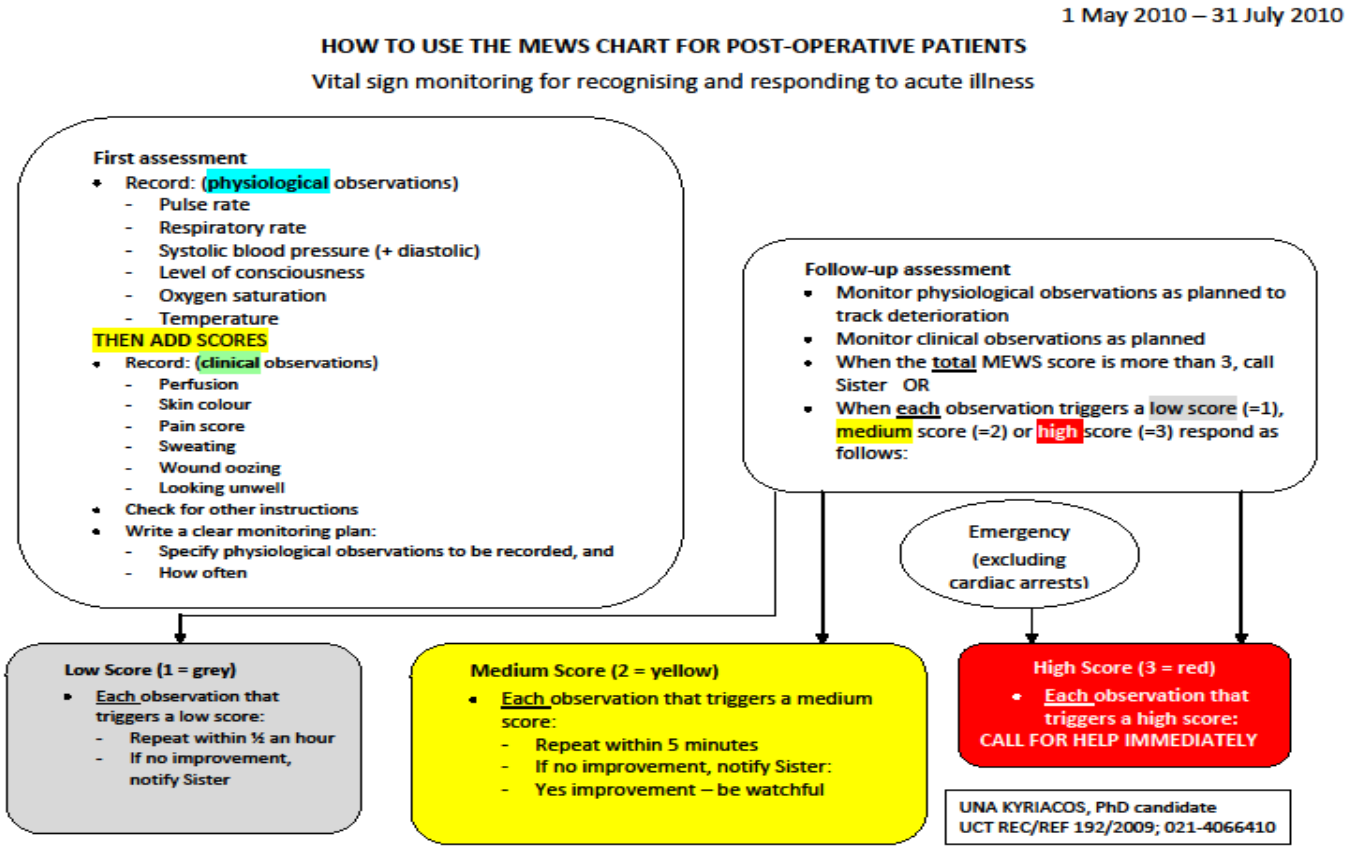


Figure 5-3: Flowchart for the MEWS callout algorithm

(Adapted from the UK NHS National Institute for Health and Clinical Excellence Quick reference guide: Acutely ill patients in hospital, 2007)[128]

5.5.7.4 Record review

The criterion based record review form designed for Study Two and described in section 4.5.3.1 (Table 4-4) was used in Study Three for retrospective review of patient case-notes from the cluster of three intervention wards and the cluster of three control wards

5.5.8 Procedure

5.5.8.1 Implementing the MEWS Training programme

- **Intervention group**

A pre-intervention knowledge test (Appendix 5.5) based on the contents of the training manual (section 5.5.7.1) was administered to nurses from the intervention wards in March 2010 and was followed immediately by the training programme prior to the implementation of the MEWS chart on 1 May 2010. The training venue was a pre-booked seminar room located between two wards.

- Administration of pre- and post-intervention knowledge tests

For administrative purposes the surgical clinical instructor recruited participants, although participation was voluntary. At scheduled times arranged by the clinical instructor there was a 48.5% turnout (n=30/62) for the pre-test from the three clusters. The researcher administered the pre-intervention test to groups of participants ranging from 3 to 5. Written consent was obtained (Appendix 5.7).

Following introductions the Information Sheet on the Consent Form was used to explain the study. Code numbers on test papers provided anonymity and confidentiality of data and only the researcher knew participants' names and code numbers.

The test was marked by an independent assessor (JO)[i] blinded to the subjects' identity and to the allocated group.

- All categories of permanently employed nurses with a large range of educational preparation were eligible to participate in the study. Notwithstanding, no provision was made for different levels of complexity of questions because in practice all categories of nurses are responsible for monitoring, recording and interpreting patients' vital signs.
- An identical post-test for comparison of scores was administered the week following the completion of the trial in July 2010. Five participants from both the intervention wards (N=25 remaining) and control wards (N=25 remaining) were lost to the study at this point and their pre-intervention test scores were excluded from the sample (Figure 5-4).

Control group

- The consent form (Appendix 5.8) was signed.
- The procedure for administering the pre- and post-tests to nurses (N=30) was the same as that for the intervention wards but during different weeks to avoid contamination.

- Administration of the training programme

Attendance at training sessions was dependent on staffing and workload as there were no additional resources to replace nurses on training that often required rescheduling for specific nurses. Wards released one to three nurses at a time so five repeat training sessions were needed for day staff. At each of the five sessions four to seven nurses attended. In this way 27 day duty nurses received training (the remaining three were on night duty). Training was reduced from the planned four to two hours due to day staff shortages. Training the three nurses on night duty was

[i] A registered nurse educator employed at another hospital.

abandoned due to heavy workload and they were subsequently trained individually or in pairs on the wards when they were next on day duty.

The revision training session in April was reduced from two to one hour and nurses were given relevant pages not in the first manual (Appendix 5.9). Nurses were given MEWS charts populated with dummy data, some of which were incorrectly placed for example a respiratory rate of 22 placed in the grey partition for cut points of 15-20 and they had to mark the accuracy of each entry.

- Interactive teaching process

After the pre-intervention tests participants (n=27 as 3 completed this on night duty) remained for the 2-hour training session. The training programme was implemented by the researcher, a registered nurse educator. The training schedule served as the attendance list.

The medium of instruction was English (the official language used for documentation at the Hospital)[ii]. Seats were arranged in a circle that included the researcher. Principles of adult learning (a learner-centred approach, relevance of content, self-identification of learning needs, and contributing personal experiences to classroom discussions) underpinned the approach to the training sessions. Refreshments were available.

Basic physiology of blood pressure, cardiac output, respiration and urine production was revised using slides. The MEWS was explained by application to fictional case studies using interactive group work. Probing questions were asked during a discussion of published case studies. Fictional scenarios were used for individual recordings of data on the MEWS chart and for calculating a total score.

- *Accuracy of calculating a total MEWS*

To ensure accuracy of calculating a total MEWS, four fictional scenarios were analysed by the nurses (professional nurses, staff nurses and nursing auxiliaries) (n=26, after which one nurse was lost to the study, Figure 5-4) from the three intervention wards. The nurses were asked to derive a

[ii] Questions posed in Afrikaans were answered in that language as the majority of nurses were not English first language speakers.

total MEWS from each of four patient scenarios (two paired sets) with true MEWS values of 5, 5, 9 and 11 points respectively. Fictional scenarios were employed to establish a true MEWS as patient acuity (for example respiratory rate) in an actual clinical setting may change rapidly between two observers' assessments making it difficult, if not impossible, to establish an interobserver true MEWS.

Results for the calculation of an aggregated MEWS using four fictional scenarios by three categories of nurses on the three intervention wards are presented in Table 5-9.

Table 5-9: Accuracy of nurses' (three levels) calculations of aggregate MEWS for each patient scenario

		Professional Nurses (N=15)	Staff Nurses (N=6)	Nursing Auxiliaries (N=5)
Patient scenario	True MEWS	n (%) correct	n (%) correct	n (%) correct
Patient 1 (Time A)	5	13 (86.7)	3 (50.0)	2 (40.0)
Patient 1 (Time B)	5	14 (93.3)	5 (83.3)	4 (80.0)
Patient 2 (Time A)	9	10 (66.7)	3 (50.0)	1 (20.0)
Patient 2 (Time B)	11	10 (66.7)	3 (50.0)	1 (20.0)
Total		47/60 (78.3)	14/24 (58.3)	8/20 (40.0)

Results for the group as a whole are shown in Table 5-10.

Table 5-10: Accuracy of calculation of aggregate MEWS by all nurses (N=26)

Patient scenario	True MEWS	n (%) correct [95% CI]
Patient 1 (Time A)	5	18 (69.23) [48.10-84.91]
Patient 1 (Time B)	5	23 (88.46) [68.72-96.97]
Patient 2 (Time A)	9	14 (53.85) [33.75-72.86]
Patient 2 (Time B)	11	14 (53.85) [33.75-72.86]
Total		69/104 (66.3) [56.33-75.13]

Calculation of an aggregated MEWS was most accurate for Professional Nurses (47/60; 78.3%), followed by Staff Nurses (14/24; 58.3%) and then Nursing Auxiliaries (8/20; 40%) (Table 5-9). As a group, the nurses scored 66.4% in accurately calculating a MEWS (Table 5-10). There was lower accuracy for a higher true MEWS but small numbers in this study could not produce statistical trends in the data.

5.5.8.2 Implementing the MEWS observation chart

In addition, to ensure full implementation, two MEWS Project Leaders for each ward (one for each team working opposite shifts) were identified by the 'head nurse' of each ward. The researcher invited these named nurses to assume this responsibility. Each project leader received a UCT lanyard bearing a laminated card with the title: MEWS Project Leader. They had the researcher's contact details and undertook to ensure that all patients 14 years of age and older who had a general anaesthetic would have a MEWS chart for recording vital signs by placing the chart in the patients' file preoperatively. Alternatively, following surgery, they undertook to place the chart at the patients' bedside.

For patients in the intervention wards not meeting inclusion criteria and who may develop critical illness, a laminated calling criteria chart (Table 3-29**,** see sections 5.5.7.3, 5.5.10.2) was provided.

5.5.9 Statistical methods

Statistical analyses were undertaken with IBM SPSS Statistics version 19, DAG-Stat[222] and EpiCalc 2000 on an intention-to-treat basis (ITT).[26] However, for illustration only,a *per protocol* analysis was undertaken of the proportion of patients in the *intervention arm* on the MEWS chart and those with the existing chart in the *control arm* (Table 5-24). Per protocol analysis may be defined as a 'method of analysis for randomized controlled trials in which individuals are included in the analysis only if they followed the assigned protocol and are removed from the analysis entirely if they do not follow the protocol' (Sussman & Hayward, 2010:1181).[289] Per protocol analysis includes only those who follow protocol exactly. These participants are not selected at random and are likely to be different in some way. Selectively excluding those who violate protocols introduces bias. Accordingly, intention-to-treat is reported with a per protocol analysis as a secondary sensitivity analysis for comparison (Nuesch et al 2009).[290]

The probability value p.05 was accepted as the level of significance throughout.[291] Tests of normality of distribution of variables followed the convention of using the Shapiro-Wilk test for a sample size smaller than 50 and the Kolmogorov-Smirnov test for a sample size greater than 50.[291]

Statistical methods that were employed for analysis of data for knowledge tests and for record review are presented separately in this section in two tables. Conventional statistical symbols are described in Table 5-12 and thereafter these are used in data tables without explanation. The purpose of statistical tests employed for the variables is only described in this section and not repeated thereafter. In the results section data tables are followed by statistical commentary.

Results are presented in tables as outlined in Table 5-11.

Table 5-11: Presentation of data

Presentation of results: statistical methods employed	Examples
Description of variable	Age, trial arm (intervention and control)
Measures of central tendency	Mean, median
Measures of dispersion	Number (N=114), proportion (35/114) and percentage (30.7%). Minimum to maximum. Standard deviation (SD) set at 95% Confidence Intervals (CIs). Interquartile range (IQR). Tests of normality for distribution of data (Shapiro-Wilk, Kolmogorov-Smirnov).
Measures of association	(Chi-square (χ^2) between nominal data variables
Measure of effect size	Odds ratio (OR), a descriptive statistic, provides a measure of the strength of relationship between two variables.[292]
To compare normally distributed means within one trial arm	A parametric paired (dependent) t-test was used with reporting of mean difference and SD and 95% CI of this difference and results of the test: t-value, degrees of freedom (df) and probability (p-value).
To compare two sets of scores not normally distributed within one trial arm	A Wilcoxon Signed-Ranks test was used for reporting of mean rank, sum of ranks, Z-value, significance (p-value).
To compare normally distributed means between the two intervention arms	A parametric independent t-test was used with reporting of equality of variances (measure of dispersion) using Levine's Test and indicated by a p-value for significance and F-statistic and results of the test: t-value, df, significance, mean difference and 95% CI of the difference.
To compare a variable not normally distributed between the two trial arms	A nonparametric Mann-Whitney U test was used with reporting of the median, IQR and results of the test: mean rank, sum of ranks, U-test statistic, Z-value[iii] and significance (p-value).
To determine whether there were significant differences between the normally distributed means of three groups (ward clusters within one trial arm; professional categories of nurses)	A parametric Analysis of Variance (ANOVA) test was used with reporting of sums of squares (SS), df, mean square (MS), F-statistic and significance (p-value) and Scheffe post hoc test.
To compare a variable not normally distributed between or within three groups (eg. professional categories of nurses) within the two trial arms	A nonparametric Kruskal-Wallis test was used with reporting of mean rank and results of the test statistics: χ^2-value (Kruskal-Wallis H), df and significance (p-value).

Sample SPSS printouts can be found in Appendix 5.10, 5.10a, 5.10b.

[iii] Z-value is related to sample size and can be used to approximate the significance level for the test.

5.5.9.1 Statistical analysis of knowledge questionnaire

Specific statistical methods for knowledge tests are presented in Table 5-12.

Table 5-12: Statistical analysis of knowledge questionnaire

Indicator variables	Data	Statistical analysis
Test scores	Interval	Parametric tests for normally distributed values: Mean percentage (%) SD 95% CI Min-max Paired t-test for equality of means Independent t-test ANOVA, Scheffe post hoc test
Test scores	Interval	Nonparametric tests for values not normally distributed: Median % IQR Mann-Whitney U-test Kruskal-Wallis test Wilcoxon Signed-Rank test
Distribution of nurses by category, cluster and trial arm	Categorical	χ^2, df, p-value

Cluster analysis of test scores by *professional categories* is not directly related to study objectives and therefore the distribution of nurses and their respective pre- and post-test scores are presented in the ancillary analyses section (section 5.6.6.1) by cluster within trial arms (χ^2 p-value, df). This data informs interpretation of the nurses' recording behaviour.

Further analysis of test scores by professional categories first within trial arms and then within clusters in trial arms is presented in Appendix 5.11. Differences between *pre*-and *post*-intervention test scores were analysed at individual level (Appendix 5.10a, b) using the Wilcoxon Signed-Ranks test.

5.5.9.2 Statistical analysis of patient datasets by record review

Analysis was on an intention-to-treat basis,[26] however, for purposes of illustration a *per protocol* analysis was undertaken of recordings on the MEWS chart in the intervention arm compared to those on the existing chart in the control arm. Statistical analysis for the same

variables as presented in Table 4-6 for Study Two pertains to Study Three and is presented in Table 5-13. The same process for data summary was followed as described in section 4.5.5.

Table 5-13: Statistical analysis of record review

Socio-demographic variables	**Indicator variables**	**Data**	**Statistical analysis**
Sex	Female=1, male=0	Categorical Binary	Descriptive summary statistics: Proportion (%), Chi-Square (χ^2), degrees of freedom (df), significance (p-value)
Surgery specialty	General Vascular Gastrointestinal Orthopaedic	Categorical	Proportion, percentage
Type of pre-existing comorbid condition	8 pre-listed	Categorical	Proportion, percentage χ^2, df, p-value, Odds ratio (OR) (95% Confidence Intervals (CI)
Age Days in hospital		Interval	Nonparametric tests : Mann-Whitney U: mean rank, sum of ranks, Z-value, p-value Tests of central tendency (median) and dispersion: min-max, interquartile range (IQR)
7 Physiological parameters	Number of patients with prescribed parameters	Interval	Mann-Whitney U
	Number of patients with prescribed cut points (thresholds) for a callout	Interval	Proportion and percentage
	Number of patients with parameter recordings postoperatively	Binary 1=Done; 0=Not done	χ^2, p-value, OR, df, CI
	Number of recordings in first 8 postoperative hours	Interval	Mann-Whitney U test
	Number of MEWS trigger points/ number of nurses' responses	Interval	Proportion
All 7 parameters recorded	Retrospective sample size calculation	Binary Done/not done	Analysis of Variance (ANOVA): sums of squares (SS), df, mean square (MS), F-statistic and significance (p-value) Intracluster correlation coefficient

The design of the MEWS observation chart and clinical record review form used in Study Two and here has been covered elsewhere.[iv] The research setting is described in section 1.5.

5.5.10 Ethical considerations

Cluster randomised controlled trials raise new ethical issues in relation to "the nature and practice of informed consent, because of the levels at which consent can be sought, and for which it can be sought."[229] Study Three is an individual-cluster trial rather than a cluster-cluster trial.[293] This means that at the cluster level, consent for trial entry and consent for one of the interventions (implementation of the MEWS chart) was given by the hospital gatekeepers (guardians)[293] However, at the individual level, consent for trial entry to the second intervention (training programme and knowledge test), was at the individual consent level for nurses. Nurses in the intervention ward clusters could not have introduced the MEWS chart if they did not have training so if all nurses refused the training this would have raised ethical issues in this trial. The risk of the individual-cluster trial failing if nurses refused to be trained had to be taken.

5.5.10.1 Autonomy, beneficence and respect of persons

- Intervention: the training programme

Participants for Study Three were recruited by the surgical clinical nurse instructor from Study One before randomization to limit possible bias.[229] Written consent to participate in the training programme and in the pre- and post-intervention knowledge test, was subsequently obtained by the researcher after randomization. The consent form incorporated an Information Sheet (5.7: intervention group; Appendix 5.8: control). The Consent Form for the control group did not include training or use of the MEWS chart. Consent was at two levels: the administration of an intervention (training) and collection of data (knowledge tests) and this is ideal.[229]

Participants were known to the researcher and therefore not anonymous. However, an unique identification code was assigned to each participant on the test sheet and confidentiality of data was protected by not linking participants' names to data. The name of the participant linked to the code number was known only to the researcher. The name of the research site will

[iv] MEWS observation chart – Study One (Chapter 3). Clinical record review form – Study Two (Chapter 4)

not be reported by name in the publication of findings. The confidential nature of participants' test results was respected.

In relation to ease of withdrawing from the trial[229], some participants did withdraw voluntarily from the training programme (section 5.6.1.1). In relation to the subsequent clinical record review that was explained during the training session, nurse participants were assured that even if, in the opinion of the researcher, the record review reveals evidence of inappropriate or inadequate clinical decisions, there will be no disclosure of personnel's personal information.

- Intervention: implementation of the MEWS observation chart

In each intervention ward the researcher briefed the medical staff about the study and the chart and there was verbal approval. Once the chart had been implemented it was not possible for participants to withdraw from the trial.

A practical issue that faced the researcher at this point was the best way to explain the trial to nurses allocated to the control wards who saw little benefit to them of doing the pre- and post-knowledge test (Table 5-6), particularly as the senior ward nurses had been part of Study One (design of the MEWS). Honesty and courtesy helped to some extent.

- Clinical record review

The ethical considerations in record review for adverse events have been described in Study Two (section 4.5.6). Of relevance to this part of the cluster trial (record review) is that institutional consent was for data collection only and seeking patient consent may have vitiated the intervention[229] and been impractical (Clause 25, Declaration of Helsinki, 2008)[223] therefore this decision was left to the ethics committee to grant approval.

5.5.10.2 Justice

The training programme and MEWS observation chart were intended to raise participants' awareness of and competence in early recognition of signs of clinical deterioration and to respond to a predetermined callout algorithm to reduce avoidable SAEs. Improving patient safety in hospitals is a moral imperative, in this way upholding the ethical principle of justice. Every effort

was made to ensure that both day and night staff were given a fair opportunity to participate in the study. For patients not meeting inclusion criteria who may experience critical illness, posters listing calling criteria were prepared for the three intervention wards and copies were included in the training manual.

5.5.10.3 Risks and benefits

The research process for Study Three was carefully planned to consider ethical principles related to human research in an effort to do good in respect of participants (nurses) and not to do them or patients any harm thereby avoiding violation of the ethical principle of nonmaleficence. The possibility that patients not meeting inclusion criteria may be missed for early signs of deterioration raised an ethical issue and it was agreed that calling criteria would be used during Study Three as an adjunct to the MEWS chart for such patients. Furthermore, if it became apparent that patients in the trial had better outcomes than patients in control wards, the study would have to be stopped early.[229] There was no evidence of an increased incidence of SAEs amongst non-trial patient in the nurses' Activities of Daily Living (ADL) book which was searched for SAEs weekly for eight weeks and compared to 2009 entries for the same period. The Ethics Committee had approved weekly rapid review of patients' case-notes for SAEs but records were not always available.

Having a system of 'tracking' early clinical and physiological deterioration in a patient and 'triggering' a predetermined callout algorithm by specially trained nurses ought to benefit patients as this should improve patient safety and reduce the incidence of in-hospital morbidity and mortality.

5.5.10.4 Ethical aspects of the pragmatic cluster trial

Cluster randomised controlled trials raise new ethical issues in relation to "the nature and practice of informed consent, because of the levels at which consent can be sought, and for which it can be sought. In addition, careful consideration of the principles relating to the quality of the scientific design and analysis, balance of risk and benefit, liberty to leave a trial, early stopping of a trial and the power to exclude people from potential benefits is required".[229] At the cluster (ward level) level, consent for trial entry and consent for one of the interventions (implementation of the

MEWS chart) was given by the hospital gatekeepers (guardians).[293] Even so, "[S]ometimes, people who object strongly to specific cluster policies find ways of deliberate non-compliance" (Edwards 1999:1408).[293]

However, at the individual level, consent for trial entry to the second intervention (training programme and knowledge test), was at the individual consent level for nurses. It would have been easier to have designed a cluster-cluster trial where community consent must be considered as a single package[293] by the hospital gatekeepers (guardians). In other words, nurses in the intervention ward clusters could not have introduced the MEWS chart if they did not have training and all nurses would have had to be trained. This would have raised ethical issues in this trial. The risk of the individual-cluster trial failing if nurses refused to be trained had to be taken.

The faculty Human Research Ethics Committee had approved weekly rapid review of patient case-notes for evidence of an increased incidence of SAEs amongst non-trial patients but records were not always available so the nurses' handwritten Activities of Daily Living (ADL) books were searched weekly for eight weeks and compared to 2009 entries for the same period.

5.6 Results

The effectiveness of the MEWS training programme and observation chart was examined through a cluster randomised parallel group clinical trial of intervention versus standard care. To ensure adequacy of reporting of results, Consort 2010 guidelines extended to cluster randomized trials and pragmatic approaches to trials were used to evaluate the study (Table 5-36) and where not done, this is reported.

5.6.1 Participants (nurses) and sampling of records

5.6.1.1 Participant flow for the MEWS training intervention

The flow of participants recruited for the training intervention on an intention to treat basis is shown in Figure 5-4.

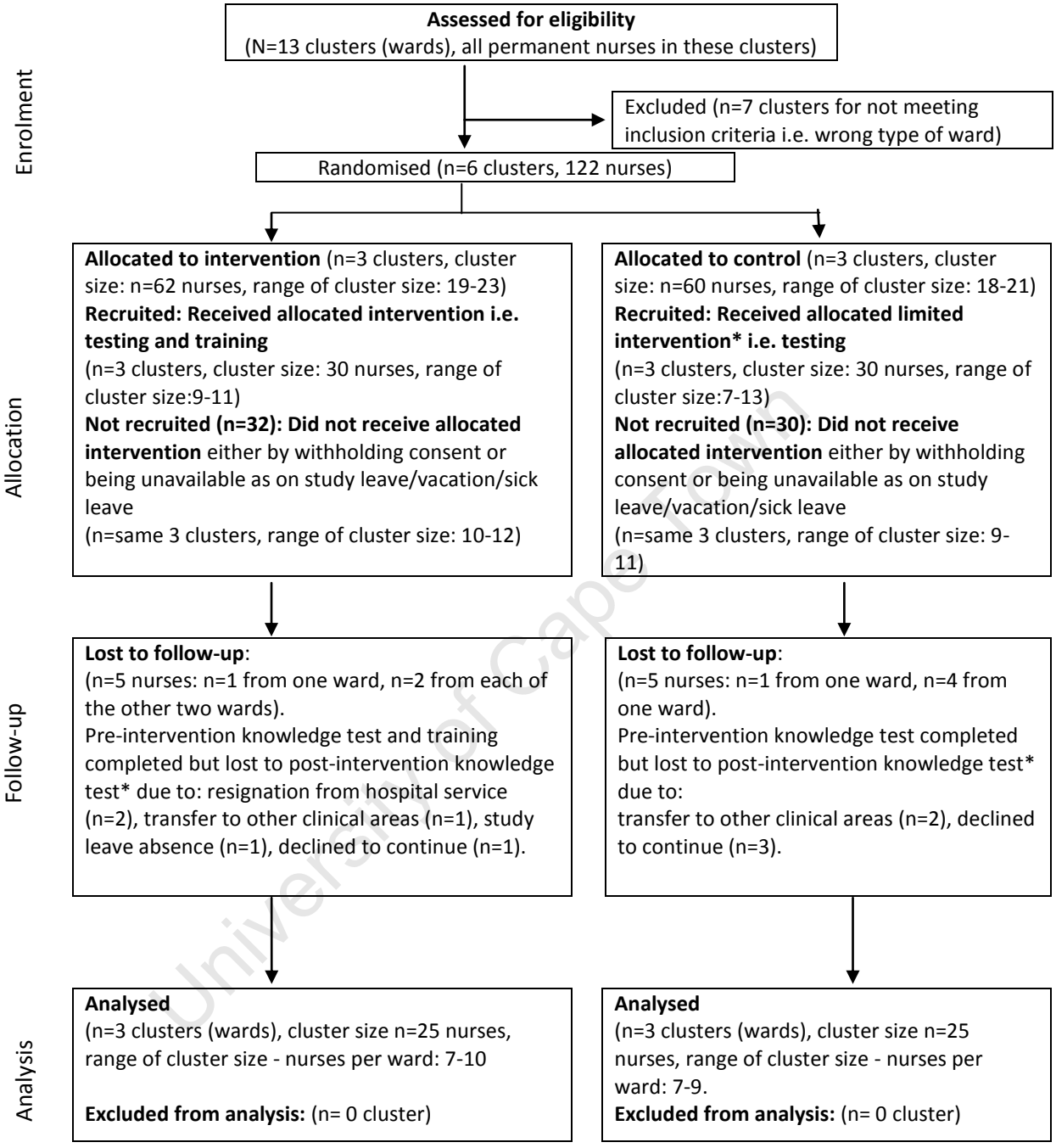


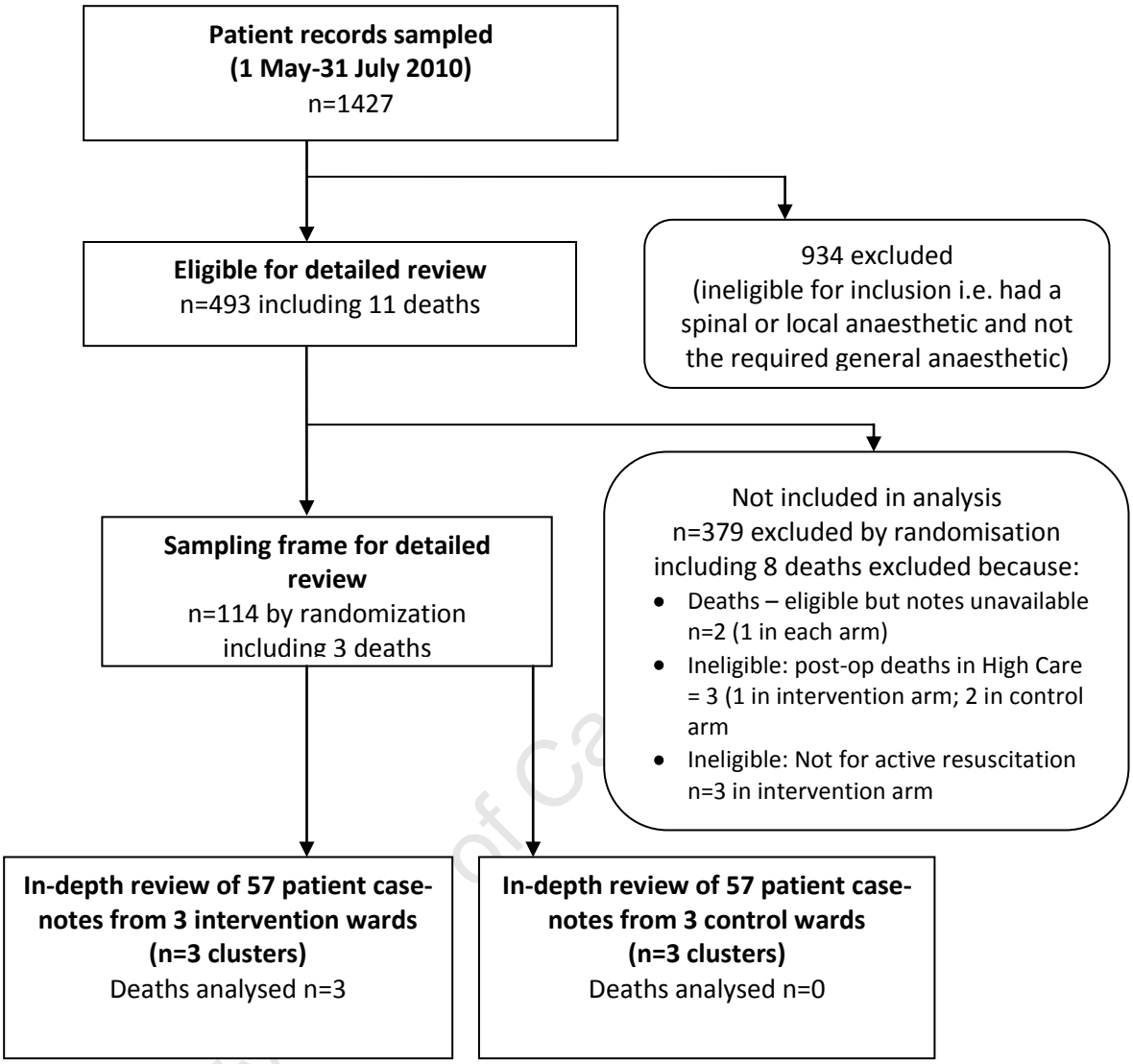
Figure 5-4: Flow diagram of clusters and nurses for the intervention group (MEWS training programme and knowledge testing) and control group (only knowledge testing*)

5.6.1.2 Sample of records for review

A total of 1427 patients were admitted to the six wards during the study period (excluding n=27 patients transferred out of the wards to other wards prior to having surgery). Of these patients 493 (34.6%) had a general anaesthetic and 11 patients had died.

Records of the 493 patients including those who had died, fulfilled specified criteria for inclusion (section 5.5.3.2) and were randomized to achieve an estimated sample size of 114 records (57 from each group (intervention and control) comprising 19 from each of the six ward clusters) (section 5.5.5.2).

An eventual sample of 114 records (23.1%) was reviewed to meet the objectives. The review process and eventual sample is shown in Figure 5-5.



(Adapted from Wilson, Runciman, Gibberd, Harrison, Newby & Hamilton, 1995).[92]

Figure 5-5: Flow chart of record review process of MEWS trial

Note on figure: All records were sampled from the 6 research wards.

5.6.2 TRAINING PROGRAMME INTERVENTION: Objective 1 - to explore the effect on nurses' knowledge test scores

5.6.2.1. Scores obtained on the pre-and post-intervention tests within trial arms

• *Pre-intervention test scores*

Results are presented in Table 5-14.

Table 5-14: Nurses' (N=50) *pre-intervention* test scores *by cluster* within trial arms

Clusters	Mean % score by cluster	SD	Min-max	95% Confidence interval CI	Mean % score for trial arms	SD	Min-max	95% Confidence interval CI
Intervention arm (N=25)								
1	46.19	11.13	30.4-60.9	36.89 –55.50	41.9	14.63	13.0 – 65.2	35.9-47.9
2	39.13	14.19	17.4-60.9	25.99 –52.26				
3	40.43	17.75	13.0-65.2	27.73 – 53.13				
Control arm (N=25)								
4	30.43	11.50	17.4-47.8	21.59 –39.27	37.2	18.19	8.7 – 69.6	29.7-44.7
5	39.13	20.50	8.7-69.6	23.36 –54.89				
6	43.47	21.59	13.0-65.2	23.50 –63.44				

• *Post-intervention test scores*

Results are presented in Table 5-15.

Table 5-15: Nurses' (N=50) *post-intervention* test scores *by cluster* within trial arms

Clusters	Mean % score by cluster	SD	Min-max	95% Confidence interval CI	Mean % score for trial arms	SD	Min-max	95% Confidence interval CI
Intervention arm (N=25)								
1	71.2	21.66	34.8-100.0	53.07 – 89.31	61.4	27.90	13.0 – 100.0	49.9-72.9
2	59.0	24.44	26.1-100.0	36.39 – 81.61				
3	55.2	34.36	13.0-100.0	30.64 – 79.79				
Control arm (N=25)								
4	40.6	14.08	13.0-60.9	29.75 – 51.40	41.2	16.22	13.0 – 65.2	34.5-47.9
5	38.6	16.33	21.7-65.2	26.09 – 51.20				
6	45.3	20.06	21.7-65.2	26.78 – 63.89				

Procedures for statistical analyses and tests are outlined in Table 5-12 (section 5.5.9.1).

5.6.2.2 Comparison of scores within trial arms

- *Comparison of pre- and post-intervention scores within the intervention arm*

Data were normally distributed and parametric tests were used to present the analysis in Table 5-16.

Table 5-16: Nurses' (N=25) *pre- and post*-intervention scores within the *intervention arm*

Pre-intervention scores	**Post-intervention score**	**Paired t-test for Equality of Means**				
Mean % (SD)	Mean % (SD)	Mean difference %	SD	95% CI of difference	t-value (df)	p-value
41.9 (14.63)	61.4 27.90	19.48	25.60	-30.046--8.909	3.804 (24)	0.001

The difference between pre- and post-intervention scores within the intervention arm reached statistical significance (p=0.001).

Data for the control arm are presented in Table 5-17

Table 5-17: Nurses' (N=25) *pre- and post*-intervention scores within the *control arm*

Pre-intervention scores	**Post-intervention score**	**Paired t-test for Equality of Means**				
Mean % (SD)	Mean % (SD)	Mean difference %	SD	95% CI of difference	t-value (df)	p-value
37.2 (18.19)	41.2 (16.22)	3.99	13.22	-9.455-1.459	-1.512 (24)	0.144

The difference between pre- and post-intervention scores within the control arm did not reach statistical significance (p=0.144).

5.6.2.3 Comparison of scores between trial arms

- *Comparison of nurses' pre-intervention test scores*

Pre-intervention scores were normally distributed and parametric tests were used to compare scores as shown in Table 5-18.

Table 5-18: Nurses' (N=50) *pre*-intervention knowledge test scores *between both trial arms*

Intervention arm (n=25)		**Control arm (n=25)**		**t-test for Equality of Means**			
Mean %	SD	Mean %	SD	Mean difference [95% CI]	p-value	t-value (df)	**F-statistic**
41.9	14.63	37.2	18.19	4.695 [-4.692 - 14.083]	0.320	1.006 (48) Equal variances assumed	F=2.38, p=0.129

There were no significant differences in the pre-intervention knowledge scores between control and intervention arms (t-value 1.006, df 48, p=0.320).

- *Comparison of nurses' post-intervention scores*

Post-intervention test scores were not normally distributed (Shapiro-Wilk =.920, df=25, p=0.051) in the control arm (Table 5-19) therefore non-parametric tests were used to compare post-intervention test scores by trial arm.

Table 5-19: Test of normality for post-test results

INTERVENTION ARM=1 CONTROL ARM=0		Shapiro-Wilk		
		Statistic	df	Significance
Post-test %	0	.920	25	.051
	1	.937	25	.124

Table 5-20: Nurses' (N=50) *post*-intervention knowledge test scores *between both trial arms*

Trial arm	Median %	IQR	Mann-Whitney U test				
			Mean Rank	Sum of Ranks	U test statistic	Z-value	Significance (2-tailed)
Intervention (n=25)	60.8	50.00 (13-100)	30.88	772.00	178.000	-2.619	p=0.009
Control (n=25)	34.8	28.26 (13-65	20.12	503.00			

There were statistically significant differences in the post-intervention knowledge scores between intervention and control arms (Z=-2.619, p=0.009) (Table 5-20).

- *Mean differences between pre- and post-intervention scores at trial arm level*

Data are presented in Table 5-21.

Table 5-21: Mean differences between nurses' (N=50) *pre- and post*-intervention test scores of *both trial arms*

Intervention arm (n=25)		Control arm (n=25)		Independent t-test			
Mean difference % (SD)	95% CI	Mean difference % (SD)	95% CI	Mean difference [95% CI]	p-value	t-value (df)	**F**
19.5 (25.6)	8.907-30.044	4.0 (13.2)	-1.455-9.471	15.48 [3.790- 27.166]	0.011	2.686 (35.9) Equal variances not assumed	F=16.982 p=0.000

The improvement in scores after training in the intervention arm was significantly better (t-value 2.686, df 35.9, p=0.011) than that in the control arm (Table 5-21).

Results for patients included in the clinical record review are presented next.

5.6.3 MEWS CHART INTERVENTION: Objective 2a - to explore the effects of training and the MEWS chart on nurses' recordings of *postoperative vital sign data* at trial arm level

Intervention wards had used the MEWS observation chart as a *single parameter* track and trigger system. That means nurses did not total the MEWS for each observation time-point. Nurses on the control wards continued to use the existing observation chart.

5.6.3.1. Baseline demographic and clinical characteristics of patients: clinical record review

The same quality control process for record review as for Study Two (section 4.6.1.2) was undertaken, this time using a 9% random sample (10/114) of anonymized[7] reviewed records and achieving 92.5% agreement. The same data captured on the criterion record review form for Study Two described in section 4.5.5 (Table 4-4) pertains to Study Three. Data were captured from the same type of source documents as for Study Two (Table 4-5).

Baseline demographic data and clinical characteristics of patients analysed in randomized wards in the intervention and control arms are presented in Table 5-22. The difference in proportion of patients undergoing different surgery reflected the various wards that comprised the intervention and control arms. Analysis was by intention to treat.

Table 5-22: Baseline data of patients (N=114) in intervention and control arms by demographic and clinical characteristics (intervention arm is the reference and = 1 for calculation of the OR)

Characteristic	**Intervention arm (n=57)**	**Control arm (n=57)**		
Categorical Variables	**Number (%)**	**Number (%)**	**χ^2 (df)**	**p-value**
Sex: Female	*21 (36.8)*	*36 (63.2)*	*7.89 (1)*	*0.005*
Type of surgery:			**Proportion of sample (N=114)**	
General	16 (28.1)	19 (33.3)	35 (30.7)	
Vascular	2 (3.5)	6 (10.5)	8 (7.0)	
Gastrointestinal	1 (1.8)	13 (22.8)	14 (12.3)	
Orthopaedic	38 (66.7)	19 (33.3)	57 (50.0)	

Pre-existing comorbid conditions:[1]

	Intervention Arm (n=57) Number	**Control arm (n=57)** Number	**Proportion of sample (N=114)**	χ^2 (df=1)	**p-value**
Myocardial infarction	0	3	3 (2.6)	3.081	0.079
Renal	1	0	1 (0.9)		
Diabetes Mellitus	*13*	*4*	*17 (14.9)*	*5.600*	*0.018*
Carcinoma	4	10	14 (12.3)	2.931	0.087
Respiratory	9	9	18 (15.8)	.000	1.000
CVA/ Hypercholesterolaemia	5	7	12 (10.5)	.373	0.542
Hypertension	17	19	36 (31.6)	.162	0.687

Interval Variables

Patients' age in years:				**Mann-Whitney U-test**				
	Median	**min-max**	**IQR[4]**	**Mean Rank**	**Sum of Ranks**	**U-value**	**Z-value**	**p-value**
Intervention arm	49.00	14-76	29	57.14	3298.00	1604.0	-.116	0.907
Comparator arm	45.00	14-84	26	57.86	3257.00			
Hospital stay (days):								
Intervention group	4.0†	2-23	4	56.23	3205.00	1552.0	-.415	0.678
Comparator group	4.0†	1-43	7	58.77	3350.00			

Note on table:

1. Some patients had more than 1 comorbid condition recorded.
2. There is not a normal distribution for age or hospital stay therefore nonparametric tests are used.

Significant baseline demographic data and clinical characteristics of patients are discussed next.

- *Gender and pre-existing comorbid conditions*

As indicated in (Table 5-22) there were significantly more females (Chi-Square 7.89, df=1, p=0.005) in the control arm and more patients with diabetes mellitus in the intervention arm (Chi-Square 5.60, df=1, p=0.018), otherwise the two groups were equivalent.

5.6.3.2 Patients with recorded postoperative parameters by trial arm

The number of patients in the intervention arm (n=57) and control arm (n=57) with vital sign recordings [Done/Not done] within the first 8 hours following surgery is shown in Table 5-23.

Table 5-23: Patients (N=114) with postoperative parameter recordings by trial arm (intervention arm is the reference and = 1 for calculation of the OR)

Parameter	Intervention arm N=57 patients	Control arm N=57 patients	x^2	p-value	OR (df=1)	95% CI
	Number (%)	Number (%)				
Respiratory rate recorded	27 (47.4)	2 (3.5)	28.905	0.00	24.75	5.50-111.32
Respiratory rate not recorded	30 (52.6)	55 (96.5)				
Heart rate recorded	57 (100.0)	57 (100.0)				Not computed
Heart rate not recorded	0	0				
Oxygen saturation recorded	7 (12.3)	2 (3.5)	3.016	0.08	3.85	.76-19.41
Oxygen saturation not recorded	50 (87.7)	55 (96.5)				
Systolic blood pressure recorded	57 (100.0)	57 (100.0)				Not computed
Systolic blood pressure not recorded	0	0				
Temperature recorded	55 (96.5)	54 (94.7)	Fisher's	1.00	1.53	.25-9.51
Temperature not recorded	2 (3.5)	3 (5.3)	taken			
Conscious level[1] recorded	45 (78.9)	37 (64.9)	2.780	0.10	2.03	.88-4.68
Conscious level not recorded	12 (21.1)	20 (35.1)				
Urine output recorded	49 (86.0)	51 (89.5)	.326	0.57	0.72	.23-2.23
Urine output not recorded	8 (14.0)	6 (10.5)				
All vital signs recorded	5 (4.4)	0[2] (0.0)	Fisher's	0.06	Risk Estimate	1.01-1.19
Incomplete recording of all vital signs	52 (45.6)	57 (100.0)	taken		1.10	

Note on table:

1. Conscious level denotes the patients' state of wakefulness and not Glasgow Coma Scale assessment.
2. If Haldane's estimator is used to calculate OR this circumvents 0s in cells by adding ½ to each cell and gives OR=12.05 (95% CI: 0.650 - 223.185, p=0.022).

All patients in each trial arm had recordings for blood pressure and heart rate. The odds for patients in the intervention arm of having respiratory rate recordings were 24.8 (CI 5.50-111.32) times higher than for those in the control arm and this reached statistical significance (p<0.001). The odds for the other parameters included unity and therefore were not significant. However, there was a strong trend towards an increased number of patients having all vital signs recorded (p=0.06).

The proportion of completeness of recordings[v] (as for Study Two, section 4.6.2.1) was:

- Good for BP and heart rate and met the *a priori* level of 100% coverage for the intervention and control arm (N=114);
- Poor for respiratory rate in the intervention (47%, n=27) and control arm (4%, n=2);
- Poor for oxygen saturation in the intervention (12%, n=7) and control arm (4%, n=2)
- Fair for temperature in the intervention (97%, n=55) and control arm (95%, n=54);
- Poor for conscious level and urine output in the intervention arm (79%, n=45; 86%, n=49) and control arm (65%, n=37; 90%, n=51) respectively.

The exclusive use of the MEWS chart was intended for all patients in the intervention arm but the chart was only used with 63.2% (36/57) of patients.

- *Per protocol analysis: number of patients in the intervention arm with parameter recordings on the MEWS and those in the control arm with the existing chart*

Per protocol analysis is explained in section 5.5.9. Data are presented in Table 5-24.

[v] Criteria for proportion of completeness of recording should be interpreted as coverage, i.e. each patient having at least one recording of a parameter: Good=100%; Fair=95-99%; and Poor=<94% coverage.

Table 5-24: Per protocol analysis of patients in the *intervention arm* (N=36) with parameter recordings on the MEWS and those in the *control arm* (N=57) with the existing chart (MEWS chart is the reference and = 1 for calculation of the OR)

Parameter	MEWS chart n=36 patients	EXISTING chart n=57 patients	x^2	p-value	OR (df=1)	95% CI
	Proportional Number (%)	Proportional Number (%)				
Respiratory rate recorded	25 (69.4)	2 (3.5)	46.56	0.000	62.50	12.89-303.15
Respiratory rate not recorded	11 (30.6))	55 (96.5)				
Heart rate recorded	36 (100.0)	57 (100.0)				Not computed
Heart rate not recorded	0	0				
Oxygen saturation recorded	6 (16.7)	2 (3.5)	Fisher's exact	0.052	5.50	1.05-28.96
Oxygen saturation not recorded	30 (83.3))	55 (96.5)				
Systolic blood pressure recorded	36 (100.0)	57 (100.0)				Not computed
Systolic blood pressure not recorded	0	0				
Temperature recorded	35 (97.2)	54 (94.7)	Fisher's exact	1.00	1.94	.19-19.49
Temperature not recorded	1 (2.8)	3 (5.3)				
Conscious level recorded	33 (91.7)	37 (64.9)	8.48	0.004	5.95	1.62-21.84
Conscious level not recorded	3 (8.3)	20 (35.1)				
Urine output recorded	33 (91.7)	51 (89.5)	Fisher's exact	1.000	1.29	.30-5.54
Urine output not recorded	3 (8.3)	6 (10.5)				
All parameters recorded	5 (13.9)	0 (100.00)	8.37	0.003	20.08*	1.08-375.09*
Incomplete recording of all parameters	31 (86.1)	57				

Note on table: *Haldane's estimator was used for calculating OR

All patients (N=57) had recordings of heart rate and systolic BP (Table 5-24). The odds of having recordings of the following parameters were higher in patients with the MEWS chart in the intervention arm than for patients in the control arm with the existing chart and all reached statistical significance: respiratory rate (OR 62.5, CI 12.89-303.15); oxygen saturation (OR 5.5, CI

1.05-28.96), conscious level (OR 5.95, CI 1.62-21.84) and for having all parameters recorded (OR 20.1, 95% CI 1.08-375.09 using Haldane's estimator).

The odds of patients with the MEWS chart having recordings of temperature and urine output respectively were 1.94 (CI .19-19.49) and 1.29 (CI .30-5.54) times higher than for patients with the existing chart but this did not reach statistical significance.

5.6.3.3 Number of recordings of parameters by trial arm

Table 5-25: Number of postoperative vital sign recordings (for 8 hours)

				Mann-Whitney U test				
Parameter	Number of recordings			Mean rank	Sum of Ranks	U statistic	Z-value	p-value
RESPIRATORY RATE	Total number	Median	Min-max					
Intervention arm (N=57)	73	0	0	70.33	4009.00	893.00	-5.42	0.000
Control arm (n=57)	2	0	0-2	44.67	2546.00			
HEART RATE								
Intervention arm (N=57)	285	4	1-16	51.08	2911.50	1258.50	-2.09	0.036
Control arm (n=57)	346	5	1-16	63.92	3643.50			
OXYGEN SATURATION								
Intervention arm (N=57)	10	0	0-3	60.04	3422.00	1480.00	-1.75	0.080
Control arm (n=57)	2	0	0-1	54.96	3133.00			
SYSTOLIC BLOOD PRESSURE								
Intervention arm (N=57)	325	6	1-18	48.24	2749.50	1096.50	-3.03	0.002
Control arm (n=57)	414	7	1-19	66.76	3805.50			
TEMPERATURE								
Intervention arm (N=57)	134	2	1-10	65.69	3744.50	1157.50	-2.742	0.006
Control arm (n=57)	113	2	0-7	49.31	2810.50			
CONSCIOUS LEVEL[3]								
Intervention arm (N=57)	134	1	0-10	70.39	4012.00	890.00	-4.44	0.000
Control arm (n=57)	38	1	0-2	44.61	2543.00			
URINE OUTPUT								
Intervention arm (N=57)	93	2	0-6	58.60	3340.00	1562.00	0-.373	0.709
Control arm (n=57)	87	1	0-4	56.40	3215.00			

The number of recordings (Table 5-25) was significantly different between the intervention and control arms for respiratory rate (Z=-5.42, p<0.001), heart rate (Z=-2.09, p=0.036), systolic blood pressure (Z=-3.03, p=0.002), temperature (Z=-2.742, p=0.006) and conscious level (Z= -4.44, p<0.001).

- Patients in the intervention arm had more recordings for respiratory rate, oxygen saturation, temperature, conscious level and urine output;
- Patients in the control arm had more recordings for heart rate and blood pressure.

The frequency that vital signs were prescribed by doctors is shown in Table 5-26.

Table 5-26: Number of patients (N=114) with prescribed vital signs in the intervention arm (n=57) and control arm (n=57)

Number of patients with prescribed vital signs		Mann-Whitney U				
		Mean rank	Sum of Ranks	U statistic	Z-value	p-value
Respiratory rate						
Intervention arm	1	57.50	3277.50	1624.50	.000	1.000
Control arm	1	57.50	3277.50			
Oxygen saturation						
Intervention arm	1	57.50	3277.50	1624.50	.000	1.000
Control arm	1	57.50	3277.50			
Heart rate						
Intervention arm	0	56.00	3192.00	1539.00	-1.748	.243
Control arm	3	59.00	3363.00			
Blood pressure						
Intervention arm	1	56.50	3220.50	1567.50	-1.014	.618
Control arm	3	58.50	3334.50			
Temperature						
Intervention arm	0	57.00	3249.00	1596.00	.317	1.000
Control arm	1	58.00	3306.00			
Conscious level						
Intervention arm	0	57.50	3277.50	1624.50	.000	1.000
Control arm	0	57.50	3277.50			
Urine output						
Intervention arm	1	57.00	3249.00	1596.00	-.583	1.000
Control arm	2	58.00	3306.00			
Specific parameters						
Intervention arm	2	56.00	3192.00	1539.00	-1.165	.244
Control arm	5	59.00	3363.00			
Cut points						
Intervention arm	1	57.50	3277.50	1624.50	.000	1.000
Control arm	1	57.50	3277.50			
Other eg. neurovascular checks						
Intervention arm	26	56.00	3192.00	1539.00	-.560	.576
Control arm	29	59.00	3363.00			

Observations were monitored for more patients than had prescriptions[vi] (Table 5-26). Doctors prescribed observations for four (7.0%) patients in the intervention arm and for 11 (19.3%) patients in the control arm but these did not reach statistical significance. Cut points for vital signs were prescribed for 1.8% of patients (2/114, one in each arm), meaning that for the majority of patients nurses were required to use clinical judgement in deciding to call for more skilled assistance. 'Other' parameters such as haemoglobin and neurovascular checks (for pulse and motor function) following orthopaedic surgery were prescribed for 48.2% of patients (55/114).

5.6.4 Objective 2b: To explore nurses' responses to high and low threshold vital sign recordings

Data were then examined for nurses' responses to signs of disturbed physiology (a high or low MEWS) and by reviewing patient progress notes for recorded interventions (Table 4-5). Nurses had used the MEWS chart as a single parameter tracking tool and had not calculated a total MEWS for each observation time-point. Vital sign datasets of patients on existing observation charts were recoded as MEWS. The proportion of nurses' responses to disturbed single parameter MEWS for both trial arms is shown in Table 5-27.

[vi] Prescriptions worded 'regular observations/vitals' were interpreted by ward nurses as half hourly monitoring of respiratory rate, heart rate and BP and one hourly for temperature for four hours.

Table 5-27: Summary of nurses' responses to disturbed physiology (upper and lower MEWS 1 to 3 that should have triggered a callout) in the first 8 postoperative hours

PARAMETER	Number of MEWS trigger points	Intervention Arm response		Number of MEWS trigger points	Control Arm response	
		YES	NO		YES	NO
Respiratory rate MEWS†						
1	15	0	15	0	0	0
2	6	0	6	0	0	0
3	0	0	0	0	0	0
Heart rate MEWS						
1	11	0	11	13	0	13
2	7	1	6	6	0	6
3	1	0	1	0	0	0
Oxygen saturation MEWS						
1	0	0	0	1	0	1
2	1	0	1	0	0	0
3	0	0	0	0	0	0
Systolic BP MEWS						
1	11	1	10	20	0	20
2	7	0	7	4	0	4
3	7	2	5	3	1	2
Temperature MEWS						
1	22	2	20	18	0	18
2	7	0	7	4	0	4
3	0	0	0	1	0	1
Conscious level MEWS						
1	9	0	9	7	0	7
2	0	0	0	0	0	0
3	0	0	0	0	0	0
Urine output MEWS						
1	11	0	11	5	0	5
2	6	0	6	4	0	4
3	7	1	6	7	1	6

Note on table: †No distinction is made between lower and upper MEWS trigger points (see Appendix 5.12 for details).

Data in Table 5-23, Table 5-25 and Table 5-27 are summarized below:

- Respiratory rate: in the intervention arm 21/73 recordings for 27 patients should have triggered a callout. Nurses did not respond to any.
- Heart rate: all patients in both trial arms had recordings. In the intervention arm 19/285 recordings should have triggered a callout; nurses responded to one of seven with scores of 2 but not to a critical score of 3. In the control arm 19/346 recordings should have triggered a callout; nurses did not respond to any.

- Oxygen saturation: In the intervention arm 1/10 recordings for seven patients should have triggered a callout for a score of 2 to which nurses did not respond. In the control arm two patients each had one recording. One recording was within normal range and one had a MEWS of 1 to which nurses did not respond.
- Blood pressure: all patients in both trial arms had recordings. In the intervention arm 25/325 recordings should have triggered a callout; nurses responded to three callouts which included two responses to seven critical MEWS of 3. In the control arm, 27/414 recordings should have triggered a callout to which nurses responded to one of three critical MEWS of 3.
- Temperature: In the intervention arm 29/134 recordings for 55 patients should have triggered a callout. Nurses responded to two callouts. In the control arm 23/113 recordings for 54 patients should have triggered a callout and nurses did not respond to any, including a critical score of 3.
- Conscious level: In the intervention arm 9/134 recordings for 45 patients should have triggered a callout at a MEWS of 1 (reacting to voice/drowsy) to which nurses did not respond. In the control arm 7/38 recordings for 37 patients should have triggered a callout at a MEWS of 1 to which nurses did not respond.
- Urine output: In the intervention arm 24/93 recordings for 49 patients should have triggered a callout to which nurses responded to one callout at a critical MEWS of 3. In the control arm 16/87 recordings for 51 patients should have triggered a callout to which nurses responded to one callout at a critical MEWS of 3.

Nurses' responses have to be interpreted with caution as the absence of recorded interventions does not mean that there were no interventions.

The section concludes with a calculation of the intracluster correlation coefficient for the outcome variable: proportion of all seven vital signs recorded.

5.6.5 Retrospective sample size calculation

It was clear that the number of SAEs was too small to determine the impact of intervention on reducing this number. Therefore a sample size calc was undertaken to inform a multi-centre trial. A factor that has to be taken into account when utilising clusters such as wards is the impact of the amount of intracluster correlation. Using existing data relating to vs recorded the ICC was determined. This calc is described below.

5.6.5.1 Outcome for all vital signs recorded for calculating Intracluster Correlation Coefficient

The number of patients in Study 2 (n=55, pre-intervention) and those in Study 3 (n=114, post-intervention) who had recordings for all seven vital signs and the risk estimate (95% Confidence Intervals) are presented in Table 5-28.

Table 5-28: Number of patients with recordings of all parameters (intervention arm (study 3) is the reference and = 1 for calculation of the risk estimate)

	All Vital signs recorded	***Incomplete recording of vital signs***	***x²***	**p-value**	**Risk estimate**	**95% Confidence Interval (CI)**
Pre and post intervention						
Pre-intervention (Study 2) (n=55)	0/55	55/55	Fisher's taken	0.06	1.10	1.01-1.19
Post-intervention (Study 3 Intervention arm)	5/57	52/57				
Post intervention						
Control arm (Study 3)	0/57	57/57	Fisher's taken	0.06	1.10	1.01-1.19
Intervention arm (Study 3)	5/57	52/57				

No patient (0/57) in the control arm in Study 3 (post-intervention) had recordings for all seven vital signs. The probability of patients in the intervention arm having all seven vital signs

recorded was 1.10 (CI 1.01-1.19) times greater than for patients in the control arm but this did not reach statistical significance. When compared with the results from Study Two, where 0 of 55 patients had all vital signs recorded, results were not statistically significant (p=0.06)]. However, results should be interpreted with caution, due to the 0 in cells. See SPSS printout below:

SPSS: Comparison of Study 2 (n=55) and Intervention arm in Study 3 (n=57) - All 7 vital signs recorded:

Count

		All 7 vital signs recorded		
		no	yes	Total
Study	2	55	0	55
	3	52	5	57
Total		107	5	112

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)
Pearson Chi-Square	5.050[a]	1	.025	.057
Fisher's Exact Test				.057
N of Valid Cases	112			

a. 2 cells (50.0%) have expected count less than 5. The minimum expected count is 2.46.

Risk Estimate

		95% Confidence Interval	
	Value	Lower	Upper
For cohort All7VSrec = no	1.096	1.011	1.188
N of Valid Cases	112		

Comparison of Study 3 Intervention & Control arms - All 7 vital signs recorded:

Count

		All7VSrec		
		no	yes	Total
Intervention=1 Comparator=0	comparator ward	57	0	57
	intervention ward	52	5	57
Total		109	5	114

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)
Pearson Chi-Square	5.229[a]	1	.022	.057
Fisher's Exact Test				.057
N of Valid Cases	114			

a. 2 cells (50.0%) have expected count less than 5. The minimum expected count is 2.50.

Risk Estimate

		95% Confidence Interval	
	Value	Lower	Upper
For cohort All7VSrec = no	1.096	1.011	1.188
N of Valid Cases	114		

5.6.5.2 Intracluster Correlation Coefficient (ICC) for number of patients with all vital signs monitored

As indicated in section 5.5.4.1, to increase the proportion of patients with all vital signs recorded from 1.8% to 20% would require 57 patients in each study arm. However, this calculation took no account of clusters, and the low number of patients with all vital signs recorded precluded calculation of ICC at this stage.

Since no patient had all vital signs monitored in Study Two, sums of squares from one-way ANOVA in Study Two were not used. In Study Three, all control wards had 0 patients with all 7 vital signs monitored; therefore, sums of squares were all 0, and variances could not be meaningfully calculated.

ANOVA

All 7 VITAL SIGNs done all 3 wards

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	.246	2	.123	1.537	.224
Within Groups	4.316	54	.080		
Total	4.561	56			

The sums of squares between and within groups were calculated from 1 way ANOVA in spss taking the number of patients with all 7 vital signs for each ward as the variable (output below). The three intervention wards using the MEWS were used to calculate the ICC.

The calculation is therefore described to guide further work.

Variance = sums of squares/df

$$ICC = \frac{\text{variance between groups}}{(\text{variance between groups} + \text{variance within groups})}$$

$$= \frac{0.246/2}{(0.246/2 + 4.316/54)}$$

$$= \frac{0.123}{(0.123 + 0.08)}$$

= 0.61
Design Effect = 1 + ICC(m-1) m= number in cluster, in this case 19

= 1 + (0.61x18)
= 11.98

From above, effective sample size needed = 57

Sample size (mxk) = effective sample size x design effect (where k = number of groups)

= 57 x 11.98
=683

The intracluster correlation coefficient for numbers of patients with all 7 vital signs monitored was calculated to be 0.61, with 19 patients in each cluster, therefore to give an effective sample size of 57, we would need 683 patients to be recruited (Killip et al 2004).[294] This would not be feasible within the resources of a doctorate.

Ancillary results in the next section deal with aspects of the training intervention not directly related to study objectives but to nurses' responses to further questions on the knowledge questionnaire.

5.6.6 Ancillary analyses

Limited demographic data relate to the number of nurses in each cluster in the trial arms. Test scores are provided for each professional category that may be useful for drawing inferences in relation to the nurses' performance in recording vital signs and responding to abnormal physiology that is central to this nursing study.

5.6.6.1 Distribution of nurses by professional categories

Nurses indicated their professional category on the test questionnaire and no further demographic data were collected. Data are presented by cluster and trial arm in Table 5-29 for descriptive purposes only and not for the purpose of testing randomization.[295] As cluster randomization was at ward level for trial arms, participation by nurses within each trial arm was voluntary and not by randomisation.

Table 5-29: Distribution of nurses by category, cluster and trial arm

	Intervention arm (N=25)			Control arm (N=25)			χ^2	df	p-value
	Clusters								
Category	1	2	3	4	5	6	.178	2	p=0.915
Registered Professional Nurse	5	4	4	4	5	4			
Registered Staff Nurse	2	1	2	1	1	2			
Registered Nursing Auxiliary	1	2	4	4	3	1			
Total	8	7	10	9	9	7			

At baseline, the distribution of the three categories (RPN, RSN, RNA) in the intervention (N=25) and control arms (N=25) did not differ significantly (p=0.915).

5.6.6.2 Nurses' test scores

- *At individual level*

For the sake of completeness, there is some reporting of analysis at *individual participant* level but as many cells have small numbers, results and calculations are reported in Appendices 5.8a and b.

- *Pre-intervention test scores by professional categories overall*

Results for pre-intervention scores were distributed normally for professional categories and parametric tests were used. Data are shown in Table 5-30.

Table 5-30: Pre-intervention knowledge test scores (N=50) by category overall

				ANOVA				
Category	**Mean % score by category [95% CI]**	**SD**	**Mean % score for all nurses**	**Sum of Squares**	**df**	**Mean Square**	**F**	**p-value**
Registered Professional Nurse (n=26)	47.5 [41.80-53.17]	14.07	39.6	Between groups = 3483.06	2	1741.53	8.291	p=0.001
Registered Staff Nurse (n=9)	33.3 [18.10-48.56]	19.80		Within groups = 9872.33	47	210.05		
Registered Nursing Auxiliary (n=15)	29.6 [23.31-35.82]	11.29						

Overall, RPNs performed the best (47.5%, SD 14.07), followed by RSNs (33.3%, SD 19.80) and RNAs (29.6%, SD 11.29) and this was statistically significant (p=0.001). The Scheffe post hoc test showed that the difference in scores between RPNs and RSNs was statistically significant (mean difference=14.16, p=0.050) and between RPNs and RNAs was statistically significant (mean difference=17.93, p=0. 002).

- *Post-intervention test scores by professional categories overall*

Data were not normally distributed for RNAs (Table 5-31) therefore nonparametric tests were used to compare nurses' post-intervention test scores (Table 5-32).

Table 5-31: Test of normality for post-test results

	Professional category	Shapiro-Wilk		
		Statistic	df	Sig.
Post-test %	Registered professional nurse (RPN)	.955	26	.306
	Registered Staff Nurse (RSN)	.910	9	.315
	Registered Nursing Auxiliary (RNA)	.776	15	.002

Table 5-32: Post-intervention knowledge test scores (N=50) by category overall

Category	Mean % score by category [95% CI]	SD	Mean % score for all nurses	SD	Kruskal-Wallis		
					Mean Rank	χ^2	Significance (df)
Registered Professional Nurse (n=26)	59.03 [50.91-67.14]	20.10	51.30	24.78	30.85	8.691	P=0.013 (2)
Registered Staff Nurse (n=9)	49.28 [28.40-70.14]	27.15			24.17		
Registered Nursing Auxiliary (n=15)	39.13 [24.12-54.13]	27.10			17.03		

Overall, RPNs performed the best (59.0%, mean rank=30.85), followed by RSNs (49.3%, mean rank=24.17) and RNAs (39.1%, mean rank=17.03) and this reached statistical significance (p=0.013, df=2). The improvement in scores was greatest with the RSN category (16% compared to 11% and 10% for RPNs and RNAs respectively).

Further analysis of test scores by professional categories first within trial arms and then within clusters in trial arms is presented in Appendix 5.11.

5.6.6.3 Nurses' perceptions of when to call for assistance for clinical deterioration

The pre-and post-intervention tests included seven questions intended to explore nurses' clinical decision-making skills in relation to calling for skilled assistance for patients in whom physiological parameters deteriorated for ten events (this question generated two events). An example for respiratory rate changes is presented below:

Question:

There is a sudden change in a patients' condition: circle the 2 respiratory rate readings in the list below for which you will summon more skilled assistance (help): in other words draw a circle around one group of slow rate readings and one group of fast rate readings.

Less than 8	8-9	10-11	12-14	15-20	21-29	30 or more

Overall, in the intervention arm, nurses' responses indicated that they would respond to *late* signs of physiological deterioration (a critical MEWS of 3) in patients in 8/10 events *before* training and in 9/10 events *after* the intervention. Before training, nurses would respond to a MEWS trigger of 2 (serious) for a high BP and low urine output, whereas after the training they would respond to a MEWS of 2 only for respiratory rate.

In the control arm, nurses' responses in the pre-intervention test indicated that they would respond to *late* signs of physiological deterioration in patients in 6/10 events and in 8/10 events in the post-intervention test. In the pre-test, nurses' responses indicated that they would respond to a MEWS trigger of 2 for a low respiratory and heart rate, low BP and low urine output, whereas post-test results indicated they were would respond to a MEWS of 2 for a low respiratory rate and BP.

5.6.6.4 Measurement of oxygen saturation levels

In response to the question: "Do you personally measure and record oxygen saturation (SAT/SpO_2) on your ward?" 24 nurses in the intervention arm (excluding one RPN) and 20 nurses in the control arm (excluding 3 RPNs and 2 RNAs) responded in the affirmative. Notwithstanding, seven patients (12.3%) in the intervention arm and two (3.5%) in the control arm had postoperative recordings of oxygen saturation (Table 5-23). In the control arm there were ten recordings for seven patients and one recording each for two patients (Table 5-25).

5.7 Discussion

The aim of the study was to implement and explore the effectiveness of a local MEWS training programme and consensus derived MEWS observation chart through a prospective pragmatic cluster randomised parallel group clinical trial of intervention versus standard care. Results for each objective are summarized.

5.7.1 Summary of results/new knowledge generated

The main findings of Study Three are summarized.

- **Objective 1 – To establish whether the MEWS training programme resulted in a significant difference in knowledge test scores**

Analysis by intention-to-treat showed that training resulted in a significant difference between post-intervention knowledge test scores of nurses in the intervention wards who had training and those in the control arm (Table 5-20) who had no training. Overall, registered professional nurses (RPNs) performed the best in the post-test, followed by registered staff nurses (RSNs) and registered nursing auxiliaries (RNAs) and this was statistically significant (Table 5-32).

Objective 2 - To establish whether the MEWS training programme and observation chart resulted in a change in practice

The 'typical' patient admitted to the intervention wards was male, median age 49 years (IQR=29, 14 to 76), having orthopaedic surgery who had a hospital stay of 4 days (Table 5-22). He was more likely to have pre-existing diabetes mellitus (Chi-Square 5.60, df=1, p=0.018) than the patient in the control arm. Postoperatively, he had significantly more recordings of respiratory rate (Z=-5.42, p<0.001), temperature (Z=-2.742, p=0.006) and conscious level (Z= -4.44, p<0.001) than the patient in the control arm (Table 5-25). If he had the MEWS chart, recordings increased significantly for respiratory rate (OR 62.5, CI 12.89-303.15, p<0.001); oxygen saturation (OR 5.5, CI 1.05-28.96, p=0.052), conscious level (OR 5.95, CI 1.62-21.84, p=0.004) and for having all parameters recorded (5/57, OR 20.1, 95% CI 1.08-375.09, p=0.003 using Haldane's estimator) compared to the patient in the control arm (Table 5-24). He had significantly fewer recordings of heart rate and BP than the patient in the control arm.

The 'typical' patient admitted to the control arm was female (Chi-Square 7.89, df=1, p=0.005), median age 45 years (IQR=26, 14 to 84), having orthopaedic or general surgery and a hospital stay of 4 days but a trend towards longer hospitalisation (range 1-43) than the patient in the intervention arm (range 2-23) (IQR=4 for the intervention arm and 7 for the control arm) (Table 5-22). She had significantly more recordings of heart rate (Z=-2.09, p=0.036) and systolic blood pressure (Z=-3.03, p=0.002) than the patient in the intervention arm (Table 5-25) but no recordings of all seven parameters.

Data for the intracluster correlation coefficient for numbers of patients with all seven vital signs monitored was calculated post hoc to give an effective sample size (explained in section 5.5.4.1 and demonstrated in section 5.6.5.2).

Records show that nurses in both trial arms failed to respond appropriately to recorded disturbed physiological parameter readings (Table 5-27). However, these results should be interpreted with caution as entries in the patient progress notes provided the only record of the nurses' responses. On a busy surgical ward it is not always possible to record all interventions but it may not mean that no action was taken. The possible reasons and implications of this finding are discussed in the limitations section (5.7.4.6).

5.7.2 Generalisability of results

Generalisability (external validity) of the study results is limited by the small sample of clusters and nurses from these clusters. Nevertheless, reviewed clinical records (n=114) may be adequate.

Given the impact of clustering, the study's power to detect a difference was considerably reduced. However, the impact of clustering was minimised by practical considerations: nurses worked on more than one ward; management, documentation and policies were consistent between wards. The same doctors worked on intervention and cluster wards. The difference in the outcome (having recordings for seven parameters) used to calculate sample size indicated an improvement, but, due to reduced power, this was of borderline significance (Table 5-28, RE 1.10, 1.01-1.19, p=0.06). However, this study has achieved its purpose in indicating that improvements in patient monitoring can be achieved by implementation of a MEWS in the Hospital. There is sufficient evidence to conclude that a multi-site RCT is warranted for a larger sample size with adequate power to show that the MEWS chart results in improvements in patient monitoring of all seven parameters.

5.7.3 Study results compared to existing literature and in wider context

The conduct and reporting of cluster trials have been poor[281, 296-298] and there are continuing problems with the design and analysis of cluster trials both in the developed countries and sub-Saharan Africa.[281, 299-301] Poor cluster trial reporting includes not accounting for the clustering in planning the trial,[296] or in the analysis,[281] not providing a rationale for using a cluster design and

not accounting for clustering in sample size calculations.[284] This is described in section 5.5.4. To improve reporting of Study three, an extension of the CONSORT[vii] 2001 Statement (replaced by 2010 guidelines)[276, 277] to cluster randomised trials by Campbell et al. (2004)[281, 282] and Zwarenstein et al. (2008)[280] is used to evaluate results as outlined in Table 5-36. The extension of the CONSORT 2010 guidelines to cluster trials has not yet been published.

When the MEWS observation chart was implemented on the three intervention wards consent was not obtained from individual nurses or patients as the institutional consent (guardianship)[293] was considered to be the 'community consent'[229] on behalf of individuals in the intervention clusters. Taken further, it is argued that one person's choice would impinge on another's[293] but this is refuted by others[229] with examples of individual consent given within cluster trials. Furthermore, community consent for the clusters was assumed particularly as individual nurses on these wards had signed consent for the training programme. This raises the question of timing of consent and randomization. The issue here is what is the best way to deal with individual nurses not wanting to use the new MEWS observation chart or not able to use the chart if recently allocated to the intervention wards and having had no training? This may account for the lack of improvement in post-intervention test scores for three RPNs, one RSN and three RNAs in the intervention arm.

A staff training programme is only one belief of many views[229] on what is important to nurses. Problems arise when nurses are competent in using technology for vital sign monitoring but lack clinical knowledge in making sense of the data and intervening appropriately to ensure optimum and safe patient care. Poor recording of oxygen saturation following the administration of a general anaesthetic and the use of opioids[302] is of concern. It is reported that a new vital signs chart improving charting may be due to "nurses' interest levels being raised by the accompanying educational sessions, or simply the effect of a new development" (McBride et al, 2005:43).[186] Efforts to reduce the gap between best evidence and practice include educational strategies towards behaviour change and organisational and administrative interventions[246] such as knowledge translation models. Published studies have explored nurses' clinical decision making during haemodynamic assessment and management in the natural setting [303] and during

[vii] Consolidated Standards of Reporting Trials

emergency department triage[81] using the 'think aloud' method and this may be useful for further work.

Testing the accuracy of calculating an aggregated MEWS using four fictional scenarios (Table 5-10) revealed that as a group (n=26), the nurses scored 66.4% (69/104) in accurately calculating an aggregated MEWS which was an improvement on the performance (58%; 152/260) of the same number of nurses in a UK study but scoring ten patient scenarios.[175] There was a lower accuracy for calculation of a higher true MEWS in the Cape Town study (section 5.5.8.1) (but small numbers in this study could not produce statistical trends in the data) which is supported in two published studies[14, 175] that found a trend towards decreased accuracy in MEWS calculations as the value of the true MEWS (an indication of severity of illness) increased. Poor performance of Nursing Auxiliaries (n=5) (8/20; 40%) compared with Professional Nurses (n=15; 47/60 correct responses; 78.3%) and Staff Nurses (n=6; 14/24; 58.3%) is of great concern. Monitoring vital signs on the research wards had devolved to Nursing Auxiliaries and Staff Nurses (field notes) and this trend is supported in the published literature.[267] The educational preparation and scope of practice of these nurses is for basic and elementary nursing practice respectively[50] and does not include the interpretation of data. Poor performance of Nursing Auxiliaries in accurate calculation of an aggregated MEWS has serious implications for the WHO strategy of task shifting to lesser qualified persons to deal with critical health personnel shortages.[271] It is not known if, or to what extent, non-involvement of medical staff served as a barrier to better performance of nurses in use of the MEWS system during pilot testing. It is suggested that if doctors and nurses are not educated on the MEWS it could 'misfire' and become a 'meaningless tool'.[176]

Concerns about accuracy in calculating a MEWS found in Study One are supported by a UK study where 571 (21.9%) of observations from 2607 sets of observations had been incorrectly calculated.[14] Incorrect scoring meant that observations of 66 of 270 patients (24.2%) in the UK study should have reached the trigger value but did not. In a further UK study of a prospective audit of 30 postoperative patients' observation charts from the same classification of wards as for the research wards (General, Vascular and Orthopaedic), a recently implemented MEWS was documented correctly for only 42% of patients,[176] forecasting a great likelihood that the MEWS could 'misfire' (Ismail & Davies, 2007:150).[176]

This is of concern as the core function of the nurse in avoiding SAEs should go beyond the recording of patients' physiological vital signs[119] and it is the nurse's professional responsibility to understand the significance of patient observations.[50, 96, 97] Misinterpretation of clinical data is associated with poor clinical reasoning skills and in some cases, nurses have been found to overestimate the risk and the need to intervene in studies using computer-based clinical scenarios.[78]

Strategies for implementing and monitoring patient safety policies in a teaching hospital ought to consider the complexity of such an organisation. Patients admitted to this level of care have complex conditions requiring treatment not available at secondary level hospitals that increase their risk of an AE regardless of their comorbidities. In the Cape Town study, patient progress notes revealed few entries of nurses' responses to signs of physiological deterioration and this was interpreted as inappropriate responses to MEWS that should have triggered a callout. Although these data should be interpreted with caution, a South African author (Geyer, 2005:25) reports that "[I]t sometimes happens that, due to the pressure of work, an entry is omitted or made late. It can be explained to a court of law why it was not possible to make an entry contemporaneously with the happening of the event. It will, however, never be possible to explain why an action was done but never recorded and, in fact, the court will regard it as never done!"[130, 304]

- Nurse-related determinants of hospital mortality

The results of this study contribute to Aiken et al.'s (1994, 1997)[257, 258] revised Mortality Model[135, 254] and have been added to selected predictors of the model in Table 5-33 which provides a conceptual framework to guide nursing practice in improving patient safety.

Table 5-33: Selected predictors from the Mortality Model (Aiken et al. 1994, 1997)[257, 258] revised by Tourangeau et al. (2002)[135]

Predictors	Revised model hypothesis[254] showing more complex relationships among predictors	Application to the Cape Town MEWS study
Nursing skill mix	Direct and indirect effects on mortality – a richer RN skill mix (having more RNs) results in lower mortality	Not examined but a non-response of 95-98% to the MEWS callout algorithm implies that lesser qualified nurses (RNAs) responsible for monitoring vital signs may not know how to detect signs of clinical deterioration in patients. *After training*: RNAs achieved the lowest mean scores (50.9%) for knowledge tests in relation to the recognition of early warning signs of deterioration; RSNs achieved 60.0% whereas RPNs achieved 67.6%. In control wards where there was no training, RNAs achieved 28.8%, RSNs 35.9% and RPNs 50.5% (Table 5.2A, Appendix 5.11).
Professional Role Support:	Indirect effect on mortality through Condition of the Nursing Practice Environment	Not examined but RPNs' supervision of vital sign monitoring by RNAs and RSNs is a factor in light of knowledge test results and poor response to MEWS callout algorithms.
Nursing Practice Environment Condition	Direct and indirect effects on mortality	The hospital policy of admitting postoperative patients having had certain high risk surgical procedures to High Care Units may have resulted in fewer deaths in the six surgical wards.
Patient characteristics: • age	Direct effect on mortality	Study Two: Age (≥61 years) was significantly associated with SAEs (p<.001). The calculation of the OR indicates that the odds of an SAE were 14.2 (95% CI=3.0-68.0) times higher in patients who were 61 years or older (Table 4-17).
• sex		There was a smaller proportion of females in the SAE group, but this was not statistically significant (p=0.074) and the number of subjects was disproportionate (SAE=11; No SAE=44) (Table 4-9.)
• comorbidity		Having two or more pre-existing comorbid conditions was significantly associated with SAEs (p<.001, OR 75.3, 95% CI 3.7-1527.4) (Table 4-17). No patients in the control group had two or more comorbid conditions on admission.
Other Determinants: • teaching hospital status	Indirect effect on mortality mediated through Nurse Capacity to Work, Nurse Experience and Physician Expertise	Not examined but the research setting is a specialist referral public teaching hospital more likely to admit very ill patients, often for emergency surgery.
PREDICTORS FROM THE CAPE TOWN MEWS STUDY • *Vital sign recordings*	*Direct effect on mortality*	*Having a high or low systolic BP on admission was significantly associated with mortality (p=0.015, OR 7.2, 95% CI 1.5-34.2) (three missing values in each group) (Table 4-17).* *A fast heart rate during the first 8 postoperative hours was significantly associated with SAEs (p=0.018, OR 6.6, 95% CI 1.4-30.0) (Table 4-17).* The odds of dying were 8 times (95% CI 1.9-33.1) higher in patients with a low systolic BP in the postoperative period (p=0.003*) (Table 4-17).* *The association between low urine output and SAEs approached significance (p=0.053, OR 4.1, 95% CI 1.0-17.3).*

The association between vital sign parameters (fast pulse rate and low systolic BP) and mortality established by this study and others[22, 35, 36, 99, 100, 102] challenges traditional assumptions that mortality outcomes and determinants of survival fall solely within the domain of medical care, and provides further evidence that these outcomes are 'nursing sensitive' (Tourangeau et al. 2005:2).[254]

Nurses' concerns about the context of caring for critically ill patients on general wards are that patients are having increasingly more complex surgery, increasing their dependence and morbidity, which, in the face of understaffing, results in increased workload and suboptimal quality of care, leaving less time to apply learning in practice.[269] Context is an important consideration that influences the design of more effective education and support systems.[265] The MEWS training programme included literature on the advantages of using patients' early warning scores as part of the handover process in this way putting patient safety at the centre of the handover.[247]

The Situation-Background-Assessment-Recommendation (SBAR)[248] communication tool (Appendix 5.4.b) is recommended for standardizing the reporting of incidents to reduce AEs, enhancing nurses' confidence and competence in reporting disturbed physiology in a uniform manner and having a record of such communication in the event of a medico-legal enquiry. A study of patient handover by Chaboyer et al. (2010)[249] found that one of two hospitals used the SBAR tool as it formalizes patient information and data is presented in an objective manner.

A comparison of Study Three findings to selected findings of MEWS implementation studies described in Chapter Two (Table 2-5) including reasons for differences/similarities and for including each is presented in Table 5-34.

Table 5-34: Comparison of Study Three findings to MEWS implementation studies

Author and study design	Findings relevant to Study Three	Application to Study Three and reasons for differences/similarities and for including each
Stenhouse et al. 2000[5] Prospective cohort: Prospective evaluation of a modified Early Warning Score to aid earlier detection of patients developing critical illness on a general surgical ward; No comparator group.	After one month: scores were modified for urine output scores for systolic blood pressure were normalized (i.e. interpreted as % deviation from the patient's norm). the sensitivity of scores for temperature was decreased Patients with a total score of 4 were reviewed over 9 months leading to earlier referral [not defined] to the ICU of 26 patients compared to 11 patients from a surgical ward not using the MEWS and having less physiological derangement.	Design and setting similarity: prospective study on six surgical wards. Difference: a pragmatic parallel group cluster randomized control trial with 2 arms. Inclusion of selected findings relevant to Study Three. After three months: A recommendation that cut points for the variable urine output be changed from ≤50ml/hr to <60ml for a MEWS of 1, from ≤30ml/hr to <30ml for a MEWS of 2 and from <20ml/hr to NIL for a lower MEWS of 3 (Revised Cape Town MEWS Figure 5-6) (i.e. reducing sensitivity). Not having a record of the patients' normal systolic BP on the MEWS chart is a limitation and it is recommended that this be added (Figure 5-6). A recommendation that the sensitivity of scores for temperature should be decreased (Figure 5-6) by collapsing 7 cut point ranges to 5. Clinical impact of MEWS: Nurses treated the MEWS chart as a single parameter chart and did not calculate a total MEWS for each observation period. From entries in the patient progress notes it appears that nurses did not respond adequately to MEWS that should have triggered therefore the study does not report on earlier admission to ICU.
Subbe et al. 2003[185] Prospective cohort Effect of introducing the Modified Early Warning score on clinical outcomes, cardio-pulmonary arrests and intensive care utilization in acute medical admissions	Increased incidence of cardio-pulmonary arrests in the study group in patients with a MEWS 3 or 4. A MEWS of 4 triggered urgent medical referral and critical care outreach team review. Respiratory rate was the best discriminator to identify patients at risk.	The design and setting were different: cluster randomization of 6 surgical wards into 2 trial arms Not established. Nurses used the MEWS chart as a single parameter tool and did not calculate a total MEWS. From entries in the patient progress notes it appears that nurses' responses to single parameter scores that should have triggered were poor (95-98% non-response). Results have to be interpreted with caution. Not established but 27 (47.4%) patients in

Author and study design	Findings relevant to Study Three	Application to Study Three and reasons for differences/similarities and for including each
	The MEWS is suitable for identifying patients at risk of deterioration.	the intervention arm having the MEWS chart had respiratory rate recordings compared to 2 (3.5%) patients on the existing chart in the control arm. Single parameter MEWS of 3 identified patients at risk of deterioration but further work on validity of the MEWS is needed.
Quarterman et al. 2005[177] Prospective: Use of a patient information system to audit the introduction of modified early warning scoring. No comparator group	An aggregated MEWS of 3 or more triggered the need to call for assistance but survival was worse at this level (p< 0.004)	Design was different: study had 2 trial arms of intervention versus standard care. Clinical validity of MEWS is limited as no total MEWS was calculated nevertheless single parameter MEWS of 3 identified patients at risk of deterioration
Odell et al. 2007[4] Longitudinal surveys The effect of a critical care outreach service and an early warning scoring system on respiratory rate (RR) recording on the general wards Comparator group	RR recording increased from 6.0% (1st survey) to 77.9% (last survey), which correlated with the incremental implementation of the R-MEWS system and may have been enhanced by a critical care outreach service	Similar to this study: having a control group. Difference: design and intervention. In Study Three the effect of a training programme and implementation of the MEWS observation chart on nurses' knowledge and the quality and quantity of their recordings of postoperative vital sign data was established. 27 (47.4%) patients in the intervention arm having the MEWS chart had respiratory rate recordings compared to 2 (3.5%) patients on the existing chart.

5.7.4 Critique of Study

5.7.4.1 Strengths of study methods

Throughout the reporting of Study Three, the researcher followed the CONSORT checklist items extended to pragmatic[280] cluster randomized trials[281] to facilitate clarity, completeness and transparency[277] in describing and interpreting results. Analysis has been by intention to treat, in accordance with the pragmatic nature of the trial. Although adherence was not the focus of this study, the checklist provided useful guidelines. Shortcomings in adherence have been highlighted.

Unusually for a RCT, this work was conducted in a real world setting in a resource poor environment in a developing country. The study focused on nursing, rather than medical care, and was conceived and led by nurses.

Despite known contamination arising from nurses in control wards working extra shifts in intervention wards, post-intervention knowledge test scores were significantly higher in intervention wards than in control wards.

5.7.4.2 Limitations of study methods

Trial size

The reliability of the information produced by the study is directly related to its power,[305] therefore not having considered design effect or intracluster correlation coefficient in cluster sampling estimation, albeit for pragmatic reasons, has reduced the ability of the study to produce statistically significant results. However, feasibility of the method has been demonstrated, in readiness for a larger, externally funded, trial. “Small trials are not necessarily unethical, provided the aim of the trial is consistent with its size.”[229]

These findings will allow a UCT-specific sample size to be calculated. Our aims, as in section 5.5.4.1 of increasing recording of all vital signs to 20% was unduly optimistic, affecting the power of the trial.

Hawthorne effect

Interpretation of results of the training programme in which 30 nurses from the three intervention wards and the same number of nurses from control wards participated has to consider the possibility of the Hawthorne effect. Nurses in the intervention arm who implemented the MEWS chart were under scrutiny although certain nurses made no attempt to improve their knowledge. Attrition (Figure 5-4) accounted for the loss of five nurses from each cluster for the post-intervention knowledge test, resulting in the analysis of results for 25 nurses from each cluster for the first intervention.

Practical issues

Understaffing (approximately 6 full-time nurses on wards on day duty; 4 nurses on night duty) and heavy workload reportedly prevented nurses from attending scheduled training slots, requiring rescheduling. Wards released one to three nurses at a time with four to seven nurses from different wards attending each session given to Day Staff so five repeat training sessions were needed. Training was reduced from the planned four to two hours for the first session and to one hour for a revision session in April due to staff shortages. Training the Night Staff was abandoned as nurses were not able to attend for more than 45-minutes during visiting hours and staff were not keen to attend a late night or early morning training session. These nurses were subsequently trained individually or in pairs on the wards when they were next on day duty.

To earn additional income, a few nurses from the control wards worked on the intervention wards on their days off, in this way contaminating the study. The 4.0% improvement between the pre-and post-intervention knowledge test scores of nurses in the control wards might be attributed to contamination.

On occasions during the study period the researcher found that the existing chart rather than the MEWS chart was used for patients who met inclusion criteria. Nurses had either forgotten to use the MEWS chart, charts were locked away or nurses newly allocated to the ward had not been trained, resulting in only 63.2% of patients in the intervention wards having the MEWS charts. The intention to treat approach disallowed exclusion of those patients in the intervention ward who had been randomly selected and who had the existing chart. For illustration only, a *per protocol*

analysis was undertaken of the proportion of patients in the *intervention arm* with recordings on the MEWS chart compared with those *in the control arm* with recordings on the existing chart (Table 5-24). The odds of having respiratory rate recordings were 21.6 (CI 4.27- 109.14) times higher in patients with the MEWS chart than for those who did not and this reached statistical significance ($p<0.001$) and for conscious level the odds were 8.25 (CI 1.91- 35.67) higher and this reached statistical significance ($p=0.002$).

Certain factors made it difficult to control who charted vital signs other than nurses trained in the MEWS system. Staff shortages necessitated charting by untrained part-time agency nurses[114] and others from the same hospital working overtime in research wards including student nurses. This raised concerns about the required level of skill-mix.[114]

Demographic data for the nurses was limited to category on the SA Nursing Council register so inferences about years of experience and type of qualification (degree versus diploma) impacting on the practice of recording could not be drawn. Nevertheless, inferences were drawn in relation to test scores by professional category. The homogeneity of the patients in the trial arms in terms of demographic and clinical characteristics was a limitation.

5.7.4.3 Strengths of the Cape Town Ward MEWS chart

In Study Two vital sign data on existing observation charts were recoded retrospectively for MEWS values and in the first 8 postoperative hours a fast heart rate ($p=0.018$, OR 6.6, 95% CI 1.4-30.0) and low systolic BP ($p=0.003$, OR 8.0, 95% CI 1.9-33.1) were found to be significantly associated with mortality. Both of these MEWS callout algorithms are unchanged from published values and were validated in Study One (section 3.6.1).

In Study Three the MEWS chart resulted in significantly more patients in the intervention wards than control wards having recordings of respiratory rate ($p<0.001$), the best discriminator for clinical outcomes.[185] This may be directly attributable to the absence of this parameter on the existing chart. The study showed that if included, respiratory rate will be monitored. Record review showed clearly that the MEWS chart is a more precise system of recording vital signs as it requires actual numbers (Appendix 5.6) rather than estimations of physiological readings using symbols (X, •) used on the existing chart (Appendix 5.13).

5.7.4.4 Limitations of the Cape Town ward MEWS chart

In Study One certain questionnaire respondents (Table 3-20) anticipated that the complexity and detail of the MEWS chart may increase error in charting and in interpreting data particularly if charting was done by lesser qualified nurses[114] during staff shortages. The 19.5% improvement in scores between the pre- and post-intervention knowledge tests of nurses in the intervention arm did not translate into improved practice. In this context improved practice was interpreted as appropriate triggered responses (Table 5-27) in relation to MEWS algorithm callouts in the postoperative period. Nurses in the intervention wards did not respond to MEWS callouts for 95.0% of the time and for 98.0% of the time in the control wards. This may be attributed to the delegation of vital sign monitoring to nurses with fewer qualifications (RNAs and RSNs).

It is unlikely that the chart (that incorporates an AVPU system for limited assessment of conscious level and monitoring of pupil size and reaction) will be used in specialist neurosurgical wards where the Glasgow Coma Scale (GCS) is in use for a more comprehensive assessment. Even so, the local chart provides the GCS equivalence albeit without GCS criteria. It may be possible to convert the GCS to AVPU but not the other way round.[133]

Cut points for each parameter may not be generalizable across broad diagnoses[8] (respiratory disease, cardiac disease) and settings (patients not needing admission to ICU and those that do). Adverse events are also affected by other factors such as clinical experience and professional education of nurses, nurse–patient ratios, and the environment but these aspects were not objectives of the study. Nurses used the chart for single parameter monitoring and they did not calculate an aggregate MEWS. Furthermore, as reported for Study Two (section 4.7.3), heart rate, systolic BP, temperature and urine output were recorded graphically on the existing chart, portraying observations by symbols (X, •) reflecting estimations open to interpretation. Conversely, actual parameter readings (pulse of 95) were recorded on the MEWS chart. One study reported that graphical plots portrayed observations better than written values for all parameters except tachypnoea.[196]

The Cape Town MEWS chart did not require each patient's 'normal' SBP to be used as a baseline for interpreting MEWS.[5, 198]

Finally, the Cape Town MEWS may be too sensitive in that it has more cut points than the published MEWS for each parameter (for example temperature has a range of seven cut points) requiring more and possibly unnecessary callouts.

5.7.4.5 Strengths of the study

This appears to be the only South African cluster randomized pragmatic trial to: examine nurses' knowledge of early warning signs of physiological deterioration, to implement a training programme for the early detection of deterioration, to implement a MEWS observation chart and to examine records of adult patients on surgical wards who did or did not have a MEWS chart to investigate the quantity of nurses' recordings of postoperative vital sign data and nurses' responses to signs of deterioration. Uniquely too, vital sign recordings were recoded into a MEWS format to explore the efficacy of a MEWS in identifying these events. It did just that. For at least 27 patients (47.4%), a respiratory rate was recorded postoperatively compared to two patients (3.5%) in the control arm and seven patients (12.3%) had recordings of oxygen saturation compared to two (3.5%) in the control arm who did not. At least 45 patients (79%) in the intervention wards had a criterion-based measurement of conscious level (AVPU) compared to a subjective assessment of 37 patients (65%) in the control wards. Five patients in the intervention arm (4.4%) had recordings of all seven parameters compared to 0 in the control arm.

The rigour of the trial is described in section 5.7.4.8.

5.7.4.6 Limitations of the study

Expected limitations of the study were in the implementation phase considering the difficulties and unpredictability of a 'real life' situation in which the study was located. Nurses were short-staffed and research was a low priority. In practice RPNs are the lead nurses who supervise the work of RSNs and RNAs in their capacity as ward managers. RPNs were in short supply, also having to work shifts including night duty to make provision for vacation, off-duties and study leave allowances of fellow RPNs. Nevertheless, patient assessment, care planning and evaluation remains the responsibility of the RPN although in practice this task is delegated to lesser qualified nurses because of the considerable workload involved in ward administration which includes absences from the ward to attend management and clinical meetings.

Main outcome measures of the study were limited to three SAEs initially but only death was found and excluded those reported in major studies such as hospital-incurred patient injury, adverse drug reaction, unplanned return to the operating theatre, unplanned removal, injury or repair of organ during surgery, other patient complications (such as acute myocardial infarction (AMI), cardiovascular accident (CVA), diabetic ketoacidosis (DKA)), development of neurological deficit not present on admission, hospital-acquired infection/sepsis[92] and other outcomes of serious morbidity (e.g., renal failure, limb ischaemia).[306]

Incomplete recording of all seven vital signs in the postoperative period was high in the intervention arm (52/57, 45.6%) and worse in the control arm (100.0%) implying poor quality of care of these surgical patients.

The apparent low response by nurses to recorded disturbed physiological parameters should be interpreted with caution. Patient progress notes were searched for evidence of interventions. Entries such as '[analgesic] given for pain', were not linked to the presence of tachycardia or tachypnoea, for example. From clinical experience and published literature,[304] nurses do not report all interventions for all patients and therefore the need for caution. However, the golden rule guiding documentation is that 'if it is not documented, it was not done' may have to be considered in this instance.

The training programme may have failed to meet the educational needs of nurses within each professional category. Whether nurses should be trained separately for each professional category can be explored in postdoctoral work.

5.7.4.7 Bias

Test marking was undertaken by an independent person (JO). To maintain consistency record review was undertaken by the researcher (UK) as for Study Two and was not independent of the study. Quality control of record review was ensured (section 5.6.3.1). As the record review form was a summary of the variables on the consensus validated MEWS observation chart, further construct and content validity testing would have repeated work completed in sections 3.4.4 and was therefore deemed unnecessary. Methodological bias in cluster randomised trials has been reported.[307] During the sampling, intervention and record review processes every effort was made

to minimize bias as classified by the Cochrane group.[200] Evidence from the study is presented in Table 5-35 using the Cochrane classification and 'Risk of bias'[200] assessment tool.

Table 5-35: Application of the Cochrane (2009) common classification scheme for bias[200]

Type of bias	Description	Relevant domains in the Collaboration's 'Risk of bias' tool – evidence from the study
Selection bias	Systematic differences between baseline characteristics of the groups that are compared.	• Cluster randomization was at the level of ward selection. The total population of surgical wards (N=13) was purposively sampled to locate general surgical wards, orthopaedic wards and vascular surgical wards (n=6) and these wards were selected and randomized into two clusters. • Independent person drew lots for random selection of intervention wards (first three) and was blinded to outcome. • Researcher was not blinded to outcome and implemented the interventions to the respective clusters. • Allocation concealment – until the implementation of the intervention therefore low risk of bias. • The same number of patient records were randomly selected for each cluster (n=19) and for each ward (n=6) in the intervention and control arms.
Performance bias	Systematic differences between groups in the care that is provided, or in exposure to factors other than the interventions of interest.	• The researcher as record reviewer was not blinded to allocation but there was a low risk of bias as outcome measurements were not likely to be influenced by lack of blinding. • 9% (10/114 records) double data entry achieved 92.5% agreement between two reviewers. • Other potential threats to validity were minimised by training the independent marker for the tests. • For the training programme the same instruction material was used and distributed to each group of nurses in the intervention arm. • The same pre- and post-intervention tests were used for the intervention and control arms.
Attrition bias	Systematic differences between groups in withdrawals from a study.	• Incomplete outcome data – low risk of bias as incomplete and unavailable records were excluded. • Self-selection: serendipitously the same number of nurses declined to continue from the intervention and control arms (Figure 5-4).
Detection bias	Systematic differences between groups in how outcomes are determined.	• Other potential threats to validity were minimised by having an index of content validity (CVI) of the training material and tests by an independent reviewer. • Record review consistency.
Reporting bias	Systematic differences between reported and unreported findings.	• Selective outcome reporting – low risk of bias by using explicit review criteria (see Study Two) and CONSORT guidelines extended to cluster randomised trials and pragmatic trials.

5.7.4.8 Evaluation of Study

Study Three was evaluated using CONSORT guidelines extended to pragmatic[280] cluster randomized trials[281] as outlined in Table 5-36.

Table 5-36: CONSORT Statement extended to pragmatic cluster trials

PAPER SECTION and topic	Item	Descriptor	Application to Study Three relevant sections
TITLE & ABSTRACT			
Design	1*	How participants were allocated to interventions (*e.g.*, "random allocation", "randomized", or "randomly assigned") *specifying that allocation was based on clusters.* [Describe the health or health service problems that the intervention is intended to address and other interventions that may commonly be aimed at this problem]	5.5.1
INTRODUCTION			
Background	2*	Scientific background and explanation of rationale, *including the rationale for using a cluster design.*	5.1 5.2
METHODS			
Participants	3*	Eligibility criteria for participants *and clusters* and the settings and locations where the data were collected. [Eligibility criteria should be explicitly framed to show the degree to which they include typical participants and/or, where applicable, typical providers (eg, nurses), institutions (eg, hospitals), communities (or localities eg, towns) and settings of care (eg, different healthcare financing systems]	5.5.3
Interventions	4*	Precise details of the interventions intended for each group, *whether they pertain to the individual level, the cluster level, or both,* and how and when they were actually administered. [Describe extra resources added to (or removed from) usual settings in order to implement intervention. Indicate if efforts were made to standardise the intervention or if the intervention and its delivery were allowed to vary between participants, practitioners, or study sites]	5.5.1 Figure 5-1 Figure 5-2 5.5.6 Table 5-6 5.5.7 5.5.8
Objectives	5*	Specific objectives and hypotheses *and whether they pertain to the individual level, the cluster level, or both*.	5.3 5.4
Outcomes	6*	Clearly defined primary and secondary outcome measures, *whether they pertain to the individual level, the cluster level, or both,* and, when applicable, any methods used to enhance the quality of measurements (*e.g.*, multiple observations, training of assessors). [Explain why the chosen outcomes and, when relevant, the length of follow-up are considered important to those who will use the results of the trial]	5.3.1
Sample size	7*	How *total* sample size was determined *(including method of calculation, number of clusters, cluster size, a coefficient of intracluster correlation (ICC or k), and an indication of its uncertainty)* and, when applicable, explanation of any interim analyses and stopping rules. [If calculated using the smallest difference considered important by the target decision maker audience (the minimally important difference) then report where this	5.5.4 ICC could not be calculated until data had been collected (section 5.6.5)

PAPER SECTION and topic	Item	Descriptor	Application to Study Three relevant sections
		difference was obtained]	
Randomization			5.5.5.1
Sequence generation	8*	Method used to generate the random allocation sequence, including details of any restrictions (*e.g.*, blocking, stratification, *matching*).	5.5.5.2
Allocation concealment	9*	Method used to implement the random allocation sequence *specifying that allocation was based on clusters rather than individuals and* clarifying whether the sequence was concealed until interventions were assigned.	5.5.5.3
Implementation	10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups.	5.5.5.4
Blinding (masking)	11	Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment. If done, how the success of blinding was evaluated. [If blinding was not done, or was not possible, explain why]	5.5.5.6
Statistical methods	12*	Statistical methods used to compare groups for primary outcome(s) *indicating how clustering was taken into account*; Methods for additional analyses, such as subgroup analyses and adjusted analyses.	5.5.9 No additional analyses were undertaken therefore no adjusted analyses
RESULTS			
Participant flow	13*	Flow of *clusters and individual* participants through each stage (a diagram is strongly recommended). Specifically, for each group report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome. Describe protocol deviations from study as planned, together with reasons. [The number of participants or units approached to take part in the trial, the number which were eligible, and reasons for non-participation should be reported]	5.6.1.1 Figure 5-4 5.6.1.2 Figure 5-5
Recruitment	14	Dates defining the periods of recruitment and follow-up.	5.5.5.5
Baseline data	15*	Baseline information [demographic and clinical characteristics] for each group *for the individual and cluster levels as applicable*.	5.6.3.1 5.6.2.1 Appendix 5.10
Numbers analyzed	16*	Number of *clusters and* participants (denominator) in each group included in each analysis and whether the analysis was by "intention-to-treat". State the results in absolute numbers when feasible (*e.g.*, 10/20, not 50%).	5.6.1.1 5.6.1.2
Outcomes and estimation	17*	For each primary and secondary outcome, a summary of results for each group *for the individual or cluster level as applicable*, and the estimated effect size and its precision (*e.g.*, 95% confidence interval) *and a coefficient of intracluster correlation (ICC or k) for each primary outcome*.	5.6.1 – 5.6.5

PAPER SECTION and topic	Item	Descriptor	Application to Study Three relevant sections
Ancillary analyses	18	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those pre-specified and those exploratory.	5.6.6 No adjusted analyses
Adverse events	19	All important adverse events or side effects in each intervention group.	No adverse events
DISCUSSION			
Interpretation	20	Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision and the dangers associated with multiplicity of analyses and outcomes.	5.7.3 – 5.7.6
Generalizability	21*	Generalizability (external validity) *to individuals and/or clusters (as relevant)* of the trial findings. [Describe key aspects of the setting which determined the trial results. Discuss possible differences in other settings where clinical traditions, health service organization, staffing, or resources may vary from those of the trial.]	5.7.2

From Campbell MK, Elbourne DR, Altman DG. CONSORT statement: extention to cluster randomized trials. British Medical Journal 2008; 328: 703.

[From Zwarenstein M, Treweek S, Gagnier JJ, Altman DG, Tunis S, Haynes B, Oxman AD, Moher D. British Medical Journal 2008;337; a2390:3.]

5.7.5 Conclusions, implications and recommendations

Study Three generated new knowledge by answering two research questions. Each question is dealt with separately.

Would the introduction of an early warning vital signs chart and a training programme make a difference to the knowledge, recording and clinical responses of nurses?

The interventions significantly improved test scores compared to scores for nurses who had no training and compared to pre-intervention scores. Before and after the interventions RPNs had significantly higher scores than other categories of nurses and this reached statistical significance. Overall, RSNs showed the greatest improvement in scores. The implication is that learning takes place even in non-ideal circumstances such as a considerably shortened training programme.

All patients in both trial arms had recordings for heart rate and blood pressure. The reason may be that these are routine parameters taken on all hospitalized patients at least twice daily. More patients in the intervention arm had recordings of respiratory rate and there were

significantly more recordings for respiratory rate, oxygen saturation, temperature and conscious level than in the control arm. The reason could simply be that these are on the MEWS chart but absent on the existing chart (except for temperature). Temperature recordings are usually taken 4-12 hourly. Notwithstanding, recordings were inadequate (median of two in the intervention arm; and one recording in the control arm).

The few entries made in patient progress notes suggest that nurses did not respond appropriately to signs of recorded disturbed physiology but these data have to be interpreted with caution. There were no entries to indicate escalation of reporting particularly in the presence of a critical MEWS of 3 but this does not mean no action was taken. RSNs and RNAs obtained significantly lower test scores than the RPNs yet they measured and recorded vital sign data and it may be that they did not interpret signs of deterioration and therefore did not report these.

There is published evidence[186] supported by this study that the MEWS system and a hospital-based training programme for the recognition of early warning signs of clinical deterioration are effective.

Recommendations for education

- The Cape Town MEWS training programme could be adapted for hospital inservice education programmes for nurses and doctors; and
- for nursing higher education institutions that offer undergraduate education.

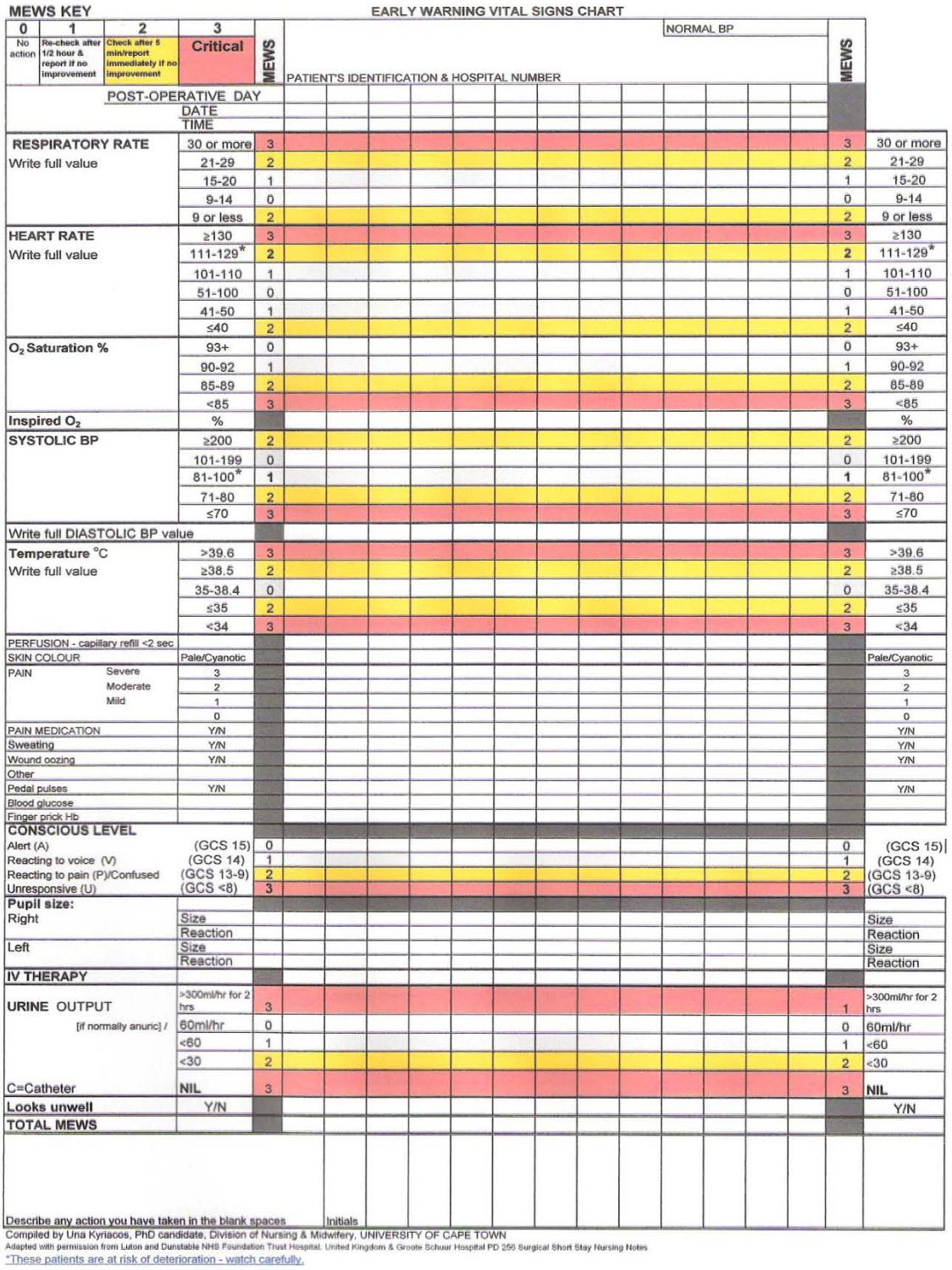
Recommendations for clinical practice

- The MEWS chart should be used for handover rounds to provide evidence of physiological and clinical status rather than subjective interpretations in patient progress notes.
- Patient safety initiatives should be established at The Hospital and should be the focus of morbidity and mortality meetings at which there is reporting of vital sign monitoring.
- The use of the MEWS observation chart as a combined (aggregated and single parameter) track-and-trigger tool is recommended.

- Poor recording of vital signs and poor responses to signs of physiological deterioration may be linked to 'task allocation' which was the preferred method of patient care in the research wards versus 'patient allocation'.

Recommendations for research

The Cape Town Ward MEWS system generally has lower cut points (a greater range) than the published MEWS (usually associated with higher sensitivity) but it may therefore have lower specificity than the published MEWS so that the calling triggers are activated earlier than for the published MEWS, increasing workload. A revised version of the Cape Town MEWS chart is presented (Figure 5-6) for further research to improve recording.



MEWS KEY

0	1	2	3
No action	Re-check after 1/2 hour & report if no improvement	Check after 5 min/report immediately if no improvement	Critical

EARLY WARNING VITAL SIGNS CHART

NORMAL BP

PATIENT'S IDENTIFICATION & HOSPITAL NUMBER

		MEWS	MEWS	
POST-OPERATIVE DAY				
DATE				
TIME				
RESPIRATORY RATE	30 or more	3	3	30 or more
Write full value	21-29	2	2	21-29
	15-20	1	1	15-20
	9-14	0	0	9-14
	9 or less	2	2	9 or less
HEART RATE	≥130	3	3	≥130
Write full value	111-129*	2	2	111-129*
	101-110	1	1	101-110
	51-100	0	0	51-100
	41-50	1	1	41-50
	≤40	2	2	≤40
O_2 Saturation %	93+	0	0	93+
	90-92	1	1	90-92
	85-89	2	2	85-89
	<85	3	3	<85
Inspired O_2	%			%
SYSTOLIC BP	≥200	2	2	≥200
	101-199	0	0	101-199
	81-100*	1	1	81-100*
	71-80	2	2	71-80
	≤70	3	3	≤70
Write full DIASTOLIC BP value				
Temperature °C	>39.6	3	3	>39.6
Write full value	≥38.5	2	2	≥38.5
	35-38.4	0	0	35-38.4
	≤35	2	2	≤35
	<34	3	3	<34
PERFUSION - capillary refill <2 sec				
SKIN COLOUR	Pale/Cyanotic			Pale/Cyanotic
PAIN Severe	3			3
Moderate	2			2
Mild	1			1
	0			0
PAIN MEDICATION	Y/N			Y/N
Sweating	Y/N			Y/N
Wound oozing	Y/N			Y/N
Other				
Pedal pulses	Y/N			Y/N
Blood glucose				
Finger prick Hb				
CONSCIOUS LEVEL				
Alert (A)	(GCS 15)	0	0	(GCS 15)
Reacting to voice (V)	(GCS 14)	1	1	(GCS 14)
Reacting to pain (P)/Confused	(GCS 13-9)	2	2	(GCS 13-9)
Unresponsive (U)	(GCS <8)	3	3	(GCS <8)
Pupil size:				
Right	Size			Size
	Reaction			Reaction
Left	Size			Size
	Reaction			Reaction
IV THERAPY				
URINE OUTPUT	>300ml/hr for 2 hrs	3	1	>300ml/hr for 2 hrs
[if normally anuric] /	60ml/hr	0	0	60ml/hr
	<60	1	1	<60
	<30	2	2	<30
C=Catheter	NIL	3	3	NIL
Looks unwell	Y/N			Y/N
TOTAL MEWS				

Describe any action you have taken in the blank spaces — Initials

Compiled by Una Kyriacos, PhD candidate, Division of Nursing & Midwifery, UNIVERSITY OF CAPE TOWN

Adapted with permission from Luton and Dunstable NHS Foundation Trust Hospital, United Kingdom & Groote Schuur Hospital PD 256 Surgical Short Stay Nursing Notes

*These patients are at risk of deterioration - watch carefully.

Figure 5-6: Revised Cape Town MEWS chart

Changes to the chart include reverting to the preliminary MEWS (Figure 3-2) which supports the sensitivity and specificity of cut points for heart rate and systolic BP found in Study Two and provides fewer cut points (see comparison in section 3.6.1). Changes to the layout include graying out unused blocks, a space for the patients' normal BP, having parameter values on both sides, the words "Describe any action you have taken in the black spaces", an asterisk to highlight Study Two cut points for sensitivity and specificity for heart rate and systolic BP with the words "*These patients are at risk of deterioration – watch carefully" and replacing the need for a signature with initials to save time and improve legibility.

Would the introduction of an early warning vital signs chart and a training programme make a difference to patient outcomes?

There were few deaths in all the wards and too many confounding factors in a clinical setting to attribute the deaths to inadequate recording and reporting. This question will be discussed in the next chapter.

In conclusion, the following hypotheses were examined and are reported on.

If nurses are trained in the use of a MEWS observation chart:

1. their knowledge of early warning signs of physiological deterioration in patients will improve: accepted;
2. the number of recordings of vital sign data will improve compared to that of nurses using the existing observation chart: accepted with caution;
3. they will respond more frequently to patients with disturbed physiology than nurses receiving no training and using the existing observation chart: rejected.

Why did knowledge not translate into improved reporting and outcomes? The results from Study Three are inconclusive but this question and further testing of the revised MEWS chart are recommended for future research.

6 CONCLUSIONS AND RECOMMENDATIONS

This concluding chapter focuses on new knowledge generated by the thesis and the implications, practical applications and recommendations for practice (related to vital signs monitoring), education, hospital organisational systems and research for the field[308] of nursing.

6.1 New knowledge generated by the thesis

This appears to be the only South African study to describe the design, validation and evaluation of a MEWS system (the Cape Town MEWS) and training programme for general hospital wards for the detection of early signs of physiological deterioration in the first eight postoperative hours and nurses' responses. A summary of new knowledge generated by the three-part study is presented in Table 6-1.

Table 6-1: New knowledge generated

Study One - Research question:
What published modified early warning scoring (MEWS) system is most appropriate for the South African context?
• A validated, consensus derived MEWS observation chart comprising seven physiological parameters with cut points (thresholds) and MEWS weighted trigger points (0-3) and clinical indicators of deterioration (• Figure 3-4) for general hospital ward use. • Consensus methods were appropriate for the study. • A consensus ranking sheet for deriving and validating a MEWS was designed. • The study has contributed to limited published literature on methods of establishing the index of content validity (CVI) of a questionnaire.
Study Two – Research questions:
1. How was the existing vital signs chart operationalised by nurses for the identification of postoperative early warning signs of clinical and physiological deterioration in patients at risk of serious adverse events (SAEs) in adult surgical wards in one public hospital in Cape Town? *2. What was the association between the number of recorded vital signs on the current observation chart and patient outcomes in those at risk of a SAE?* 3. *What was the association between the clinical responses of nurses to recordings on the current chart and patient outcomes in those at risk of a SAE?*
• A criterion-based record review form was designed for capturing data on demographic and clinical characteristics of patients with and without SAEs and data on patients' recorded vital signs. • The Cape Town MEWS observation chart was then used to recode physiological parameters recorded on existing observation charts for interpreting severity of illness (1-3) and nurses' responses to MEWS triggers. • Patients had few postoperative vital sign recordings. No patient had recordings of all seven parameters. • We have no evidence that patient outcomes were associated with the number of recorded parameters. • Record review revealed few recordings of action taken by nurses for scores that should have triggered. • We have no evidence that patient outcomes were associated with the number and appropriateness of nurses' responses to recoded parameters.

• Factors on admission significantly associated with death in the first 8 hours after surgery: having two or more pre-existing comorbid conditions and either a high or low systolic BP on admission; • Factors significantly associated with death in the first 8 hours following surgery: Age - 61 years or older; a fast heart rate and low systolic BP. • The sensitivity and specificity of the MEWS for predicting death: For heart rate, a cut-off point of 2 was 45.5% (95% CI 16.8–76.6) sensitive and 81.4% (66.6-91.6) specific; for systolic BP, the cut-off point of 1 showed 72.7% (95% CI 39.0–94.0) sensitivity and 77.3% (62.2-88.5) specificity.
Study Three - Research questions:
1. Would the introduction of an early warning vital signs monitoring tool and a training programme make a difference to the monitoring, recording and clinical responses of nurses? 2. *Would the introduction of an early warning vital signs monitoring tool and a training programme make a difference to patient outcomes?*
• Data show that a training programme for nurses designed for the recognition of early warning signs of clinical deterioration followed by the implementation of a MEWS observation chart on surgical wards did result in a significant difference in knowledge test scores compared to nurses with no training (Table 5-21). • These interventions (training programme and MEWS chart) also resulted in significant differences between the intervention and control arms in relation to the *number of patients* with recordings of postoperative respiratory rate (Table 5-23) and the *number of recordings* (Table 5-25) for certain but not all parameters. • More patients with the MEWS chart in the intervention arm had recordings of respiratory rate, oxygen saturation, conscious level and of all parameters than patients in the control arm with the existing observation chart. • Despite training, nurses in the intervention group apparently did not respond appropriately to the MEWS callout algorithm for disturbed physiological parameter readings. • The intervention improved the process of care, but we have no evidence that patient outcomes were improved.

Salient findings, implications and practical applications are presented in the context of pertinent published literature.

6.2 Implications and practical applications

6.2.1 Implications and practical applications for practice

The Cape Town MEWS is effective for recoding vital signs data on the existing chart into a MEWS format to establish severity of illness and is therefore suitable for identifying patients at risk of deterioration as for published MEWS implementation studies (Table 5-34).

The MEWS chart is effective in practice for the recording of certain vital signs, particularly respiratory rate, the best discriminator for clinical outcomes.[185] Nurses used the MEWS chart as a single parameter tool, that is, seldom calculating a total MEWS for all parameters monitored at a particular observation time-point. This finding is compared to published MEWS implementation studies (Table 5-34). Using the MEWS chart as a single parameter tool did not translate into improved responses to MEWS that triggered a callout, including critical scores of 3 and this aspect should be explored in further work. Limited reporting of nurses' responses to vital signs that should have triggered on the MEWS indicates that, despite training, their responses appear to have been less than ideal which has grave consequences for patients.

Prior to training, all categories of nurses in the intervention arm had poor (<50%) basic knowledge of recognising signs of clinical and physiological deterioration in patients, (Table 5-14) and this has serious implications for patient outcomes. Following training, test scores for all categories of nurses improved significantly and when compared with the control arm, the mean difference was significantly greater. Registered Professional Nurses' (RPNs) scores were the highest whereas Registered Nursing Auxiliaries' (RNAs) scores were the lowest. RNAs and Registered Staff Nurses (RSNs), rather than RPNs, monitored and recorded patients' vital signs and this practice will have to be reviewed as RNAs and RSNs may not have effective clinical decision-making skills which is associated with knowledge and understanding.[27] The quantity and quality of recorded parameters raises questions about nursing care processes and systems such as patient allocation (aimed at 'total patient care') versus task allocation of repetitive skills but this has resource implications. It also raises questions about the purpose of the handover round and brings into sharp relief the need for the MEWS chart to be used for this purpose to provide evidence of

the patients' physiological and clinical status rather than relying on subjective interpretations in patient progress notes.

Non-recognition of deterioration in clinical status has implications for patient survival and violates principles of professional practice as patient survival may depend on the decisions of nurses to call for assistance. Failure to adequately monitor a patient's condition also has legal implications. The South African Patients Charter,[47] Batho Pele Principles[48] and Bill of Rights[49] advocate public awareness of patients' rights and litigation. Although patients with the MEWS chart had more recordings of respiratory rate, oxygen saturation and conscious level as well as of temperature and urine output and of all seven parameters, recording generally was low and this has implications for quality of care and patient outcomes.

The study provided evidence of a significant association between mortality and certain demographic and clinical factors. This means that nurses should be instructed to monitor the following patients carefully: having surgery at the age of 61 years and older; with two or more pre-existing comorbid conditions; a high or low systolic BP on admission; a fast pulse (and known sensitivity and specificity for a high cut point of 2) and low systolic BP (and known sensitivity and specificity for a low cut point of 1) following surgery. It also means that these factors have to be emphasised during the training programme.

A comparison of parameter cut points (thresholds) of the Cape Town MEWS with existing published MEWS (see the prototype MEWS chart, Figure 3-2) is presented in Table 3-33, showing that the Cape Town MEWS has more cut points for most of the parameters. This may have made the chart complex. Results for both Study Two and Three indicate a low number of recordings of parameters. To reduce the complexity of the Cape Town MEWS chart and thereby to encourage improved recording, further changes to the Cape Town MEWS were recommended at the conclusion of Study Three (Figure 5-6). Suggested changes include: reverting to fewer parameter cut points on the prototype MEWS chart, repeating cut points and weighted trigger points (0-3) on both sides of the page and highlighting parameter cut points significantly associated with mortality - a high cut point of 2 for heart rate and a low cut point of 1 for systolic BP. In addition, the following caution has been added: "These patients are at risk of deterioration – watch carefully".

6.2.2 Implications and practical applications for education

A training programme for nurses for the detection of early signs of clinical deterioration and a MEWS chart can make a difference to knowledge and these interventions can also make a difference to the practice of recording certain vital signs. This has implications for improved patient outcomes.

These interventions alone may not improve nurses' interpretation of parameter readings and their responses to MEWS that should have triggered a callout and this has implications for the training programme which would have to include measures to ensure more effective clinical decision-making.

6.2.3 Implications and practical applications for nursing management/hospital organisational systems

A 'track-and-trigger' system such as the MEWS is aimed at limiting preventable AEs and SAEs (section 4.3.2) and is complex. The introduction of such a system requires the support of hospital management teams as it involves changing the system of documentation for vital sign monitoring and intensive training of ward staff. Despite training, some nurses in the trial arm reverted back to using the existing chart.

What nurses do ('nursing sensitive' determinants) directly or indirectly influences patient outcomes and can predict mortality. Aiken and colleagues[257] are acknowledged for their seminal hypothesis of a theoretical model of the relationships between various nurse-related hospital characteristics and mortality in the USA[135] to guide policy. To ensure optimum patient outcomes nurses need to manage what Aiken et al. (1997)[257] describe as 'operant mechanisms' (which include control over the practice setting) and 'nurse care environments' (Aiken et al. 2008)[309] and to provide 'professional role support'.[254]

For the MEWS chart to be implemented successfully, patient safety should feature prominently in the hospital management systems. A distinction needs to be drawn between a person approach that emphasizes human error and blaming; and a system approach, that looks

for solutions to clinical mishaps within the organization and encourages reporting of AEs and 'near misses' and learning from these events.[121] A combination of both approaches is recommended.[89] Human error is a prominent cause of avoidable AEs and accounts for 57% of all cases[15] even for the best-trained and best-qualified healthcare providers. Consequently insight into the causes might help in the development of prevention strategies[15] that move away from blaming clinicians who may have erred towards an understanding of how complex systems fail. Institutions need to develop a system that is as "failsafe" as possible. The role of factors such as fatigue[136] and sleep deprivation[137] needs further research as well as improved communication systems.

A training programme and the implementation of a colour-coded MEWS observation chart will require resources that may be prohibitive for a resource poor public hospital in a developing country. The best option may be a chart with different shades of grey that may be duplicated more inexpensively.

6.2.4 Implications and practical applications for research

6.2.4.1 The MEWS chart

The consensus derived and validated MEWS was effective in both Study Two and Three for recoding parameters and for interpreting severity of illness.

A comparison of Study Three findings to selected findings of MEWS implementation studies described in Chapter Two (Table 2-5) including reasons for differences/similarities and for including each is presented in Table 5-34. In these studies scores for urine output and temperature were modified and this supports recommendations for reverting to the published MEWS from which the Cape Town MEWS were derived.

The clinical usefulness of the clinical signs of deterioration (pallor, sweating, looking unwell) on the Cape Town MEWS chart was not evaluated and this and other limitations of the study are described elsewhere (section 5.7.5).

The revised MEWS (Figure 5-6) chart should be implemented and evaluated for its usefulness.

6.2.4.2 Record review

The criterion-based record review form and procedure were effective for establishing the quantity of recordings of parameters during the first eight postoperative hours in both Study Two and Three, revealing low numbers. Data concerning nurses' responses to MEWS that should have triggered callouts were limited and were located in patient's 'progress notes', having implications for research as it complicated the data analysis process. For this reason, the revised MEWS chart has a space for recording nurses' interventions in alignment with the observation time-point.

6.2.4.3 CONSORT guidelines for evaluation of the pragmatic cluster RCT

To improve reporting of Study three, an extension of the CONSORT[viii] 2001 Statement (replaced by 2010 guidelines[276, 277]) to cluster randomised trials by Campbell et al. (2004) [281, 282] and Zwarenstein et al. (2008)[280] was used to evaluate results. The study provided evidence of meeting these criteria, reported in Table 5-36. The conduct and reporting of cluster trials have been criticised as being poor[281, 296-298] and there are continuing problems with the design and analysis of cluster trials both in the developed countries and sub-Saharan Africa.[281, 299-301] It is hoped that these criticisms find no or perhaps only limited application to this study. The reasons for delaying the calculation of the intracluster correlation coefficient until after data analysis in Study Three, are provided in section 5.5.4.2, thus accounting for clustering in sample size calculations.[284] The reliability of the information produced by the study is directly related to its power,[305] therefore not having considered design effect or intracluster correlation coefficient in cluster sampling estimation, albeit for pragmatic reasons, might have reduced the ability of the study to produce statistically significant results with regard to certain outcomes. However, feasibility of the method has been demonstrated, in readiness for a larger, externally funded, trial. "Small trials are not necessarily unethical, provided the aim of the trial is consistent with its size."[229] The cluster RCT was undertaken successfully in a real world setting in a resource poor environment in a developing country. The study focused on nursing, rather than medical care, and was conceived and led by nurses and can be replicated.

[viii] Consolidated Standards of Reporting Trials

6.3 Recommendations

Recommendations are presented in the context of the study findings.

6.3.1 Recommendations for education

- The study provided evidence that the training programme improved nurses' knowledge significantly and it improved the practice of recording certain vital signs. However, training did not improve the recognition of disturbed physiology and nurses' responses to MEWS that should have triggered a callout. The training programme is recommended for rollout to all general wards in the Hospital, but with the following amendments:
    - an 8-hour training programme to run over one day;
    - separate training sessions for RPNs (including nurse managers) that should include revision of the scope of practice of the RPN in relation to vital sign monitoring as this is an independent function that may be delegated to RSNs and RNAs but is performed under the RPNs supervision. RPNs should therefore not have to rely on doctors to prescribe the monitoring of vital signs for postoperative patients as this is mandated best practice following the administration of a general anaesthetic;
    - training sessions for RSNs and RNAs to study together using a shortened version of the training programme, less physiology, more hands-on exercises for charting and calculating a total MEWS and revision of the scope of practice in relation to vital sign monitoring for nurses with these qualifications;
    - it is recommended that RNAs and RSNs should only monitor patients' vital signs once they have a certificate of competence following the attendance of a MEWS training programme.
    - 2-hour sessions for doctors on the background and use of the MEWS.
    - The MEWS flowchart should be a central focus for all training sessions.

- The Cape Town MEWS training programme should be offered at nursing higher education institutions that offer undergraduate and postgraduate educational programmes to standardise the approach to the detection and management of patients with early warning signs of clinical and physiological deterioration.

6.3.2 Recommendations for practice

- After training, the chart should be rolled out to all general wards in the Hospital over a 12 month period. The rollout should proceed sequentially, starting with the six surgical wards (intervention and control arms) that were included in the study. Nurses in the intervention wards should be mentors for the other wards.
- The use of the MEWS observation chart as a combined (aggregated and single parameter) track-and-trigger tool is recommended. The reason for the combined system is that aggregate scores may not trigger if one variable falls outside the predetermined score, even though this has not been reported as a practical problem.[172] However, single parameters with high scores may not always translate into an increased overall risk in single parameter track and trigger systems.
- It is strongly recommended that the doctors prescribing postoperative orders should prescribe against the MEWS chart and also consider the MEWS recordings on Day 1 after surgery on ward rounds. That would increase awareness of the value of the chart and encourage nurses to use it more effectively for interpreting data when deciding to summon assistance.

6.3.3 Recommendations for nursing management/hospital organisational systems

- Two MEWS project leaders should be identified for each clinical speciality to ensure availability as done in the study.
- MEWS project leaders should have membership on hospital patient safety committees and on morbidity and mortality committees where they would provide data on the incidence of AEs and SAEs on their wards and the association between the quality and quantity of vital sign monitoring and patient outcomes.

- MEWS project leaders should establish international networks with nurses involved in patient safety initiatives to provide support in developing a model to monitor patient safety practices in the Hospital.

6.3.4 Recommendations for research

- Consensus methods were effective in deriving and validating a standardised scoring system (MEWS) for interpreting signs of clinical deterioration and an observation chart incorporating the MEWS. In a resource constrained setting such as The Hospital the nominal group technique is recommended over a Delphi by electronic means.

- Further research is needed to establish the effectiveness of:
    - a MEWS training programme on nurses' ability to interpret recorded vital signs;
    - a MEWS training programme on nurses' clinical decision-making skills and responses to scores that trigger the callout algorithm;
    - the revised Cape Town MEWS chart (Figure 5-6) on recordings of vital signs data prior to the recommended rollout to all wards in the Hospital and prior to the multi-site RCT;
    - the revised Cape Town MEWS chart as a single parameter tool, an aggregate weighted tool or a combined tool on nurses' clinical decision-making skills and responses to scores that trigger the callout algorithm.
- Further research is needed to:
    - improve record keeping for tracking and reporting on nurses' interventions in response to patients with disturbed physiology prior to the multi-site RCT;
    - establish the clinical usefulness of clinical signs of deterioration (pallor, sweating, looking unwell) included in MEWS observation charts.

- Future research: a multi-site pragmatic cluster RCT is recommended.

The impact of the Cape Town MEWS on patient outcomes in limiting AEs and SAEs of in-hospital patients would be the research focus of the multi-site RCT.

There is adequate evidence to suggest that the Cape Town MEWS chart, used as a single parameter tool, has the ability to identify patients at risk of deterioration (Table 4-16, Table 5-27) and that improvements in patient monitoring can be achieved by implementation of a MEWS in the Hospital. There is sufficient evidence to conclude that a multi-site RCT is warranted.

This was a pragmatic feasibility cluster RCT with three intervention and three control wards undertaken for a future trial. A cluster trial should recruit a larger population of participants than is required for a RCT to ensure adequate statistical power[284] but this was not done due to the unknown clinical importance and value of the intracluster correlation coefficient and resource limitations. It is recommended that the two tertiary level hospitals for adult patients in the Western Cape and one randomly selected secondary level hospital be included in a future multi-site RCT.

Primary outcomes for the future multi-site RCT:

Objective 1 – Analysis of SAEs

- To assess the incidence of SAEs in postoperative patients on randomised surgical wards;
- To explore any associations between SAEs and the parameters included in the Cape Town MEWS observation chart; and
- To explore any associations between SAEs and the number of parameters recorded on existing observation charts.

Objective 2 – Sensitivity and specificity of the MEWS

- To establish the sensitivity and specificity of the Cape Town MEWS weighted trigger points (0 and upper and lower 1 to 3) of each physiological parameter where sensitivity refers to the ability of the MEWS chart to identify patients with established critical illness (SAEs) who trigger predetermined physiological thresholds and specificity means the ability of the MEWS chart not to trigger a response for inappropriate patients (without established critical illness who did not trigger).
- To establish the cut point of each parameter associated with SAEs.

- **Considerations of design and analysis**

Considerations of design, intracluster correlation coefficient, sample size and analysis would be guided by the findings for Study Three and we would work with a clinical trials unit, which includes a statistician. A UK unit (WWORTH Swansea) has expressed interest in being involved. However, for the multi-site RCT it is recommended that the six surgical wards in the Hospital and six wards in the other tertiary level hospital in the Western Cape as well as one secondary level hospital be included in the study.

6.4 Conclusion

The field of early warning scoring systems for monitoring inpatients' vital signs is under-researched in South Africa. This study has generated new knowledge in this area. A MEWS training programme improved nurses' knowledge of the recognition of signs of physiological and clinical deterioration. A consensus derived and validated MEWS observation chart resulted in improved monitoring of certain vital sign parameters and patients with the chart had more recordings than patients with the existing chart. However, this knowledge did not translate into appropriate clinical decision-making in relation to summoning assistance. The study has nevertheless provided sufficient evidence to conclude that a multi-site RCT is warranted for further evaluation of the MEWS chart towards improved monitoring and recording of vital signs on general hospital wards.

Are we any closer to improving patient safety in Cape Town public sector hospitals? We may well be:

> "Our review of the measurement of patient safety in developing and emerging countries was encouraging in one respect: it is evident that patient safety evaluations can be conducted in these countries. Moreover, we found that when charts are available, chart audit is a promising method for monitoring patient safety. Establishing fundamental safe patient practices, integrating those processes into routine health services delivery and developing

patients' expectations that such processes be present are necessary prerequisites to progress towards safe patient care in emerging and developing countries."[310]

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8 APPENDICES

CHAPTER 2: PAGES

CHAPTER 3:

CHAPTER 4

CHAPTER 5

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Monitoring vital signs using early warning scoring systems: a review of the literature

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Monitoring vital signs using early warning scoring systems: a review of the literature

Aim To evaluate the need for, and the development and utility of, pen-and-paper (Modified) Early Warning Scoring (MEWS/EWS) systems for adult inpatients outside critical care and emergency departments, by reviewing published literature.
Background Serious adverse events can be prevented by recognizing and responding to early signs of clinical and physiological deterioration.
Evaluation Of 534 papers reporting MEWS/EWS systems for adult inpatients identified, 14 contained useable data on development and utility of MEWS/EWS systems. Systems without aggregate weighted scores were excluded.
Key issues MEWS/EWS systems facilitate recognition of abnormal physiological parameters in deteriorating patients, but have limitations. There is no single validated scoring tool across diagnoses. Evidence of prospective validation of MEWS/EWS systems is limited; neither is implementation based on clinical trials. There is no evidence that implementation of Westernized MEWS/EWS systems is appropriate in resource-poor locations.
Conclusions Better monitoring implies better care, but there is a paucity of data on the validation, implementation, evaluation and clinical testing of vital signs' monitoring systems in general wards.
Implications for nursing management Recording vital signs is not enough. Patient safety continues to depend on nurses' clinical judgment of deterioration. Resources are needed to validate and evaluate MEWS/EWS systems in context.

Keywords: adverse events, deterioration, early warning scoring systems, patient safety

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Introduction: the epidemiology of serious adverse events

A serious adverse event (SAE) is defined as an untoward occurrence that: results in death; is life-threatening; requires prolongation of current hospitalization; results in persistent or significant disability or incapacity (National Patient Safety Agency 2009); results in avoidable in-hospital cardiac arrest without a pre-existing not-for-resuscitation (NFR) order; and/or requires urgent and unanticipated admission to an intensive care unit (ICU) (Story et al. 2004, Smith et al. 2006).

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Of 1804 SAEs reported in the UK during 2005 (National Patient Safety Agency 2007a), 576 deaths were potentially avoidable and related to patient safety issues. Of these reported deaths, 425 occurred in acute/general hospitals, of which 64 deaths were associated with patient deterioration not recognized or responded to (Beaumont et al. 2008). The consequences of adverse events are not only devastating for patients and their families, but are distressing for staff(Wakefield et al. 2005) as the psychological impact off ailure has a demoralizing effect (Aron & Headrick 2002). Serious adverse events decrease public confidence (National Patient Safety Agency 2004) and authorities in the developed world are concerned at the increasing number of claims for malpractice (Buist et al. 2004).

The costs for clinical negligence claims in the UK NHS during 2008–2009 amounted to £769 million (NHS Litigation Authority 2009) and 6080 claims of clinical negligence were received. These findings are not unique to the UK NHS (de Vries et al. 2008): in the USA costs of preventable adverse events (AEs) are estimated at between US$17 and $29 billion annually (Thomas et al. 1999). In Australia, nationwide, adverse events (AEs) with high preventability were estimated at 1.7 million (8% of the total) hospital bed days at a cost of Aus$4.7 billion per year (Wilson et al. 1995). In a widely cited American study of clinical antecedents to in-hospital cardiac or respiratory arrest, conducted in 1987 over 4 days, 54 patients (84%) had documented observations of at least one behavioural or physiological change 8 hours before an arrest (Schein et al. 1990).

Background: measuring vital signs

Serious adverse events can be prevented by limiting human error (Wilson et al. 1999), for example by recognizing early warning signs of clinical and physiological deterioration, and responding appropriately. Serious physiological abnormalities often precede cardiac arrest, unanticipated admission to ICU or death (Kause et al. 2004). Premonitory abnormalities in vital signs are often observed before adverse clinical outcomes (Harrison et al. 2005), and within 6 hours (Franklin & Mathew 1994) to 8 hours (Schein et al. 1990) of cardiac arrest, particularly if hypoxaemia and hypotension are not treated adequately (Smith and Resuscitation Council UK 2010). It is the nurses ' professional responsibility to understand the significance of patient observations (South African Nursing 2004, Hogan 2006, Kisiel & Perkins 2006) and patient survival often depends on the decisions of nurses to call for assistance (Cioffi 2000a).

The incidence of AEs and negligence of staffcaring for hospitalized patients is receiving serious attention at national level in developed health-care systems (NHS 2003, NCEPOD 2005, Buist et al. 2007, Gao et al. 2007, Chaboyer et al. 2008). There is particular concern over infrequent and incomplete monitoring and recording (Goldhill 2006), misinterpretation of clinical data, delays in reporting, and the paucity of convincing evidence for appropriate interventions (National Patient Safety Agency 2007b).

A variety of vital signs ' monitoring tools that incorporate early warning scoring (EWS) systems designed to 'track ' signs of deterioration and 'trigger' a rapid response to improve patient safety have been introduced across the UK (Hogan 2006) and Australasia (Green & Williams 2006, Chaboyer et al. 2008) (Table 1). The modified early warning scoring (MEWS)/EWS 'track and trigger' system (TTS) is based on physiological parameters, each of which is recorded in boxes, according to predefined ranges (NHS 2003, Gao et al. 2006). Points are allocated to disturbed physiological values, with weightings, to guide intervention (Stenhouse et al. 2000, Hodgetts et al. 2002, Goldhill et al. 2005, Smith et al. 2006, Subbe et al. 2001), and to monitor the effectiveness ofi nterventions (Subbe et al. 2001). These replace traditional charts where values are plotted on graphs and intervention levels are not specified. However, there is little research evidence available to clinicians and managers regarding selection of MEWS/EWS systems for general wards. This paper considers three questions: are these systems needed? How have they been developed and validated? What is the evidence for their clinical effectiveness for adult inpatients outside critical care areas?

Evaluation of published literature

Published literature was reviewed to describe the need for, and the development and clinical effectiveness of MEWS/EWS systems (classified in Table 1). Papers related to research involving adult inpatients outside critical care areas and emergency departments were included ifi n English and iff ull texts were available. To ensure a nursing focus, we excluded EWS employed in triage, medical emergency teams (METs), Critical Care Outreach Services (CCOS) and other organizational systems that use late signs (calling criteria) of physiological deterioration.

Searches (Table 2) covered 1998 to the present. We also included: earlier primary research articles of particular relevance, frequently referenced citations concerning in-hospital morbidity and mortality caused by

Table 1
Classification of early warning scoring track and trigger systems

Term	*Abbreviation*	*Definition*
Early warning score	EWS	A simple scoring system used at general ward level based on careful routine physiological measurement of heart rate, blood pressure, respiratory rate, temperature and conscious level each with an upper and lower score of 0–3 points from which a total score is calculated
Early warning scoring system	EWSS	As for EWS
Modified early warning score	MEWS	'a defined judgement on routinely recorded physiological data' (Subbe *et al.* 2001, p. 524); a simple algorithm based on bedside observations that include respiratory and mental function (Subbe *et al.* 2003)
Aggregate-weighted track and trigger systems	AWTTS	The trigger is achieving a previously agreed trigger threshold with the total score (Gao *et al.* 2006)
Combination track and trigger systems	Combination TTSS	Involve single- or multiple-parameter systems in combination with aggregate-weighted scoring systems (Gao *et al.* 2006)
Multiple-parameter track and trigger system	MPTTS	Two or more predefined extreme physiological or clinical parameters trigger for summoning skilled clinical assistance (Gao *et al.* 2006)
Single-parameter track and trigger system	SPTTS	One predefined abnormal physiological or clinical parameter triggers for summoning skilled clinical assistance (Gao *et al.* 2006)

Table 2
Database search results

Database/search engine	*Keywords*	*Results*	*Number of relevant papers*
MESH database/PubMed	Patient safety AND ward AND vital sign monitoring	5	3
	Inpatient mortality AND adverse events	76	4
	Early warning sign systems	138	14
	Physiological monitoring AND adverse events AND nursing	34	1
	Physiological monitoring AND adverse events AND classification	55	0
EBSCO CINAHL database	Postoperative AND vital sign assessment	202	2
	Physiological deterioration	17	7
Google search engine	The same keywords but limited to the SA context and broadened to include theses and dissertations	7	7
Total		534	38

negligence, and the first published EWS dated 1997. Of 534 papers located, 14 data papers, two reviews (Smith *et al.* 2008a,b) and two meta-analyses (Gao *et al.* 2007, Odell *et al.* 2009) contained data on the need for and the validity, reliability and utility of MEWS/EWS systems.

Findings

Modified Early Warning Scoring/Early Warning Scoring systems are deemed necessary; however, there is relatively little evidence for their validity and clinical effectiveness in general wards. Key issues are:

- The needs of critically ill patients on general wards: monitoring of vital signs;
  - Interpreting signs of clinical deterioration;
  - Calling for skilled clinical assistance.
- Solutions:
  - Patient safety: a national imperative
  - Patient safety: local organizational approaches.
  - Introduction of MEWS/EWS systems
  - Evaluation of MEWS/EWS: validity and reliability; utility and performance
- Limitations of MEWS/EWS

Needs of critically ill patients on general wards

Critically ill patients are usually admitted to high-dependency units or ICUs for close, electronic, even invasive, monitoring of vital signs. Several studies from developed countries indicate concerns about the safety

of acutely ill patients in general wards (Carter 2008), including the UK (NHS 2003, Gao *et al.* 2007, National Patient Safety Agency 2007a,b, NICE 2007), Australasia (Buist *et al.* 2002, 2004, 2007, Kause *et al.* 2004, Chaboyer *et al.* 2008), the USA (Berwick *et al.* 2006) and Canada (Baker *et al.* 2004, Forster *et al.* 2004), although these are not specific to adult postoperative patients. However, in the UK (Johnstone *et al.* 2007) and Israel (Zimlichman *et al.* 2009) increasing numbers of sicker and more dependent patients are admitted to general wards as a result of shortages of acute beds and staff. Patients discharged from ICUs to wards are at risk of AEs (Bhengu 2002, Chaboyer *et al.* 2008) and have a higher mortality than patients admitted from operating and recovery rooms or accident and emergency departments (Goldhill & Sumner 1998).

Suboptimal care is ascribed to failure to monitor basic clinical and physiological parameters involving the patient's airway, breathing and circulation, oxygen therapy and fluid balance; similarly, lack of knowledge may be associated with the inability to recognize deterioration in a patient's condition and the clinical urgency of a situation. When exacerbated by a lack of supervision, failure to summon assistance, poor communication and delays in responding to deteriorating vital signs compromise patient safety and suggest organizational failures (Smith *et al.* 2002, NPSA 2007b).

Older and more acutely ill patients are being cared for in general wards by fewer qualified nurses, who are not paid for study leave for post-registration education, and inexperienced, temporary nurses (McArthur-Rouse 2001). Despite the increasing technical sophistication in vital signs monitoring in the developed world, monitoring problems persist.

Monitoring vital signs

Of concern is infrequent and incomplete monitoring and recording of vital signs on general wards (Goldhill 2006, Zimlichman *et al.* 2009). Studies in the UK reveal that nurses record respiratory rate on only 55% (Chellel *et al.* 2002) or on less than 50% of scheduled occasions (Hogan 2006), and doctors act similarly (Kenward *et al.* 2001). Infrequent monitoring of basic vital signs can pre-empt early identification of deterioration in a patient's condition and delay transfer to ICU, possibly resulting in 'preventable adverse events'. These are associated with a 60% increase in hospitalisation costs (Kaboli & Rosenthal 2003). In a study using 11 predetermined physiologic threshold criteria to establish if delayed transfer of patients from general wards to ICUs was associated with increased morbidity and mortality, there was a 30% increase in mortality where transfer to ICU was delayed by 4 hours or more (Young *et al.* 2003).

Interpreting signs of clinical deterioration

There is documented concern regarding misinterpretation of clinical data and little convincing evidence of timely response to signs of deterioration (National Patient Safety Agency 2007a,b). Misinterpretation of clinical data is associated with poor clinical reasoning skills. Nurses have been found to overestimate the risk and the need to intervene in computer-based clinical scenarios (Thompson *et al.* 2009). These findings have serious implications for patients at risk of avoidable SAEs. Multidisciplinary teamwork means that medical practitioners rely on nurses to document and interpret vital signs and to report deterioration (National Patient Safety Agency 2007b).

Calling for more skilled clinical assistance

There is documented concern over delays in reporting abnormal physiology (National Patient Safety Agency 2007b). Patient survival frequently depends on nurses' decisions to call for assistance promptly (Cioffi 2000a). Ward nurses delayed calls to medical emergency teams after documenting concerns about patients' vital signs. This resulted in treatment delays of up to 1 hour for 11.3% of 168 patients, and 8.9% (15/168) patients waited more than 3 hours (Crispin & Daffurn 1998). Australian nurses surveyed would call medical emergency teams for a change in vital sign recordings in only 2.8% of incidents of at-risk patients (Daffurn *et al.* 1994). An Australian interview study (n = 32) reported that 98% of nurses made in-hospital calls to medical emergency teams (Cioffi 2000b), but when nurses report abnormal clinical observations to junior doctors, rather than seniors, appropriate intervention might be delayed (Buist *et al.* 2004).

A lack of critical care skills among undergraduate and postgraduate nursing and medical staff has been reported (Jacques *et al.* 2006). Nurses in the UK who did not use medical terms confidently feared looking stupid, and this led to delays in reporting signs of deterioration (Andrews & Waterman 2005). Clinical decision-making involves knowledge of the biosciences (Jordan 1994), knowing the patient and past experiences (Cioffi 2000a, Banning 2008). Although 70–80% of AEs in complex health-care systems may result from human error, organizational systems contribute to the problem (Wilson *et al.* 1995, Reason 2000) and the EWS literature provides some solutions.

Solutions

Achieving good patient outcomes in complex health-care environments is challenging, but national and local systems may improve patient safety.

Patient safety: a national imperative

The incidence of SAEs and negligence in hospitalized patients is receiving serious attention at national level in developed health-care systems (Smith *et al.* 2006). In the USA, concerns have been raised since the 1950s (Brennan *et al.* 1991, Dubois *et al.* 1987a,b, Duckett & Kristofferson 1978, Roemer *et al.* 1968). The US Institute for Healthcare Improvement (IHI) initiated the 100 000 Lives Campaign (Berwick *et al.* 2006), and the Agency for Healthcare Research and Quality (AHRQ) published Patient Safety Indicators (PSIs) in the early 1990s. More recently, the UK National Patient Safety Agency (NPSA) (2007a) has explored the reasons underlying 66 deaths resulting from failure to recognize patient deterioration. The UK national guidelines, MEWS/EWS charts and calling (trigger) criteria are available for the management of acutely ill ward patients (NICE 2007, Centre for Maternal and Child Enquiries 2008, Smith and Resuscitation Council UK 2010, National Patient Safety Agency 2007b, Smith *et al.* 2008a,b, Institute for Healthcare Improvement & Luton & Dunstable Trust Hospitals 2011).

Patient safety: local organizational approaches

Human error is a prominent cause of avoidable AEs and accounts for 57% of all cases (Wilson *et al.* 1999), even for the best-trained and best-qualified health-care providers. Therefore, insight into the causes of error might expedite the development of prevention strategies (Wilson *et al.* 1999) that move away from blaming clinicians who may have erred towards understanding the failure of complex systems. Institutions need to develop systems that are as 'failsafe' as possible. The roles of fatigue (Nocera & Khursandi 1998) and sleep deprivation (Leape 1997) also need further research.

Patient safety features prominently in hospital management systems. A distinction needs to be drawn between a person approach that emphasizes human error and blaming, and a system approach that looks for solutions to clinical mishaps within the organization and encourages reporting of AEs and 'near misses' (see Appendix) plus learning from these events (Reason 2000). A combination of approaches is recommended (Wakefield *et al.* 2005). To encourage reporting, effective communication systems need to be in place.

A standardized communication system designed for nurses to report a critical situation is the Situation–Background–Assessment–Recommendation (SBAR) technique (Toronto Rehab 2010) used in the USA, Canada and UK. There is little empirical data to show the effectiveness of the SBAR (Gazarian *et al.* 2010). The MEWS/EWS system is an organizational approach aimed at identifying and responding to deteriorating patients to prevent SAEs.

Introduction of early warning scoring systems

Human error may be limited by a simple scoring system for early recognition of abnormal physiological measurements. In 1997 Morgan *et al.* (1997) in the UK were the first to develop and publish the EWS of five physiological parameters not to predict outcome (Morgan & Wright 2007), but to serve as a track and trigger system (TTS) to identify early signs (ES) (Jacques *et al.* 2006) of deterioration. The EWS systems that have been introduced across the UK (Hogan 2006) have been modified (MEWS) and a standardized EWS (SEWS) (Barlow *et al.* 2006, Paterson *et al.* 2006, Gordon & Beckett 2007) was developed in Scotland (Paterson *et al.* 2006) in 2003 (see definitions in Appendix).

Evaluation of early warning scoring systems

Validity and reliability. In view of the nationwide implementation of MEWS/EWS observation charts in certain developed countries it was surprising that a search of CINAHL and PubMed databases failed to uncover criteria for validating MEWS/EWS vital signs observation charts.

An instrument can be reliable without having validity (Twomey *et al.* 2007). There is evidence of inter-rater and intra-rater reliability variability in the measurement of physiological parameters (NICE 2007), as included in MEWS systems. Potential confounders, affecting the reliability of an instrument, include haphazard variability in nurse decisions (Twomey *et al.* 2007), the so-called 'human element of reliability' (Subbe *et al.* 2007) and the reliability of electronic measurement devices. Such variation increases the error component of measurements: some of this may be random.

Seven studies validating MEWS/EWS systems, all observational, were located (Table 3). Deployment of consensus methods was not reported. Two studies addressed case mix and clinical setting (Subbe *et al.* 2001, Cuthbertson *et al.* 2007) as limitations of the MEWS: cut points for each parameter may not be generalizable across broad diagnostic groups (Subbe *et al.* 2001)

Table 3
Modified early warning score (MEWS systems) subjected to scientific enquiry for reliability and validity testing*

	Authors	*Study objective*	*Outcome measures*	*Sample size*	*Findings*
Experimental studies None					
Observational cohort studies (analytical) Prospective studies Prospective cohort study Validation of a MEWS in medical admissions No comparison group	Subbe *et al.* (2001)	To collect physiological data [systolic blood pressure, heart rate, respiratory rate, temperature, level of consciousness (AVPU)] prospectively on all patients admitted to the medical admissions unit and then to calculate a MEWS from previously published scoring criteria (Morgan *et al.* 1997, Stenhouse *et al.* 2000)	Death, intensive care unit (ICU) admission, high-dependency unit (HDU) admission, cardiac arrest, survival, hospital discharge at 60 days	Vital sign readings of 673 patients on a medical admissions unit were recorded twice daily for 5 days Single-centre study	Scores of 5 or more ('critical score'/'ScoreMax') were associated with increased risk of death (OR 5.4, 95% CI 2.8–10.7), ICU admission (OR 10.9, 95% CI 2.2–55.6) and HDU admission (OR 3.3, 95% CI 1.2–9.2). Scores of 4 demonstrated that patients were at increased risk of catastrophic deterioration requiring higher levels of care
A prospective observational study The value of MEWS in surgical in-patients No comparison group	Gardner-Thorpe *et al.* (2006)	To calculate the sensitivity, specificity, positive predictive value and negative predictive value of the aggregated MEWS	The aggregated MEWS as a predictor of critical care admission	334 patients Single-centre study	Sensitivity of the aggregated MEWS threshold of 4 was 75% for intensive treatment unit (ITU)/HDU admission with a specificity of 83% for respiratory rate, heart rate, systolic blood pressure, urine output, temperature and level of consciousness (AVPU) An early warning system is an important risk-management tool for all surgical inpatients
An observational, population-based single-centre study Worthing physiological scoring system (PSS): derivation and validation of a physiological early-warning system for medical admissions No comparison group	Duckitt *et al.* (2007)	To derive and validate a physiological EWS system for medical admissions using respiratory rate, heart rate, arterial pressure, temperature, oxygen saturation and level of consciousness (AVPU)	A simple validated scoring system to predict mortality in medical patients with precise 'intervention-calling scores' derived from the data with an intervention-calling score set at 2	4286 patients Single-centre study	Sensitivity of the Worthing PSS at a cut point of 3 for the aggregated score was 63%, comparing well with the EWS (60%); specificity was 72% compared with the EWS (67%) but for an 'intervention-calling score' above 2 mortality increased >10%

Table 3
(Continued)

	Authors	*Study objective*	*Outcome measures*	*Sample size*	*Findings*
Prospective cohort study Reproducibility of physiological track-and-trigger (TT) warning systems for identifying at-risk patients on the ward	Subbe *et al.* (2007)	To assess inter-rater and intra-rater reliability of the physiological measurements, aggregate scores and triggering events of three TT systems: the medical emergency teams [medical emergency team (MET), the MEWS and the ASSIST].	Reproducibility of TT systems using systolic blood pressure, temperature, respiratory rate, pulse rate, level of consciousness, urine output as variables	424 sets of observations from general medical and surgical wards Single-centre study	Significant variation in the reproducibility of the TT systems used by different health care professionals. Better levels of agreement on triggers than on aggregate scores. Simpler systems had better reliability
Retrospective and prospective studies					
An early warning scoring system for detecting developing critical illness	Morgan *et al.* (1997)	To devise a simple scoring system which could be readily applied by junior doctors and nursing staff to identify patients developing critical illness	An early warning scoring system using systolic blood pressure, heart rate, respiratory rate, temperature, level of consciousness (AVPU)	100 patients on surgical wards Single-centre study	A scoring system with deviations from normal scores (0) ranging from 1 to 3 (upper and lower) proved to be not too sensitive after testing
Comparative cohort study Can physiological variables and early warning scoring systems allow early recognition of the deteriorating surgical patient? Comparison group	Cuthbertson *et al.* (2007)	To test the ability of physiological variables (heart rate, respiratory rate, oxygen saturation, blood pressure and temperature), either alone or in existing EWS systems, to predict major deterioration in a patient's condition and attempt to derive functions with superior accuracy	EWS systems with good discriminatory power Physiological variables with discriminant functions that have a high predictive ability to detect differences between patients requiring admission to ICU	136 patients Single-centre study	Significant physiological differences between patient groups with regard to heart rate ($P < 0.001$, AUC = 0.7), respiratory rate ($P < 0.001$, AUC = 0.71) and oxygen saturation ($P < 0.001$, AUC = 0.78) but not for systolic blood pressure or temperature Discriminant functions were derived for heart rate and respiratory rate that have a high predictive ability ($P < 0.0001$, AUC = 0.86–0.90) to determine differences between groups of patients 6–8 hours before admission to ICU Existing EWS have comparatively good discriminatory power (AUC = 0.83–0.86) but many rules. Discriminant functions are more difficult to calculate at the bedside

Table 3
(Continued)

	Authors	*Study objective*	*Outcome measures*	*Sample size*	*Findings*
Meta-analysis† *Systematic review* Systematic review and evaluation of physiological TT warning systems for identifying at-risk patients on the ward	Gao *et al.* (2007)	To describe published TT systems and the extent to which each has been developed according to established procedures; to review the published evidence and available data on the reliability, validity and utility of existing systems; and to identify the best TT for timely recognition of critically ill patients.	A systematic review of published papers and retrospective cohort study.	36 papers and 15 datasets representing 30 hospitals in the UK, 1 in Wales	None of the published studies met all methodological quality standards. All TTs in the 15 datasets were different and were modified for local needs, having different physiological variables, scores and trigger thresholds. Sensitivities and positive predictive values of data sets were low, with median (quartiles) values of 43.3 (25.4–69.2) and 36.7 (29.3–43.8), respectively Of the 25 EWS, seven included the parameter 'concern'. Available local TTs showed little evidence of reliability, validity and utility and available data were insufficient to identify the best TT system.

ASSIST, assessment score of sick-patient identification and step-up in treatment; AUC, area under curve; CI, confidence interval; OR, odds ratio.
*Studies have been ordered chronologically.
†The systematic review has been included in the table for completeness of reporting.

Table 4
Modified early warning score (MEWS system) subjected to evaluation of performance*

	Authors	*Study objective*	*Outcome measures*	*Sample size*	*Findings*
Experimental studies None					
Observational studies (analytical) Prospective studies Prospective cohort Prospective evaluation of a modified EWS to aid earlier detection of patients developing critical illness on a general surgical ward No comparator group	Stenhouse *et al.* (2000)	To prospectively evaluate the EWS for respiratory rate, heart rate, temperature, central nervous system (AVPU score), urine output and systolic blood pressure for 1 month. After modifying scores for urine output, temperature and systolic blood pressure the EWS were prospectively evaluated for a further 9 months	Earlier detection of critical illness on a general surgical ward	206 patients on two general surgical wards Single-centre study	After 1 month scores were modified for urine output, the sensitivity of scores for temperature was decreased and scores for systolic blood pres sure were normalized (i.e. interpreted as % deviation from the patient's norm). Patients with a total score of 4 were reviewed by ward medical staff leading to earlier referral to the intensive care unit (ICU) of 26 patients compared with 11 patients from a surgical ward not using the MEWS The MEWS decreased APACHE II scores on admission to ICU meaning that patients were less ill on admission
Prospective cohort Effect of introducing the MEWS on clinical outcomes, cardio-pulmonary arrests and intensive care utilization in acute medical admissions	Subbe *et al.* (2003))	Primary aim: to prospectively measure the effect of introducing the MEWS on the rates of ICU and high-dependency unit (HDU) admission, cardio-pulmonary arrest and mortality over a 3-month period Secondary aim: to collect physiological data [systolic blood pressure, heart rate, respiratory rate, temperature, neurological status (AVPU score)] from patients before critical care admission, cardio-pulmonary arrest or death in order to improve the discrimination of the score	The ability of the MEWS to identify patients at risk	1695 study patients (medical admissions unit, medical HDU, ICU, following cardio-pulmonary arrest and death) 659 control patients (data from a 2001 study) Single-centre study	Overall, mortality was unchanged between the control group and the study group (patients with a MEWS) irrespective of risk band. There was an increased inci dence of cardio-pulmonary arrests in the study group in patients with a MEWS 3 or 4 (intermediate risk). A scoring system did not change outcomes in acute medical admissions. A MEWS of 4 triggered urgent medical referral and critical care outreach team review. Respiratory rate was the best discriminator to identify patients at risk. The MEWS is suitable for identifying patients at risk of deterioration.

Table 4
(Continued)

	Authors	*Study objective*	*Outcome measures*	*Sample size*	*Findings*
Use of a patient information system to audit the introduction of MEWS No comparator group	Quarterman *et al.* (2005)	To audit the introduction of MEWS for physiological parameters (airway, respiratory rate, systolic blood pressure, heart rate, AVPU score, temperature, urine output) using the Sunrise Clinical Manager 3.03 patient information system	The relationship between patient outcome, trigger score, age and medical speciality	365 admissions in 10 medical and general surgical and orthopaedic wards Single-centre study	The study showed a significant relationship between trigger score and patient outcome. Increasing MEWS score was associated with worse outcome across a range of specialities (medical and surgical) and nursing staff should use a patient information system to audit MEWS scores An aggregated MEWS of 3 or more triggered the need to call for assistance but survival was worse at this level ($P < 0.004$)
Research design not reported but appears to be a prospective study Long-term effect of introducing an EWS on respiratory rate charting on general wards	McBride *et al.* (2005)	To study the short- and long-term effects of introducing a new patient vital signs chart and the MEWS, which incorporates respiratory rate on the prevalence of respiratory rate recording in six general wards	The effects of a MEWS on respiratory rate recordings on general wards	Six general wards Single-centre study	There was a long-term beneficial effect of introducing the MEWS system on respiratory rate recording into the general wards
Longitudinal surveys The effect of a critical care outreach service and an EWS system on respiratory rate (RR) recording on the general wards Comparator group	Odell *et al.* (2007)	To determine whether the implementation of a Reading-MEWS (R-MEWS) system is associated with an increased recording of respiratory rate in hospital inpatients, and whether the presence of a critical care outreach service has a further impact on the recording of patients' vital signs (respiratory rate, heart rate, systolic blood pressure, level of consciousness, urine output).	The link between RR recording rates and the R-MEWS	2638 adult, non-obstetric acute inpatients in two hospitals between 2001 and 2005	RR recording increased from 6.0% (first survey) to 77.9% (last survey), which correlated with the incremental implementation of the R-MEWS system and may have been enhanced by a critical care outreach service

Table 4
(Continued)

	Authors	*Study objective*	*Outcome measures*	*Sample size*	*Findings*
Retrospective and prospective cohort study Prediction of in-hospital mortality and length of stay using an EWS system: clinical audit Comparator group	Paterson *et al.* (2006)	To assess the impact of a standardized early warning scoring (SEWS) system on physiological observations (respiratory rate, temperature, blood pressure, heart rate, conscious level and oxygen saturation) and patient outcomes (in-hospital mortality, length of stay, transfer to critical care) including staff satisfaction in unselected acute admissions on admission.	Completeness of documentation of physiological parameters, in-hospital mortality, and hospital length of stay	Two cohorts of medical and surgical emergency admissions to one area. Total of 848 patients: 413 pre-SEWS and 435 post-SEWS Single-centre study	A SEWS improved documentation of physiological parameters ($P < 0.001$–0.005) with the exception of oxygen saturation ($P = 0.069$), and at a score of ≥4 correlated with in-hospital mortality, and helped predict length of stay: in-hospital mortality decreased, there was an increased staff awareness of critical illness and prompt, earlier intervention
Cross-sectional studies					
Cross-sectional survey Signs of critical conditions and emergency responses (SOCCER): a model for predicting adverse events in the inpatient setting	Jacques *et al.* (2006)	To establish the association between recordings of disturbed physiological variables and adverse events using criteria not restricted to medical emergency team (MET) calling criteria	The association between recordings of disturbed physiological variables and adverse events using criteria not restricted to MET calling criteria	3046 inpatients multicentre study	Confirmation of current MET call criteria but these need to be expanded and to be modelled to meet individual hospital patient needs
Cross-sectional correlational survey Identifying level 1 patients. A cross-sectional survey on an inpatient hospital population Comparator group	Morrice & Simpson (2007)	To identify the characteristics of level 1 patients [using the Intensive Care Society (ICS) Levels of Care] 'at risk' of deterioration on general wards and to explore how these differed from the other levels of care (0 and 2)	A comparison of physiological (systolic blood pressure, heart rate, respiratory rate, temperature, central nervous system, urine output) and demographic variables using three validated tools: EWS, TISS-28 and APACHE II	Stage 1: 351 general adult inpatients Stage 2: 67 patients Single-centre study	(Only EWS data are reported on in this review) Blood pressure, heart rate and temperature were not useful in identifying 'at risk' patients EWS were useful for identifying level 1 patients but a triggering level of 4 for total EWS was not sensitive enough for the ICS Classification of Levels of Care. EWS triggered at a score of 4. Study results did not support the view that a physiological scoring system such as the EWs would correspond well with the ICS level of care.

Table 4
(Continued)

	Authors	*Study objective*	*Outcome measures*	*Sample size*	*Findings*
Opinions of respected authorities based on clinical experience, descriptive studies, or reports of expert reviews†					
Review and performance evaluation of aggregate-weighted 'track and trigger' systems (AWTTS) No reference to PRISMA or earlier guidelines for a sys tematic review	Smith *et al.* (2008a)	To describe the AWTTS in clinical use and assess their ability to discriminate between survivors and non-survivors of hospital admission, based on an initial set of vital signs [heart rate, systolic and diastolic blood pressure, respiratory rate, temperature, neurological status using AVPU or Glas gow coma scale (GCS), oxygen saturation]	A systematic literature review of AWTTS to analyse their ability to discriminate between survivors and non-survivors of hospital admission	33 unique AWTTS A database of 9987 admission vital signs datasets	Wide range of AWTTS in use but similar. 12 (36%) discriminated reasonably well. The top four included age; the top two included temperature. Physiology can be used to predict outcome, but further work is required to improve AWTTS models. Most differ only in minor variations in weightings for physiological abnormality and/or the cut points between physio logical weighting bands. For temperature there are 19 weighting systems; 15 for respiratory rate, 15 for blood pressure; 12 for heart rate and 6 for AVPU.
A review, and performance evaluation, of single-parameter 'track and trigger' systems (SPTTS)	Smith *et al.* (2008b)	To describe the SPTTS in clinical use and measure their sensitivity and specificity when using admission vital signs data (heart rate, respiratory rate, systolic blood pressure, temperature, oxygen saturation (high and low of each) and reduced consciousness) for predicting in-hospital mortality	A systematic literature review of physiologically based SPTTS for predicting in-hospital mortality	A database of 9987 admission vital signs datasets 39 unique classes of SPTTS identified (30 evaluated)	Considerable variation in the physiological variables used and significant variation in the physiological values used to trigger a medical emergency or critical care outreach team; marked variation in sensitivity (7.3–52.8%) but too low to confidently identify patients at risk of in-hospital death, specificity (69.1–98.1%), positive predictive values (13.5–26.1%), negative predictive values (92.1–94.2%) and the potential number of calls triggered (234–3271).
Meta-analysis‡ *Systematic review*					

Table 4
(Continued)

	Authors	*Study objective*	*Outcome measures*	*Sample size*	*Findings*
Nurses' role in detecting deterioration in ward patients: systematic literature review	Odell *et al.* (2009)	To identify and critically evaluate research investigating nursing practice in detecting and managing deteriorating general ward patients	A systematic literature review guided by recommendations of the Quorum of Reporting of Meta-analyses (QUORUM) conference	Review of 14 published studies between 1990 and 2007 describing nursing observations (vital signs) on deteriorating adult patients in general hospital wards.	Suboptimal care described as failing to respond to abnormal physiology and to report deterioration and not recognizing patient deterioration is supported in the literature. Factors include nurse staffing levels, the level of knowledge and experience of ward nurses, educational opportunities and nurse–doctor communication. Taking vital signs observations is often delegated to health-care assistants. Intuition, knowing the patient and pattern recognition are important in identifying deterioration. The context within which deterioration is detected and reported is an important consideration that will influence the design of more effective education and support systems.

APACHE II, Acute Physiology and Chronic Health Evaluation score (this is not an early warning scoring system but is used in ICUs to grade patients' health status); TISS, the therapeutic intervention scoring system.
*Studies have been ordered chronologically. AVPU, see Appendix.
†These reviews contain important information and have been included to present a complete overview of the field.
‡The systematic review has been included in the table for completeness of reporting.

(respiratory disease, cardiac disease) and settings (patients needing/not needing admission to ICU).

Studies were limited by factors such as: single-centre locations (all); low numbers of patients (most); incomplete data (Duckitt *et al.* 2007); short periods of data collection (Subbe *et al.* 2001); taking and recording repeated measurements within an hour; not reporting improvement or deterioration after interventions (Subbe *et al.* 2007); possible sample bias because of the legitimate exclusion of patients unwilling or unable to give consent (Subbe *et al.* 2007); and not identifying patients who, if managed differently, could have remained on general wards instead of being admitted to ICU (Subbe *et al.* 2001).

All the studies listed in Table 3 measured heart rate and respiratory rate. Of the six papers included in the systematic review (Gao *et al.* 2007) describing MEWS (excluding Subbe *et al.* 2001), all measured heart rate, respiratory rate, blood pressure, urine output and consciousness; four measured temperature; and two measured oxygen saturation. The finding for urine output measurement is not consistent with results summarized in Table 3, where it was found to be missing in 97.1% of sets of observations in one of the five studies (Subbe *et al.* 2007).

One systematic review (Gao *et al.* 2007) of the validity, reliability and utility of published physiological EWS used outside critical care areas was identified. In this review, the number of monitored parameters described in publications for TTS varied greatly in Australasia (5–32), USA (12–19), England (8) and Canada (15). Reviewers conclude that evidence is lacking for the sensitivity, specificity and predictive validity of published TTS, and for the optimum system for early recognition of critical illness (Gao *et al.* 2007). This implies that if ward staff were to rely only on these systems, a large number of patients requiring intervention may be missed, therefore clinical judgment is essential (Gao *et al.* 2007).

Utility of MEWS/EWS systems. Although systematic reviews and meta-analyses of randomized controlled trials (RCTs) are regarded as the 'gold standard' of evidence on which to base practice (Hudson *et al.* 2008, Grimes & Schulz 2002), the evidence-based practice (EBP) movement has been criticized for its authoritarian approach (Holmes *et al.* 2006). Although RCTs are considered the strongest form of evidence, the complexity of introducing an EWS system, with an accompanying educational programme and audit, might suggest that a single RCT of an early warning scoring system might be almost impossible (Quarterman *et al.* 2005, Grypdonck 2006, Hudson *et al.* 2008): it would be impracticable to randomize individual patients on the same ward to receive different levels of monitoring (Robson 2002). Pragmatic cluster RCTs or stepped-wedge trials would be feasible, but expensive (Brown & Lilford 2006).

Aggregate weighted track and trigger systems (AWTTS) and EWS/MEWS used in adult general ward settings that have been subjected to various levels of scientific enquiry are described within the hierarchy of evidence (Grimes & Schulz 2002) (Table 4). Only observational (and no experimental) studies on MEWS/EWS systems were located, as in the 2007 Cochrane review (McGaughey *et al.* 2007). This review describes two cluster-randomized control trials on the effectiveness of the MET system, which is outside the scope of this study.

Of the 11 papers reviewed (Table 4), one met all inclusion criteria (Stenhouse *et al.* 2000), describing a population of adult patients in surgical wards outside critical care areas and emergency departments. Two studies were included because they were undertaken on surgical wards (McBride *et al.* 2005, Quarterman *et al.* 2005). One study involved the association between a MEWS and respiratory rate recording (Odell *et al.* 2007), one tested a validated EWS (Morrice & Simpson 2007) and three explored clinical outcomes for the purpose of predicting patients at risk (Subbe *et al.* 2003, Jacques *et al.* 2006, Paterson *et al.* 2006). Three studies were relevant systematic literature reviews.

There is considerable variation in the physiological parameters used in TTS, and significant variation in the physiological values used to trigger a response. Sensitivity varies more than specificity and number of calls potentially triggered (Smith *et al.* 2008b). Nine papers (Table 4) included EWS that measured respiratory rate which was found to be the best discriminator of clinical outcomes (Subbe *et al.* 2003).

Recording of vital signs, particularly respiratory rate, improved with the introduction of MEWS vital signs charts (McBride *et al.* 2005, Odell *et al.* 2007). A large Australian cross-sectional study by record review of 26 early signs and 21 late signs concluded that many abnormal physiological variables were strongly associated with SAEs (Jacques *et al.* 2006). The four most effective aggregate weighted TTS able to discriminate between survivors and non-survivors incorporated age, and the top two incorporated temperature monitoring (Smith *et al.* 2008a). Of 23 AWTTS, only one incorporated 'nurse concern'. Reported early signs frequently associated with SAEs included systolic blood pressure of 80–100 mmHg, alteration in mentation and oxygen

saturation within the range of 90–95% (Cuthbertson *et al.* 2007). Severity of illness is indicated by an escalating value of the EWS (Mohammed *et al.* 2009) above a score of 3.

A prospective cohort study suggested that a EWS score of 4 was more effective in indentifying surgical ward patients at risk of deterioration than other monitoring systems, and these patients were admitted to ICU before catastrophic deterioration (Stenhouse *et al.* 2000). A significant relationship was shown between increasing MEWS score and worse outcome across a range of specialities (medical and surgical) (Quarterman *et al.* 2005). Intensive staff training before implementation of early warning scoring systems (Paterson *et al.* 2006) had beneficial effects.

Limitations of MEWS/EWS systems

Despite their clinical usefulness, MEWS/EWS systems have limitations:

- There is no single validated scoring tool across diagnoses (Barlow *et al.* 2006, Bell *et al.* 2006) or disciplines (Goldhill 2005); incorporating the diagnosis into a scoring system might make it too complex and less effective (Subbe *et al.* 2001).
- The specific physiological variables chosen and the scores allocated to values in most EWS have not been prospectively validated (Goldhill 2005, Cuthbertson *et al.* 2007); neither is the implementation based on robust research evidence (McGaughey *et al.* 2007).
- If single parameters are ignored, severely ill patients can be missed.
- Scoring systems have the potential to increase workload (Cuthbertson & Smith 2007): if scoring is inaccurate or thresholds are incorrect, a cascade of unnecessary events will be triggered.
- Inconsistency in neurological assessment. Not all AWTTS (Table 1) include the Glasgow Coma Scale (GCS) (Appendix) for assessment of conscious level, preferring the alert/responds to voice/responds to pain/unresponsive (AVPU) system (Appendix). Although it may be possible to convert from GCS to AVPU, to convert from AVPU may be impossible (Smith *et al.* 2008a).
- All TTSs assist in identifying parameters that predict death, but the important question is how do clinicians establish who will survive and who should be treated in the ICU, as some patients may be harmed by intensive care interventions (Fletcher & Cuthbertson 2010).
- Skin tone, sweating, nausea and other clinical signs, such as nurses' intuitive assessment of the patient being 'just not right' (Cioffi 2000a) are documented but it is unclear whether EWS charts are designed to include clinical signs such as, for example, 'patient looks well/unwell' (Centre for Maternal and Child Enquiries 2008).
- No published studies from the developing countries on the development and implementation of EWS systems were located.

Conclusions

Better monitoring of patients implies better care, but searches indicate that the impact of vital signs' monitoring and MEWS/EWS systems has yet to be tested in large, randomized controlled clinical trials. Nevertheless, there is sufficient evidence from observational work that MEWS/EWS systems facilitate recognition of abnormal physiological parameters in deteriorating patients, alerting ward staff to the need for intervention.

Over the past decade, studies into patient safety have proliferated (Lilford *et al.* 2006) but there are concerns about the quality of some of this research (Brown *et al.* 2008), and there is little consensus over methods. Consequently, the UK Medical Research Council sponsored research to provide methodological guidance on evaluation of patient safety interventions (National Patient Safety Agency 2004) and a framework for randomized control trials for complex interventions (Medical Research Council 2000). Research into AEs in developing countries is sparse.

Resources are needed for context-driven interventions, training and evaluation. Such evidence is essential to determine the effects (if any) of MEWS/EWS systems in improving patient safety and eliminating avoidable AEs, particularly those associated with suboptimal care of acutely ill patients on general wards. Research into the performance of locally validated MEWS/EWS observation charts would be expedited by linking with the World Patient Safety Alliance and the International Partnership for Acute Care Safety (IPACS) initiative, endorsed by the World Health Organization (WHO). Outcomes of an international WHO study of antecedents to cardiac arrest, death and emergency intensive care admission will inform future developments (Gao *et al.* 2007).

There is significant variability in MEWS/EWS systems concerning number of physiological parameters monitored, cut points for parameters, triggers for scoring, sensitivity and specificity. Most studies measured heart

rate and respiratory rate, some measured blood pressure, urine output and consciousness. A few measured temperature and oxygen saturation. Of these physiological parameters, respiratory rate is the most sensitive indicator of deterioration, but it is poorly recorded. When MEWS vital signs charts are used, recording improves. Too few MEWS/EWS vital signs charts include clinical signs of deterioration requiring subjective, intuitive interpretation of a change in the patient's condition.

Implications for nursing management

Recording vital signs is not enough. Nurses need to: record all vital signs frequently; recognize deterioration and the urgency of a situation; summon assistance more expert than a junior doctor without delay; communicate concerns clearly, sensibly and with confidence; and give a deadline for a response to a call.

There is potential for improvement in recording, particularly of respiratory parameters.

National Patient Safety Guidelines and local organizational reporting and learning mechanisms are imperative. To improve reporting of AEs and 'near misses', managers should avoid blame, and reassure nurses that human error is inevitable. Complex systems can fail and research is needed to make detection of clinical deterioration as 'failsafe' as possible.

Nurse managers of general wards in developing countries should consider implementation of MEWS/EWS observation charts validated at national level. Developing countries are joining global communication highways, and the time is right for our inclusion in discussions on patient safety concerning the recognition and management of early warning signs of deterioration to prevent SAEs. Accordingly, a MEWS/EWS system appropriate to developing countries should be developed.

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Appendix: Abbreviations and definitions

Abbreviation	*Glossary*	*Definition*
AE	Adverse events	Unintended injuries or complications resulting in death, disability or prolonged hospital stay that arise from health care management (Baker *et al.* 2004)
AVPU	A = alert, V = responding to verbal commands, P = responding to painful stimuli, U = unresponsive	A clinical classification system of level of consciousness
	Calling criteria	Activate a rapid response system when one or more routinely measured physiological variables fall within an extremely abnormal range (Goldhill *et al.* 1999, Smith *et al.* 2006)
CCOS	Critical care outreach team/service	A team consisting of dedicated critical care trained and experienced nurses who respond to referrals from all areas of a hospital (Odell *et al.* 2007)
GCS	Glasgow Coma Scale	A clinical tool used to assess the degree of consciousness and neurological functioning – and therefore severity of brain injury – by testing motor responsiveness, verbal acuity and eye opening (http://www.weitzlux.com/traumaticbraininjury_672.html)
METS	Medical emergency team	An Australian system first described in 1995 comprising a medical-led team summoned to hospital wards for deteriorating patients for example having a range of specific conditions (e.g. pulmonary oedema), physiological abnormalities (e.g. pulse rate <40 or >120 beats/minute) and when urgent help was required at any time (Lee *et al.* 1995).

Appendix: Abbreviations and definitions

(Continued)

Abbreviation	*Glossary*	*Definition*
	'Near misses'	Defined by the National Patient Safety Agency (2004) as 'any patient safety incident that had the potential to cause harm but was prevented, resulting in no harm to patients'
NFR	Not for resuscitation	Predetermined clinical decision that no active resuscitation measures will be taken.
SAE	Serious adverse event	An untoward occurrence that: (a) results in death; (b) is life-threatening; (c) requires prolongation of existing hospitalization; or (d) results in persistent or significant disability or incapacity (National Patient Safety Agency 2009); or as described in SAE literature (e) results in avoidable in-hospital cardiac arrest without a pre-existing NFR order; and (f) requires urgent and unanticipated admission to an intensive care unit (ICU) (Story *et al.* 2004, Smith *et al.* 2006)
SEWS	Standardized early warning score/Scottish EWS	The SEWS includes oxygen saturation monitoring in addition to respiratory rate, temperature, blood pressure, heart rate and level of consciousness (Paterson *et al.* 2006).
TTS	Track and trigger system	An EWSS to identify signs of clinical and physiological deterioration (Jacques *et al.* 2006)

Participant Code Number…D……N……..

SELF-ADMINISTERED STRUCTURED QUESTIONNAIRE

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Title of study:

The development, validation and testing of a vital signs monitoring tool for early identification of deterioration in adult surgical patients

INFORMATION: There are **5 sections** to be completed

The **purpose** of this self-completed questionnaire is to ask your opinion on the **design** of a **preliminary** prototype **early warning vital signs monitoring chart** (Appendix 6) for use in **general wards**:

- to help nurses identify patients who show signs of **physiological deterioration**
- and **clinical deterioration**
- and who may be at risk of a **serious adverse event** (cardiac arrest, unexpected admission to ICU or death).

Based on these findings, the researcher will amend the chart if necessary.

The attached consent form is optional. If you complete the researcher's copy of the consent, please detach now and place it in the **box** marked **CONSENT**: MEWS RESEARCH. A copy is provided for you. The return of a questionnaire is assumed to be consent to use the data.

Please place the **completed questionnaire** in the **box** marked **QUESTIONNAIRE**: MEWS RESEARCH in the ward registrar's office.

If you prefer an electronic copy of this questionnaire please request as per my e-mail address above. Thank you.

SECTION A: VARIABLES: early warning physiological and **clinical** signs of **deterioration.**

Please answer all the questions.

A1. Please rank the order of importance of each of the following **physiological** variables for **early recognition** of signs of **deterioration**.

1 = most important and 7 = least important.

		Ranking
A1.1	Respiratory rate	
A1.2	Heart rate	
A1.3	S_aO_2	
A1.4	Systolic blood pressure	
A1.5	Temperature	
A1.6	Neurological status/conscious level	
A1.7	Urine output	

A2. Please rank the order of importance of each of the following **clinical** variables for **early recognition** of signs of **deterioration**:

1 = most important and 10 = least important.

		Ranking
A2.1	Perfusion – capillary refill	
A2.2	Skin colour – pallor/cyanosis	
A2.3	Pain – severe, moderate, mild	
A2.4	Sweating	
A2.5	Pain medication	
A2.6	Wound oozing	
A2.7	Girth measurement	
A2.8	Blood glucose	
A2.9	Finger prick Hb	
A2.10	Looks unwell	

SECTION B: (MODIFIED) EARLY WARNING SCORE (MEWS)[1-3]

An EARLY WARNING SCORE (EWS) is a simple physiological scoring system suitable for use at the bedside utilising routine observations taken by nurses to identify patients at risk of potential and catastrophic deterioration in a busy clinical area for the purpose of securing skilled clinical help. Studies have since validated a MODIFIED EWS (MEWS). The scoring system below with the respective values for each physiological parameter is taken from the literature. The values for discrete physiological parameters (for example: heart rate of 40 bmp) are scored (MEWS = 2) but an aggregate weighted score can also be calculated for all the parameter readings taken at a particular time. If you disagree with the values for each score please give suggested values that you think are suitable for the South African context.

Please answer all the questions. Cross only one response for each question.

1. 0 = normal value; 1 (upper or lower) = early sign of deterioration; 2 (upper or lower) = serious sign of deterioration; and 3 = critical condition requiring urgent attention. You will notice that there are no values for certain scores for some of the parameters.

2. In the shaded section indicate whether you **agree or disagree** with the validated scores for EACH of the following variables for a South African context:

3. If you disagree **give a suggested value**.

B1 **RESPIRATORY RATE** MEWS score**:**

3	2	1	0	1	2	3
	9 or less		9-14	15-20	21-29	30 or more

ANSWER:

B1.1 Agree [1] **Disagree** [0]

B1.2 Suggested values:

3	2	1	0	1	2	3

SECTION B (continued): **MODIFIED EARLY WARNING SCORES (MEWS)**

Please answer all the questions. Cross only one response for each question.

1. 0 = normal value; 1 (upper or lower) = early sign of deterioration; 2 (upper or lower) = serious sign of deterioration; and 3 = critical condition requiring urgent attention. You will notice that there are no values for certain scores for some of the parameters.

2. In the shaded section indicate whether you **agree or disagree** with the validated scores for EACH of the following variables for a South African context:

3. If you disagree **give a suggested value**.

B2 **HEART RATE MEWS score**

3	2	1	0	1	2	3
<35	40 or less	41-50	51-100	101-110	111-129	130 or more

ANSWER:

B2.1 Agree [1] **Disagree** [0]

B2.2 Suggested values:

3	2	1	0	1	2	3

B3 S_aO_2 MEWS score

3	**2**	**1**	**0**	**1**	**2**	**3**
<85	**85-89**	**90-92**	**93+**			

ANSWER:

B3.1 Agree [1] **Disagree** [0]

B3.2 Suggested values:

3	**2**	**1**	**0**	**1**	**2**	**3**

SECTION B (continued): **MODIFIED EARLY WARNING SCORES (MEWS)**

Please answer all the questions. Cross only one response for each question.

1. 0 = normal value; 1 (upper or lower) = early sign of deterioration; 2 (upper or lower) = serious sign of deterioration; and 3 = critical condition requiring urgent attention. You will notice that there are no values for certain scores for some of the parameters.

2. In the shaded section indicate whether you **agree or disagree** with the validated scores for EACH of the following variables for a South African context:

3. If you disagree **give a suggested value**.

B4 **Systolic blood pressure MEWS score**

3	2	1	0	1	2	3
70 or less	71-80	81-100	101-179	180-200	200 or more	>250

ANSWER:

B4.1 **Agree** [1] **Disagree** [0]

B4.2 Suggested values:

3	2	1	0	1	2	3

B5 **Temperature MEWS score**

3	2	1	0	1	2	3
	35 or less		35-38.4		38.5 or more	

ANSWER:

B5.1 **Agree** [1] **Disagree** [0]

B5.2 Suggested values:

3	2	1	0	1	2	3

SECTION B (continued): **MODIFIED EARLY WARNING SCORES (MEWS)**

Please answer all the questions. Cross only one response for each question.

1. 0 = normal value; 1 (upper or lower) = early sign of deterioration; 2 (upper or lower) = serious sign of deterioration; and 3 = critical condition requiring urgent attention. You will notice that there are no values for certain scores for some of the parameters.

2. In the shaded section indicate whether you **agree or disagree** with the validated scores for EACH of the following variables for a South African context:

3. If you disagree **give a suggested value**.

B6 **Neurological status/conscious level MEWS score**

3	2	1	0	1	2	3
			Alert (GCS 15)[4]	Reacts to voice (GCS 14)	Reacts to pain (GCS 13-9)	Unresponsive (GCS 8<)

ANSWER:

B6.1 Agree 1 **Disagree** 0

B6.2 Suggested values:

3	2	1	0	1	2	3

B7 **Urine output MEWS score**

3	2	1	0	1	2	3
<20ml/hr	30ml/hr or less	50ml/hr or less	60ml/hr If normally anuric score 0	150ml/hr or more		

ANSWER:

B7.1 Agree 1 **Disagree** 0

B7.2 Suggested values:

3	2	1	0	1	2	3

SECTION C: Research 'Observation Chart' (Appendix 6 attached)

Please answer all the questions. Cross only one response for each question:

Indicate if you Strongly Agree (SA), Agree (A), are Undecided (U), Disagree (D) or Strongly Disagree (SD) with each of the following statements:	**SA**	**A**	**U**	**D**	**SD**
C1. The chart is very useful for the identification of **physiological** deterioration					
C2. The chart has limitations for the identification of **physiological** deterioration					
C3. The chart is very useful for the identification of **clinical** deterioration					
C4. The chart has limitations for the identification of **clinical** deterioration					

C5. OPTIONAL OPEN-ENDED QUESTIONS:

C5.1 The research chart has the following **limitations compared to the current observation chart** (Appendix 8 attached):

C5.2 The research chart has the following **strengths compared to the current observation chart** (Appendix 8 attached):

SECTION D: ALGORITHM FOR CALLOUT CRITERIA

Items D1.1-.7 below serve as a 'Physiological Track and Trigger System' to provide a threshold at which mandatory assistance is summoned.[5]

You are asked to indicate the ONE most appropriate category of professional you think should be called for each of the following situations in which a ward nurse is concerned about a change in a patients' condition.

Please answer all the questions. Cross only **one** response for each question:

D1. **If:** **Call the following person**:

ITEM	Most senior Sister (Professional Nurse)	Intern (MO) responsible for the patient	Registrar	Consultant
D1.1 the nurse is **worried about** the patient				
D1.2 Change in **respiratory rate:** D1.2.1 to less than 9/min				
D1.2.2 to 15-20/min				
D1.2.3 to 21-29				
D1.2.4 to more than 30/min				
D1.3 Change in **heart rate:** D1.3.1 to 40 bpm or less				
D1.3.2 to 41-50 bpm				
D1.3.3 to 101-110				
D1.3.4 to 111-129				
D1.3.5 to 130 or more				
D1.4 Change in **systolic BP:** D1.4.1 to 81-100 mmHg				
D1.4.2 to 71-80 mm Hg				
D1.4.3 to 70 mmHg or less				
D1.4.4 to 200 mmHg or more				

D1. (continued)

If: **Call the following person**:

ITEM	Most senior Sister (Professional Nurse)	Intern (Medical Officer) responsible for the patient	Registrar	Consultant
D1.5 Change in **pulse oximetry saturation:** D1.5.1 to 90-92%				
D1.5.2 to 85-89%, despite oxygen administration				
D1.5.3 to 85% and below, despite oxygen administration				
D1.6 Change in **conscious state:** D1.6.1 to Reacting to Voice (GCS 14)				
D1.6.2 to Reacting to Pain (GCS 13-9)				
D1.6.3 to Unresponsive (GCS 8<)				
D1.7 Change in **urine output:** D1.7.1 to less than 30 ml/hour				
D1.7.2 to less than 20ml/hour for 2 consecutive hours				
D1.7.3 to more than 150ml/hour				

(Adapted from Bellomo, Goldsmith, Uchino, Buckmaster, Hart, Opdam, Silvester, Doolan and Gutteridge, 2003)[6]

SECTION E: DEMOGRAPHICS

Cross the box that applies to you/insert information in blank spaces where applicable. Please answer all the questions.

E1.	What is your highest professional qualification?	
E2.	How long have you practised with this qualification?	☐ Years ☐ Months
E3.	How long have you been working at the hospital?	☐ Years ☐ Months
E4.	How long have you been working in this ward?	☐ Years ☐ Months
E5.	Have you attended a specific course on the **early** identification of signs of clinical and physiological deterioration (i.e. not CPR training)?	☐ Yes ☐ No

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1. Subbe CP, Kruger M, Rutherford P, Gemmel L. Validation of a modified Early Warning Score in medical admissions. *QJM : monthly journal of the Association of Physicians* 2001;94(10):521-26.
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APPENDIX 3.2

SURGICAL - POST OPERATIVE DATA SHEET

Date : .....

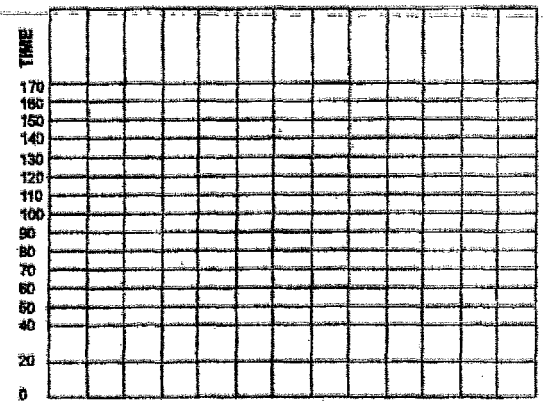
Time : .....

Operation / Procedure : .....

INITIAL OBSERVATIONS :

Temperature : .....
Pulse : .....
Blood Pressure : .....
H. B. : .....
Wound : .....
Blood loss : .....
Urinary output : .....
Circulation : .....
Girth measurement : .....
Pedal pulses : .....
Plugs : .....
Jaw wired : .....

HALF HOURLY OBSERVATIONS



EQUIPMENT

OXYGEN :	YES		NO	i.e. .....
INTRAVENOUS THERAPY :	YES		NO	i.e. .....
URINARY CATHETER :	YES		NO	i.e .....
WOUND :	YES		NO	i.e .....

OTHER : .....

NEUROLOGICAL OBSERVATIONS

DATE :
TIME :

COMA SCALES			
Eyes open	Spontaneously	4	Eyes closed by swelling = C
	To Speech	3	
	To pain	2	
	None	1	
Best verbal res - ponse	Orientated	5	Endotracheal tube or tracheostomy = T
	Confused	4	
	Inappropriate words	3	
	Incomprehensible sounds	2	
	None	1	
Best motor res - ponse	Obey commands	6	Usually record the best arm response APHASIC = A
	Localise pain	5	
	Normal flexion	4	
	Abnormal flexion	3	
	Extension to pain	2	
	None	1	

Coma scale 3 -15 : ☐

Pupil size : small ☐ Medium ☐ Large ☐

PUPILS			
	Right	Size Reaction	+ Reacts - No reaction C. Eye closed
	Left	Size Reaction	

INSTRUCTIONS :

1. Hourly BP, Pulse, Pad + Wound checks for _____ hours
2. Fluid balance : ie .....
3. Empty catheter bag _____ hourly
4. Diet : ie .....
5. Analgesia : Yes ☐ No ☐ ie .....
6. Other : ie .....

Signature : .....

Expert Code Number……..

Appendix 7

CHECKLIST
For Content and Construct Validity of the
SELF-ADMINISTERED STRUCTURED QUESTIONNAIRE

Researcher: Una Kyriacos
PhD candidate
Division of Nursing & Midwifery
Department of Health & Rehabilitation Sciences
Faculty of Health Sciences
University of Cape Town
OBSERVATORY 7925

Telephone Number: (021)406 6410

e-mail: una.kyriacos@uct.ac.za

Supervisor: Professor J Jelsma

(021) 406 6595

Title of study: **The development, validation and testing of a vital signs monitoring tool for early identification of deterioration in adult surgical patients**

INFORMATION:

Thank you for agreeing to evaluate the content and construct validity of the self-administered questionnaire (Appendix 3). Please e-mail or post the completed checklist to the researcher at the above address.

The **purpose** of this checklist is to ensure uniform evaluation by all experts using a structured procedure.

You, the expert, will establish the index of content validity (CVI) for each item using a 4-point ordinal rating scale and this will be taken as the proportion of items that received a rating of 3 or 4.[1] If, in your opinion, there are omissions, these can be listed at the end of each item.

In addition to establishing the CVI for each item, this will also be determined for the questionnaire as a whole and will be taken to be the proportion of total items judged content valid.[1]

For evaluation of construct validity, the checklist will include layout, format, quality of printing, the length of the questionnaire, the response scale of 1-4, if visually easy to read and comprehend and if instructions at the beginning of the questionnaire are clear and easy to understand.[2]

1. **Expert opinion on index of content validity (CVI) of EACH ITEM on the questionnaire:**

SECTION A: VARIABLES

Index of content validity (CVI)				
Item	1 = irrelevant	2 = unable to assess relevance without item revision or item is in need of such revision that it would no longer be relevant	3 = relevant but needs minor alteration	4 = extremely relevant
Item A1.1				
Item A1.2				
Item A1.3				
Item A1.4				
Item A1.5				
Item A1.6				
Item A1.7				

Omissions:

Comments:

Item A2.1				
Item A2.2				
Item A2.3				
Item A2.4				
Item A2.5				
Item A2.6				
Item A2.7				
Item A2.8				
Item A2.9				

Omissions:

Comments:

SECTION B: Modified Early Warning Scores (MEWS)

Index of content validity (CVI)				
Item	1 = irrelevant	2 = unable to assess relevance without item revision or item is in need of such revision that it would no longer be relevant	3 = relevant but needs minor alteration	4 = extremely relevant
Item B1.1				
Item B1.2				
Item B2.1				
Item B2.2				
Item B3.1				
Item B3.2				
Item B4.1				
Item B4.2				
Item B5.1				
Item B5.2				
Item B6.1				
Item B6.2				
Item B7.1				
Item B7.2				

Omissions:

Comments:

SECTION C: Research 'Observation Chart' (Attached)

Index of content validity (CVI)				
Item	1 = irrelevant	2 = unable to assess relevance without item revision or item is in need of such revision that it would no longer be relevant	3 = relevant but needs minor alteration	4 = extremely relevant
Item C1				
Item C2				
Item C3				
Item C4				
Item C5.1				
Item C5.2				

Omissions:

Comments:

SECTION D: ALGORITHM FOR CALL-OUT CRITERIA

Index of content validity (CVI)				
Item	1 = irrelevant	2 = unable to assess relevance without item revision or item is in need of such revision that it would no longer be relevant	3 = relevant but needs minor alteration	4 = extremely relevant
Item D1.1				
Item D1.2				
Item D1.3				
Item D1.4				
Item D1.5				
Item D1.6				
Item D1.7				

Omissions:

Comments:

SECTION E: DEMOGRAPHICS

Index of content validity (CVI)				
Item	1 = irrelevant	2 = unable to assess relevance without item revision or item is in need of such revision that it would no longer be relevant	3 = relevant but needs minor alteration	4 = extremely relevant
Item D1				
Item D2				
Item D3				
Item D4				
Item D5				

Omissions:

Comments:

2. Index of content validity (CVI) OF ENTIRE QUESTIONNAIRE

Check only one box:

1 = irrelevant	2 = unable to assess relevance without item revision or item is in need of such revision that it would no longer be relevant	3 = relevant but needs minor alteration	4 = extremely relevant

Omissions:

Comments:

3. Evaluation of CONSTRUCT VALIDITY

Please check one box for each statement relating to the questionnaire.

	Very skilful	Satisfactory	Needs improvement	Unacceptable
Layout				
Format				
Quality of printing				
Length of the questionnaire				
The response scale of 1-4				
If visually easy to read				
If visually easy to comprehend				
If instructions at the beginning of the questionnaire are clear and easy to understand				

Omissions:

Comments:

THANK YOU VERY MUCH

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Introduction

It is estimated that, in the UK, 23 000 in-hospital cardiac arrests[1] and in England, Wales and Northern Ireland 20 000 unanticipated ICU admissions[2] can be prevented with better care.[3-6] One in ten patients may experience an adverse event. Clinical negligence claims following adverse events occurring within the United Kingdom National Health Service costs the Department of Health hundreds of millions of pounds per year. These findings are not unique to the UK and similar findings are reported in the USA, New South Wales and Australia. Patient safety, and in particular avoidable in-hospital morbidity and mortality, is an unexplored research area in developing countries that demands attention at this time in South Africa's history, a period characterized by an increased public awareness of patients' rights and escalating litigation in a health care system with shrinking resources.

My PhD thesis will examine three serious adverse events (SAE) that hospitalized adult surgical patients may experience in the wards, defined operationally as **avoidable**: 1) in-hospital cardiac arrest, 2) urgent and unanticipated admission to an intensive care unit (ICU) and 3) death[2], caused by human error of omission, that is, failure to monitor patients' vital signs and/or failure of cognitive function to synthesise, decide and/or act on available information as adapted.[7]

Vital sign monitoring in the wards is only one aspect of patient safety but it is the focus of my study. In the literature there is particular concern about infrequent and incomplete monitoring and recording, misinterpretation of clinical data by nurses, delays in reporting and little convincing evidence of appropriate interventions being carried out for patients at risk of an adverse event in general wards. Studies have shown that abnormal physiology is common on general hospital wards[8] and that there is documented evidence of clinical and physiological deterioration within six[9] to eight hours[10] of cardiopulmonary arrest. In these cases, arrest often occurs after a period of slow and progressive physiological deterioration that was not recognized or when hypoxaemia and hypotension were not treated adequately.[11] However, many surgical deaths occur several days after an operation.[12]

The five most important prognostic variables for catastrophic deterioration are respiratory rate, systolic blood pressure, pulse rate, temperature and central nervous system status; in addition, urine output[13] is an early indicator of vascular compromise.[14] Skin tone, sweating, nausea and other clinical signs such as 'looking unwell' or nurses' intuitive assessment of the patient being 'just not right'[15] are also important signs which need to be monitored regularly in patients to reduce avoidable, serious adverse events (SAE) such as cardiac arrest, urgent and unanticipated admission to an ICU or even death. A number of studies have examined combinations of early signs for association with in-hospital death.[14 16-19] Adverse clinical outcomes can be reduced and even avoided if antecedent signs of clinical and physiological deterioration are identified early, particularly in the acutely ill patient on a general ward. Vital signs charts in certain countries in the developed world incorporate early warning systems (EWSs) to 'track' signs of physiological deterioration in adult patients and 'trigger' a rapid response.[20 21]

Overview of the development of EWS

Morgan, Williams and Wright (1997) in the UK were the first to develop and publish an EWS based on a 0-3 point score, where zero indicates normal range values with increasingly abnormal values being assigned points up to a maximum of three.[22] The physiological parameters are summed to obtain a total score, and the assessment takes about 30 seconds to complete.[22] The intention of the tool was not to predict outcome but to provide a bedside monitoring tool to alert staff to abnormalities in routine observations and then to summon assistance from more experienced clinical staff when a patient's condition deteriorated[2] to avoid SAEs.[3] Other than critical care units and operating theatres hospitalized patients are not monitored continuously.[23]

As at 27 November 2007 there was no up-to-date literature review of physiologically based, aggregate weighted 'track and trigger' systems (AWTTS) and few data on the predictive ability of AWTTS for SAEs.[24] A systematic review of the literature and performance evaluation of 33 aggregate weighted 'track and trigger' systems (AWTTS) by their ability to discriminate between survivors and non-survivors using the area under receiver-operating characteristics (AUROC) curve, and a database of 9987 vital signs datasets, revealed that 12 AWTTS (36%) discriminated reasonably well, with the top four incorporating age and the top two incorporating temperature monitoring.[24] Although there was no consistency in physiological components, the majority differed only in minor variations in weightings for derangement and/or the cut-off points between physiological weighting bands. The authors recommend further work to improve AWTTS models. Of 23 summarised AWTTS, only one incorporated 'nurse concern'. There is evidence of increasing sophistication in vital sign monitoring in the developed world.

Only one S African publication by a nurse describes a modified EWS (MEWS) for critically ill patients on general wards in KZN.[25] Lee Wallis, a specialist in emergency medicine, who will be a participant in the MEWS consensus group, has experience in developing and introducing a MEWS for triage in emergency departments in the Cape. The literature distinguishes between two types of track and trigger systems (TTS):

- the early warning score (EWS); and
- 'calling criteria'.[2]

For EWS, points are allocated to disturbed physiological values in a weighted manner to guide intervention, even alerting a specific team within the hospital such as a rapid response team (RRT) [2 14 19 26 27] usually for the summed value of more than one abnormal vital sign, while 'calling criteria' activate a RRT when one or more routinely measured physiological variables fall within an extremely abnormal range.[2 28]

MEWS system:

- 0 = normal value
- 1 (upper or lower) = early sign of deterioration
- 2 (upper or lower) = serious sign of deterioration
- 3 = critical condition requiring urgent attention.

We will attempt to reach consensus on both an EWS and calling criteria.

At the outset of our discussion a summary of the questionnaire results (n=13) for a MEWS for a local context will be presented, followed by private re-ranking and agreement by predetermined rules.

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17. Gao H, McDonnell A, Harrison DA, Moore T, Adam S, Daly K, et al. Systematic review and evaluation of physiological track and trigger warning systems for identifying at-risk patients on the ward. *Intensive care medicine* 2007;33(4):667-79.
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CONTEXT FOR TODAY'S CONSENSUS MEETING:

1 Questions to guide the consensus discussion: what local criteria are appropriate for:

1.1 a modified early warning scoring system (MEWS) for the nurses' observation chart (published MEWS); and for

1.2 a referral algorithm (published callout criteria)

2 To reach consensus on strict vs relaxed rules rules of agreement.

3 Disclosure that no one present has any financial interests pertaining to this subject area.

Nominal group technique (NGT) for consensus development

A NGT is used to create a structured environment in which experts are given the best available information for considering solutions that are more justifiable and credible than may be the case otherwise.[1] The aim of a consensus method such as the NGT employed in this study is to determine the extent to which experts in vital sign monitoring agreed on local criteria for, and the construct and content validity of the MEWS, the observation chart and referral algorithm. Such consensus is intended to result in the design of:

- a valid and reliable, visually enhanced chart for early recognition of clinical and physiological deterioration;
- that includes the most essential parameters found in published literature from validated studies;
- and enhances interpretation of the patients' data and clinical decision-making;
- for improved patient safety and a reduced rate of serious adverse events.

Features of consensus methods

Anonymity: To avoid dominance; achieved by private ranking.

Iteration: Processes occur in "rounds", allowing individuals to change their opinions.

Controlled feedback: Showing the distribution of the group's response.

Statistical group response: Expressing judgment using summary measures of the full group response, giving more information than just a consensus statement.

(Cited in Jones & Hunter, 1995 adapted from Pill[2] and Rowe[3])

The procedures employed are summarized in Figure 1:

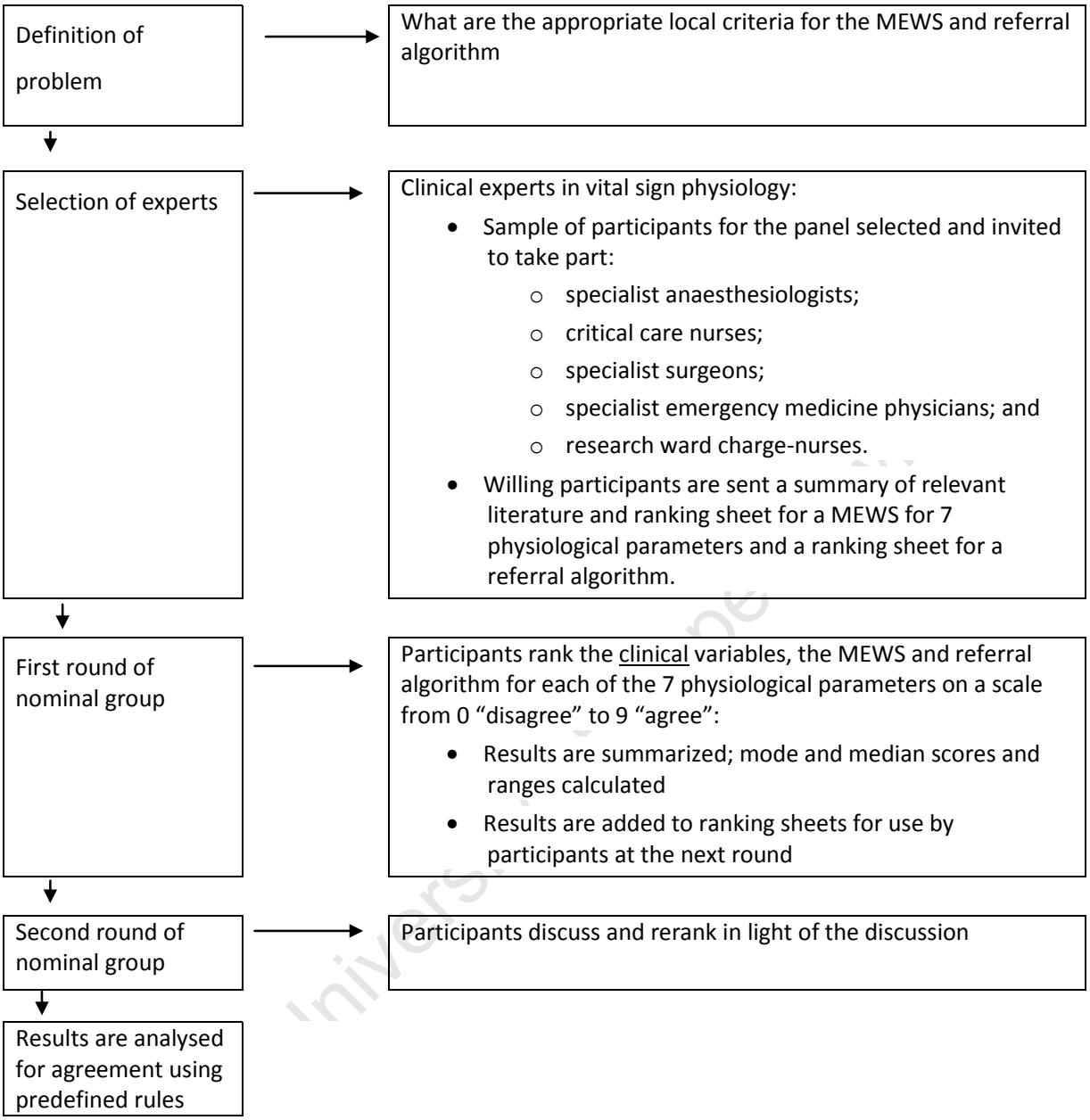

Figure 1. Modified nominal group adapted from Jones, 1995[4]

References
1. Fink A, Kosekoff J, Chassin M, Brook RH. Consensus Methods: Characteristics and Guidelines for Use. *American Journal of Public Health* 1984;74(9):979-83.
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CONSENSUS RANKING SHEET

SECTION B **Respiratory Rate**

Instruction 1:

1.1 From the published values for **each** MEWS score below and the results of the QUESTIONNAIRE for **each** MEWS score select the ONE value you prefer by making a tick √ [i.e. either a published value **or** questionnaire result value].

1.2 Indicate the extent to which you agree or disagree with your selection by circling the appropriate number (0 = total disagreement and 9 = total agreement).

RESPIRATORY RATE MEWS score**:** [12/14; 85.7% agreement]

MEWS	3	2	1	0	1	2	3
RR value (published)	Blank	9 or less	Blank	9-14	15-20	21-29	30 or more
Q. Sugg.	***<9***	***9 or less***	***10-12***	***12-14***	***15-20***	***21-29***	***30 or more***
	0 1 2 3 4 5 6 7 8 9	0 1 2 3 4 5 6 7 8 9	0 1 2 3 4 5 6 7 8 9	0 1 2 3 4 5 6 7 8 9	0 1 2 3 4 5 6 7 8 9	0 1 2 3 4 5 6 7 8 9	0 1 2 3 4 5 6 7 8 9

Instruction 2: **Change the values for each MEWS if necessary**

Instruction 3: **Tick the values requiring call-out for assistance**

Instruction 4: **Indicate the category of professional to call in each instance (PN, MO, Registrar (R), Consultant (C))**

SECTION B **Heart Rate**

Instruction 1:

1.2 From the published values for **each** MEWS score below and the results of the QUESTIONNAIRE for **each** MEWS score select the ONE value you prefer by making a tick √ [i.e. either a published value **or** questionnaire result value].

1.2 Indicate the extent to which you agree or disagree with your selection by circling the appropriate number (0 = total disagreement and 9 = total agreement).

HEART RATE MEWS score: [9/14; 64.3% agreement]

MEWS	3	2	1	0	1	2	3
HR value (published)	<35	40 or less	41-50	51-100	101-110	111-129	130 or more
Q. sugg.	***<40***	***45 or less*** ***40-49*** ***35-50***	***46-55*** ***50-60*** ***51-59***	***51-100*** ***60-100*** ***56-95*** ***50-90*** ***60-90***	***96-110*** ***91-110***	***111-129***	***130 or more***
	0 1 2 3 4 5 6 7 8 9	0 1 2 3 4 5 6 7 8 9	0 1 2 3 4 5 6 7 8 9	0 1 2 3 4 5 6 7 8 9	0 1 2 3 4 5 6 7 8 9	0 1 2 3 4 5 6 7 8 9	0 1 2 3 4 5 6 7 8 9

Instruction 2: **Change the values for each MEWS if necessary**

Instruction 3: **Tick the values requiring call-out for assistance**

Instruction 4: **Indicate the category of professional to call in each instance (PN, MO, Registrar (R), Consultant (C))**

SECTION B **S_aO_2**

Instruction 1:

1.1 From the published values for **each** MEWS score below and the results of the QUESTIONNAIRE for **each** MEWS score select the ONE value you prefer by making a tick √ [i.e. either a published value **or** questionnaire result value].

1.2 Indicate the extent to which you agree or disagree with your selection by circling the appropriate number (0 = total disagreement and 9 = total agreement).

S_aO_2 MEWS score: [9/14; 64.3%]

MEWS	3	2	1	0	1	2	3
RR value (published)	<85%	85-89%	90-92%	93%+	BLANK	BLANK	BLANK
Q. sugg.	*<90*	*91-93*	*90-94* *94-96*	*95+* *94+* *95* *97*	*BLANK*	*BLANK*	*BLANK*
	0 1 2 3 4 5 6 7 8 9	0 1 2 3 4 5 6 7 8 9	0 1 2 3 4 5 6 7 8 9	0 1 2 3 4 5 6 7 8 9	0 1 2 3 4 5 6 7 8 9	0 1 2 3 4 5 6 7 8 9	0 1 2 3 4 5 6 7 8 9

Instruction 2: **Change the values for each MEWS if necessary**

Instruction 3: **Tick the values requiring call-out for assistance**

Instruction 4: **Indicate the category of professional to call in each instance (PN, MO, Registrar (R), Consultant (C))**

SECTION B **SYSTOLIC BP**

Instruction 1:

1.1 From the published values for **each** MEWS score below and the results of the QUESTIONNAIRE for **each** MEWS score select the ONE value you prefer by making a tick √ [i.e. either a published value **or** questionnaire result value].

1.2 Indicate the extent to which you agree or disagree with your selection by circling the appropriate number (0 = total disagreement and 9 = total agreement).

SYSTOLIC BP MEWS score: [Disagreement: 8/14; 57.1%]

MEWS	3	2	1	0	1	2	3
RR value (published)	70 or less	71-80	81-100	101-179	180-200	200 or more	>250
Q. RESULTS	*75 or less* *<80*	*76-85* *71-80*	*86-10* *91-110*	*110-140* *101-149* *101-159* *100-135* *101-140* *101-150* *100-150*	*150-169* *160-180* *141-160* *151-180*	*170-189* *180 or more* *161-200* *181-200*	*>190* *>200*
	0 1 2 3 4 5 6 7 8 9	0 1 2 3 4 5 6 7 8 9	0 1 2 3 4 5 6 7 8 9	0 1 2 3 4 5 6 7 8 9	0 1 2 3 4 5 6 7 8 9	0 1 2 3 4 5 6 7 8 9	0 1 2 3 4 5 6 7 8 9

Instruction 2: **Change the values for each MEWS if necessary**

Instruction 3: **Tick the values requiring call-out for assistance**

Instruction 4: **Indicate the category of professional to call in each instance (PN, MO, Registrar (R), Consultant (C))**

SECTION B **TEMPERATURE**

Instruction 1:

1.1 From the published values for **each** MEWS score below and the results of the QUESTIONNAIRE for **each** MEWS score select the ONE value you prefer by making a tick √ [i.e. either a published value **or** questionnaire result value].

1.2 Indicate the extent to which you agree or disagree with your selection by circling the appropriate number (0 = total disagreement and 9 = total agreement).

TEMPERATURE MEWS score: [Disagreement 8/14; 57.1%]

MEWS	3	2	1	0	1	2	3
RR value (published)	BLANK	35°C or less	BLANK	35-38.4°C	BLANK	38.5°C or more	BLANK
Q. sugg.	***<33***	***33-35*** ***<35***	***35.1-35.9***	***35-38x3*** ***36-37.5*** ***36-37.7*** ***35-37*** ***35-37.5***	***37.8-38.5*** ***37.5-38***	***38.1 or more*** ***38.6-39.5*** ***38-40*** ***38-39***	***>39.6*** ***39-40***
	0 1 2 3 4 5 6 7 8 9	0 1 2 3 4 5 6 7 8 9	0 1 2 3 4 5 6 7 8 9	0 1 2 3 4 5 6 7 8 9	0 1 2 3 4 5 6 7 8 9	0 1 2 3 4 5 6 7 8 9	0 1 2 3 4 5 6 7 8 9

Instruction 2: **Change the values for each MEWS if necessary**

Instruction 3: **Tick the values requiring call-out for assistance**

Instruction 4: **Indicate the category of professional to call in each instance (PN, MO, Registrar (R), Consultant (C))**

SECTION B **Neurological status (LOC)**

Instruction 1:

1.1 From the published values for **each** MEWS score below and the results of the QUESTIONNAIRE for **each** MEWS score select **ONE or Both*** values you prefer by making a tick √.

1.2 Indicate the extent to which you agree or disagree with your selection by circling the appropriate number (0 = total disagreement and 9 = total agreement).

Neurological MEWS score: [11/14; 78.6% agreement]

MEWS	3	2	1	0	1	2	3
RR value (published)	BLANK	BLANK	BLANK	ALERT (GCS 15)	RESPONDS TO VOICE (GCS 14)	RESPONDS TO PAIN (GCS 13-9)	UNRESPONSIVE (GCS <8)
Q. sugg.	*BLANK*	*BLANK*	*BLANK*	*Consider adding motor M6*	*M5*	*Confused M4*	*M3*
	0 1 2 3 4 5 6 7 8 9	0 1 2 3 4 5 6 7 8 9	0 1 2 3 4 5 6 7 8 9	0 1 2 3 4 5 6 7 8 9	0 1 2 3 4 5 6 7 8 9	0 1 2 3 4 5 6 7 8 9	0 1 2 3 4 5 6 7 8 9

Instruction 2: **Change the values for each MEWS if necessary**

Instruction 3: **Tick the values requiring call-out for assistance**

Instruction 4: **Indicate the category of professional to call in each instance (PN, MO, Registrar (R), Consultant (C))**

SECTION B **Urinary output**

Instruction 1:

1.1 From the published values for **each** MEWS score below and the results of the QUESTIONNAIRE for **each** MEWS score select the ONE value you prefer by making a tick √ [i.e. either a published value **or** questionnaire result value].

1.2 Indicate the extent to which you agree or disagree with your selection by circling the appropriate number (0 = total disagreement and 9 = total agreement).

Urinary output MEWS score: [12/14; 85.7% agreement]

MEWS	3	2	1	0	1	2	3
RR value (published)	<20 ml/hr	<30 ml/hr or less	50 ml/hr or less	60ml/hr If normally anuric score 0	150 ml/hr or more	BLANK	BLANK
Q. sugg	***<0.5 ml/kg/hr***	***0.5-1ml/kg/hr***	***1ml/kg/hr or less***		***3ml/kg/hr or more***	***BLANK***	***BLANK***

0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9

Key: Disagree 0 1 2 3 4 5 6 7 8 9 Agree

Instruction 2: **Change the values for each MEWS if necessary**

Instruction 3: **Tick the values requiring call-out for assistance**

Instruction 4: **Indicate the category of professional to call in each instance (PN, MO, Registrar (R), Consultant (C))**

GUIDELINES FOR A NOMINAL GROUP TECHNIQUE: CONSENSUS-SEEKING FOR A MEWS SCORE AND REFERRAL ALGORITHM

Researcher: Una Kyriacos
PhD candidate
Division of Nursing & Midwifery
Department of Health & Rehabilitation Sciences
Faculty of Health Sciences
University of Cape Town
OBSERVATORY 7925

Supervisor: Professor J Jelsma

Telephone Number: (021)406 6410 (021) 406 6595

e-mail: una.kyriacos@uct.ac.za

Title of study: **The development, validation and testing of a vital signs monitoring tool for early identification of deterioration in adult surgical patients**

NOMINAL GROUP TECHNIQUE INTERVIEW SCHEDULE

Welcome and introductions

Brief overview of the development of the MEWS [will have been circulated before the meeting].

INFORMATION:

What is the study about?

The **purpose** of this three part study is to discover how registered professional nurses (RPNs) use the current vital signs chart to identify and manage post-operative adult patients who show early warning signs of deterioration. Based on these findings, the researcher will revise or design a new vital signs chart and an educational programme to improve nurses' competence in early identification and management of patients at risk of serious adverse events (SAE) such as avoidable hospital deaths, cardiac arrest and intensive care admissions.

Does the study have ethics approval?

The study has been approved by the Faculty of Health Sciences Research Ethics Committee (REC/REF 192/2009). Dr B Patel, Senior Medical Superintendent Groote Schuur Hospital, Provincial Government of the Western Cape has approved the study (Ref: Research 24 June 2009), as well as the Director of Nursing at the hospital (Ref: F/9/2 20 July 2009). Your voluntary participation in this study is requested by signing

this consent form if you wish, once you are satisfied that you have been fully informed of all aspects of the study or by remaining in the group for this session and assisting us to reach consensus about the most suitable early warning scoring system for a South African context.

What is required of you?

Please participate as fully as possible and ask questions at any stage.

THE PROCESS:

Please identify your completed questionnaire – if not completed previously one will be given now. The facilitator will explain each of the questions. You then have an opportunity to amend your previous MEWS score, in private in the group. The facilitator collates the results during the tea break which are presented to the group on a flipchart and analysed for agreement using predefined rules.

SECTION B:

Question B1.2: RR MEWS
Question B2.2: HR MEWS
Question B3.2: S_aO_2 MEWS
Question B4.2: Systolic BP MEWS
Question B5.2: Temperature MEWS
Question B6.2: Consciousness MEWS
Question B7.2: Urine output MEWS

SECTION D: ALGORITHM FOR CALL-OUT CRITERIA FOR:

RR
HR
S_aO_2
Systolic BP
Temperature
Level of consciousness
Urine output

Thank you for your assistance

OPTIONAL CONSENT FORM:

CONFIDENTIALITY/ANONYMITY: The researcher has explained that all information is confidential and that my name will not appear on the data emerging from the study.

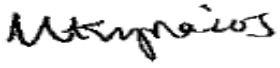
RISKS: The researcher has explained that there are no physical risks involved. Information offered by me is confidential and protected. There are no known or anticipated risks.

BENEFITS: The researcher has explained that the new vital signs chart should help nurses to identify patients at risk of an adverse clinical outcome and help nurses to gain improved competence and confidence in patient monitoring to reduce avoidable hospital deaths, cardiac arrests and intensive care admissions.

AUTONOMY/RIGHT TO WITHDRAW: The researcher has explained that participation is voluntary and that I have the right to withdraw from the study at any stage without penalties. All my questions will be answered by the researcher.

I agree to participate in this research study **(Nominal Group Technique)** on the terms specified above.

Date _____ Participant's Signature



Date _____ Researcher's Signature

Ranking sheet

Cape Town Modified Early Warning Scoring System (MEWS)

MEWS	3	2	1	0	1	2	3
Respiratory rate/min	<8 *9 or less* <8	≤9 8-9	10-11 10-11	12-14 *9-14* 12-14	15-20 *15-20* 15-20	21-29 *21-29* 21-29	≥30 *30 or more* ≥30
Final ranking	0 1 2 3 4 5 6 7 **8** **9** 6 2			**8/8 = 100% agreement**			
SaO_2 %	**<85** *<85* <85	**85-89** *85-89* 85-89	**90-93** *90-92* 90-94	**94+** *93+* 95+			
Final ranking	0 1 2 3 4 5 6 7 **8** **9** 1 3			**4/8 = 50% agreement but accepted**			
Heart rate/min [consensus Round4]	**<40** *40 or less*	**40-50** *41-50*	**51-59** *51-100*	**60-100** *101-110*	**101-110** *111-129*	**111-129** *130 or more*	**≥130**
BP systolic [consensus R4]	**≤70** *70 or less*	**71-80** *71-80*	**81-100** *81-100*	**101-149** *101-199*	**150-169**	**170-179** *200 or more*	**>180**
Temperature °C	<33 *35 or less* <34	33-35 34-35	35.1-35.9 35.1-35.9	36-37.7 *35-38.4* 36-37.7	37.8-38.5 37.8-38.5	38.6-39.5 *38.5 or more* 38.6-39.5	>39.6 >39.6
Final ranking	0 1 2 3 4 5 6 7 **8** **9** 6 2			**8/8 = 100% agreement**			
AVPU CONSCIOUS LEVEL * [consensus Round4 – for all wards excluding neurosurgical ward]				**Alert** (GCS 15) *Alert* *(GCS 15)*	**Reacting to voice** (GCS 14) *Reacting to voice* *(GCS 14)*	**Reacting to pain/ Confused** (GCS 13-9) *Reacting to pain* *(GCS 13-9)*	**Unresponsive** (GCS <8) *Unresponsive* *(GCS 8<)*
**Urine ml/hr	<20 *NIL* <20	≤30 *<30* ≤30	≤50 *<60* ≤50	60 If normally anuric score 0 60 If normally anuric score 0	≥150 *>150*		>300 ml/hr for 2 hrs
Final ranking	0 1 2 3 4 5 6 7 **8** **9** 7 1			**8/8 = 100% agreement**			
Aggregated score =							
Interpretation: Aggregated MEWS: 3 = critical score							

Key: Row 1 = Cape Town MEWS derived by consensus 20/01/2010; *Row 2 = Template of published MEWS*

Row 3: Finalised cut points as at 11/02/2010

Row 4 = Ranking results: Total disagreement = 0 1 2 3 4 5 6 7 8 9 = Total agreement

Finalised at NGT workshop 11 February 2010

UNIVERSITY OF CAPE TOWN

Health Sciences Faculty
Research Ethics Committee
Room E52-24 Groote Schuur Hospital Old Main Building
Observatory 7925
Telephone [021] 406 6626 • **Facsimile** [021] 406 6411
e-mail: shuretta.thomas@uct.ac.za

05 June 2009

REC REF: 192/2009

Mrs U Kyriacos
Health & Rehab

Dear Mrs Kyriacos

PROJECT TITLE: THE DEVELOPMENT,VALIDATION AND TESTING OF A VITAL SIGNS MONITORING TOOL FOR EARLY IDENTIFICATION OF DETERIORATION IN ADULT SURGICAL PATIENTS.

Thank you for submitting your study to the Research Ethics Committee for review.

DATE OF MEETING: 29 MAY 2009

DECISION:
It is a pleasure to inform you that the Ethics Committee has **formally approved** the above-mentioned study.

Approval is granted for one year till the 10th June 2010.

Please submit an annual progress report if the research continues beyond the expiry date. Please submit a brief summary of findings if you complete the study within the approval period so that we can close our file.

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

Please quote the REC. REF in all your correspondence.

Yours sincerely,

PROFESSOR M BLOCKMAN
CHAIRPERSON, HSF HUMAN ETHICS

Federal Wide Assurance Number: FWA00001637.

S Thomas

Institutional Review Board (IRB) number: IRB00001938

This serves to confirm that the University of Cape Town Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Convention on Harmonisation Good Clinical Practice (ICH GCP) and Declaration of Helsinki guidelines.

The Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

S Thomas

From: "Health Research" <Healthres@pgwc.gov.za>
To: "Una Kyriacos" <Una.Kyriacos@uct.ac.za>
Date: 02/10/2009 15:28
Subject: Re: Fwd: Ethical clearance: PhD study
Attachments: ANNEXURE 2.doc

Dear Una

Thank you for submitting this. The Annexure 2 that you have used is outdated, could you kindly resubmit an updated version (see attached). Your proposal will then be entered onto our provincial database.

Because this study only proposes to access GSH, no further approval is required, and researchers can proceed with the research, having obtained ethics approval and approval from GSH hospital management.

Kind regards
Gina

Enquiries : Dr B Patel
Telephone : (021) 404-4256
Fax : (021) 404-4304
E-mail : bpatel@pgwc.gov.za
Reference : Research
Date : 24 June 2009

Departement van Gesondheid
Department of Health
ISebe lezeMoilo

Ms U Kyriacos
Division of Nursing & Midwifery
F56
School of Health & Rehabilitation Sciences
Old Main Building
GROOTE SCHUUR HOSPITAL

Dear Ms Kyriacos

RESEARCH: THE DEVELOPMENT, VALIDATION AND TESTING OF A VITAL SIGNS MONITORING TOOL FOR EARLY IDENTIFICATION OF DETERIORATION IN ADULT SURGICAL PATIENTS

Your recent letter to the hospital refers.

You are hereby granted permission to proceed with your research.

Please note the following:-

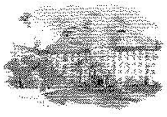
a) Your research may not interfere with normal patient care.
b) Hospital staff may not be asked to assist in the research.
c) No hospital consumables and stationery may be used.
d) Please introduce yourself to the person in charge of an area before commencing.

I would like to wish you every success with your project.

Yours truly

DR B PATEL
For CHIEF EXECUTIVE OFFICER

BP/em 25/05/09



Groote Schuur Hospital
Private Bag,
Observatory, 7935
Telephone: 404-9111

Enquiries : C Thorpe
Telephone : (021 404-2071
Fax : (021) 404-2370
E-mail : cjthorpe@pgwc.gov.za
Reference : F/9/2
Date : 20 July 2009

Departement van Gesondheid
Department of Health
ISebe lezeMpilo

Mrs U Kyriacos
Division of Nursing and Midwifery
Faculty of Health Sciences
Observatory
7925

Dear Mrs Kyriacos

THE DEVELOPMENT, VALIDATION, AND TESTING OF A VITAL SIGNS MONITORING TOOL FOR EARLY IDENTIFICTION OF DETERIORATION IN ADULT SURGICAL PATIENTS.

Thank you for your letter dated 22 June 2009.

Your research proposal has been discussed with the Nurse Managers and there is agreement that you may proceed.

When you are ready to distribute your questionnaires or interview staff I would suggest you contact the Nurse Manager of the area concerned and make an arrangement that will be mutually acceptable.

Your project sounds exciting and has potential to be very useful in the clinical areas.

It would be appreciated if a copy of the final report could be submitted to my office.

Yours sincerely

C J THORPE (MISS)
MANAGER: NURSING
For Chief Director
Groote Schuur Hospital

Groote Schuur Hospital
Private Bag,
Observatory, 7935
Telephone: 404-9111

CONSENT TO PARTICIPATE IN RESEARCH

Researcher: Una Kyriacos
PhD candidate
Division of Nursing & Midwifery
Department of Health & Rehabilitation Sciences
Faculty of Health Sciences
University of Cape Town
OBSERVATORY 7925

Telephone Number: (021)406 6410

e-mail: una.kyriacos@uct.ac.za

Supervisor: Professor J Jelsma

(021) 406 6595

Title of study: **The development, validation and testing of a vital signs monitoring tool for early identification of deterioration in adult surgical patients**

INFORMATION:

What is the study about?

The **purpose** of this three part study is to discover how registered professional nurses (RPNs) use the current vital signs chart to identify and manage post-operative adult patients who show early warning signs of deterioration. Based on these findings, the researcher will revise or design a new vital signs chart and an educational programme to improve nurses' competence in early identification and management of patients at risk of serious adverse events (SAE) such as avoidable hospital deaths, cardiac arrest and intensive care admissions.

Does the study have ethics approval?

The study has been approved by the Faculty of Health Sciences Research Ethics Committee (REC/REF 192/2009). Dr B Patel, Senior Medical Superintendent Groote Schuur Hospital, Provincial Government of the Western Cape has approved the study (Ref: Research 24 June 2009), as well as the Director of Nursing at the hospital (Ref: F/9/2 20 July 2009). Your voluntary participation in this study is requested by signing this consent form once you are satisfied that you have been fully informed of all aspects of the study.

What is required of you?

You have been selected to participate in this part of the study (Study One) as you are considered to have expert knowledge of early warning signs of clinical and physiological deterioration and vital sign monitoring in the post-operative period.

If you agree to participate in the study you will be required to complete a **self-administered questionnaire** that should take about 15 minutes. You will be anonymous. The name of the research site will not be reported by name in the publication of findings.

What is the purpose of the questionnaire?

The **purpose** of the questionnaire is to ask your opinion on local criteria for the **design of a preliminary prototype monitoring tool** (observation chart) (Appendix 6) that incorporates a modified early warning scoring system (MEWS) for seven physiological parameters based on available literature. The MEWS should help nurses identify patients who show signs of **clinical and physiological deterioration** and who may be at risk of a SAE. Most of the published literature is from the developed countries such as the UK, USA and Australia. The questionnaire will provide data to assist with the content and construct validity testing of the preliminary prototype monitoring tool.

OPTIONAL CONSENT FORM:

CONFIDENTIALITY/ANONYMITY: The researcher has explained that all information is confidential and that my name will not appear on the data emerging from the study.

RISKS: The researcher has explained that there are no physical risks involved. Information offered by me is confidential and protected. There are no known or anticipated risks.

BENEFITS: The researcher has explained that the new vital signs chart should help nurses to identify patients at risk of an adverse clinical outcome and help nurses to gain improved competence and confidence in patient monitoring to reduce avoidable hospital deaths, cardiac arrests and intensive care admissions.

AUTONOMY/RIGHT TO WITHDRAW: The researcher has explained that participation is voluntary and that I have the right to withdraw from the study at any stage without penalties. All my questions will be answered by the researcher.

I agree to participate in this research study **(self-administered questionnaire)** on the terms specified above.

_____ _____

Date Participant's Signature

28 August 2009 _____

Date Researcher's Signature

Thank you for your assistance.

Kindly detach the consent form from the questionnaire and deposit it in the box in the registrar's office marked: **CONSENT**: MEWS RESEARCH. Please deposit your completed questionnaire in the box in the registrar's office marked: **QUESTIONNAIRE**: MEWS RESEARCH.

Round 1 generated 32 MEWS value sets from an existing* 7 MEWS for 7 physiological variables

Range of value sets generated for a RESPIRATORY RATE MEWS (n=4)

MEWS	3	2	1	0	1	2	3
Set 1*		≤9		9-14	15-20	21-29	≥30
2		≤9		9-12	13-20	21-29	≥30
3	<8	8-10	Blank	11-14	15-20	21-29	≥30
4	<8	≤9	10-11	12-14	15-20	21-29	≥30
5	<9	≤9	10-11	12-14	15-20	21-29	≥30

Range of value sets generated for a HEART RATE MEWS (n=7 new value sets replace published MEWS)

MEWS	3	2	1	0	1	2	3
Set 1	<35	≤40	41-50	51-100	101-110	111-129	≥130
2	<35	36-40	41-50	51-100	101-110	111-129	≥130
3	<35	35-50	51-59	60-100	101-110	111-129	≥130
4	<40	40-49	50-59	60-90	91-110	111-129	≥130
5	<40	40-49	50-60	61-100	Blank	≥120	≥130
6	<40	40-50	51-59	60-100	101-110	111-129	≥130
7	<40	41-49	50-59	60-90	91-110	111-129	≥130

Range of value sets generated for a SpO_2 % MEWS (n=3)

MEWS	3	2	1	0	1	2	3
Set 1*	<85%	85-89%	90-92%	93%+	Blank	Blank	Blank
2	<85%	85-89%	90-93%	94%+	Blank	Blank	Blank
3	<85%	85-89%	90-94%	95%+	Blank	Blank	Blank
4	<90%	91-93%	94-96%	97%+	Blank	Blank	Blank

Range of value sets generated for a SYSTOLIC BP MEWS (n=7 new value sets)

MEWS	3	2	1	0	1	2	3
Set 1	≤70	71-80	81-100	101-179	180-200	>200	>250
2	≤70	71-80	81-100	101-149	150-169	170-179	>180
3	≤70	71-80	81-100	101-159	160-180	>180	>250
4	≤75	76-85	86-100	101-159	160-180	181-200	>200
5	≤75	76-85	86-100	101-149	150-169	170-189	>190
6	≤80	81-90	91-100	101-140	141-160	161-180	>180
7	≤80	81-85	86-100	101-140	141-160	161-190	>190

Range of value sets generated for a TEMPERATURE MEWS (n=5)

MEWS	3	2	1	0	1	2	3
Set 1*		≤35°C		35-38.4°C		38.5°C or more	
2	≤33°C	<35°C		35-38.4°C		38.5°C or more	
3	<33°C	33-35°C		35-38°C	38-39 °C	>39 °C	
4	<33°C	33-35°C		36-37.5°C	37.6-38°C	>38.1-39.5°C	>39.6°C
5	<33°C	33-35°C	35.1-35.9°C	36-37.7°C	37.8-38.5°C	>38.6-39.5°C	>39.6°C
6	<35°C	35-36°C		36.1-38°C		>38°C	

Range of value sets generated for a NEUROLOGICAL STATUS/CONSCIOUS LEVEL MEWS (n=2)

MEWS	3	2	1	0	1	2	3
Set 1*				ALERT (A)	RESPONDS TO VOICE (V)	RESPONDS TO PAIN (P)	UNRESPONSIVE (U)

The next rows mean that it may be possible to convert the GCS to AVPU but not the AVPU to the GCS[1]

2*				ALERT (A) (≅GCS 15)	RESPONDS TO VOICE (V) (≅GCS 14)	RESPONDS TO PAIN (P) (≅GCS 13-9)	UNRESPONSIVE (U) (≅GCS <8)
3				ALERT (A) (≅GCS 15)	RESPONDS TO VOICE (V) (≅GCS 14)	RESPONDS TO PAIN (P) (≅GCS 13-9) Confused	UNRESPONSIVE (U) (≅GCS <8)
4				ALERT (A) (≅GCS 15) GCS M6	RESPONDS TO VOICE (V) (≅GCS 14) GCS M5	RESPONDS TO PAIN (P) (≅GCS 13-9) GCS M4	UNRESPONSIVE (U) (≅GCS <8) GCS M3

Range of value sets generated for a URINE OUTPUT MEWS (n=4)

MEWS	3	2	1	0	1	2	3
Set 1*	<20 ml/hr	<30 ml/hr or less	50 ml/hr or less	60ml/hr If normally anuric score 0	150 ml/hr or more		
2	<30 ml/hr	30 ml/hr		60ml/hr If normally anuric score 0			>200 ml/hr
3	≤30 ml/hr	≤40 ml/hr	<50 ml/hr	50-60ml/hr If normally anuric score 0	150 ml/hr or more		>200 ml/hr
4	<0.5 ml/kg/hr	0.5-1 ml/kg/hr		1-2.9 ml/kg/hr	3ml/kg/hr or more		
5	<0.3 ml/kg/hr	0.3- 0.5 ml/kg/hr	0.5-1 ml/kg/hr	60ml/hr If normally anuric score 0	3ml/kg/hr or more		

Round 2 results

Range of value sets generated for a RESPIRATORY RATE MEWS within the high tertile scores (7-9)

Agreement: 40%	0 1 2 3 4 5 6 7 8 9 2 *2 = 4/10*		Ranking key: Total disagreement: 0 1 2 3 4 5 6 7 8 9 Total agreement				
RRMEWS	**3**	**2**	**1**	**0**	**1**	**2**	**3**
	<8	≤9	10-11	12-14	15-20	21-29	≥30

Agreement: 10%	0 1 2 3 4 5 6 7 8 9 *1 = 1/10*						
RR MEWS	**3**	**2**	**1**	**0**	**1**	**2**	**3**
	<9	≤9	10-11	12-14	15-20	21-29	≥30

Agreement: 30%	0 1 2 3 4 5 6 7 8 9 2 *1 = 3/10*						
RR MEWS	**3**	**2**	**1**	**0**	**1**	**2**	**3**
		≤9		9-14	15-20	21-29	≥30

Agreement: 20%	0 1 2 3 4 5 6 7 8 9 *2 = 2/10*						
RR MEWS	**3**	**2**	**1**	**0**	**1**	**2**	**3**
	<8	≤9	10-11	12-14	15-20	21-29	≥30

Range of value sets generated for a HEART RATE MEWS

Agreement: 20%	0 1 2 3 4 5 6 7 8 9 *2 = 2/10*						
HR MEWS	**3**	**2**	**1**	**0**	**1**	**2**	**3**
	<40	40-49	50-59	60-90	91-110	111-129	≥130

Agreement: 20%	0 1 2 3 4 5 6 7 8 9 *2 = 2/10*						
HR MEWS	**3**	**2**	**1**	**0**	**1**	**2**	**3**
	<40	41-49	50-59	60-90	91-110	111-129	≥130

Agreement: 20%	0 1 2 3 4 5 6 7 8 9 *2 = 2/10*						
HR MEWS	**3**	**2**	**1**	**0**	**1**	**2**	**3**
	<40	40-50	51-59	60-100	101-110	111-129	≥130

Agreement: 10%	0 1 2 3 4 5 6 7 8 9 *1 = 1/10*						
HR MEWS	**3**	**2**	**1**	**0**	**1**	**2**	**3**
	<35	≤40	41-50	51-100	101-110	111-129	≥130

Agreement: 10%	0 1 2 3 4 5 6 7 8 9 *1 = 1/10*						
HR MEWS	**3**	**2**	**1**	**0**	**1**	**2**	**3**
	<35	36-40	41-50	51-100	101-110	111-129	≥130

Agreement: 10%	0 1 2 3 4 5 6 7 8 9 *1 = 1/10*						
HR MEWS	**3**	**2**	**1**	**0**	**1**	**2**	**3**
	<40	40-49	50-60	61-100		≥120	≥130

Agreement: 10%	0 1 2 3 4 5 6 7 8 9 *1 = 1/10*						
HR MEWS	**3**	**2**	**1**	**0**	**1**	**2**	**3**
	<35	35-50	51-59	60-100	101-110	111-129	≥130

Range of value sets generated for a SpO_2 %MEWS

Ranking: 30%	0 1 2 3 4 5 6 7 8 9 *1 2 = 3/10*						
SpO_2 % MEWS	**3**	**2**	**1**	**0**	**1**	**2**	**3**
	<85%	85-89%	90-93%	94%+			

Ranking: 30%	0 1 2 3 4 5 6 7 8 9 *2 1 = 3/10*						
SpO_2 % MEWS	**3**	**2**	**1**	**0**	**1**	**2**	**3**
	<85%	85-89%	90-94%	95%+			

Ranking: 20%	0 1 2 3 4 5 6 7 8 9 *1 1 = 2/10*						
SpO_2 % MEWS	**3**	**2**	**1**	**0**	**1**	**2**	**3**
	<85%	85-89%	90-92%	93%+			

Ranking: 20%	0 1 2 3 4 5 6 7 8 9 *1 1 =2/10*						
SpO_2 % MEWS	**3**	**2**	**1**	**0**	**1**	**2**	**3**
	<90%	91-93%	94-96%	97%+			

Range of value sets generated for a SYSTOLIC BP MEWS

Ranking: 30%	0 1 2 3 4 5 6 7 8 9 *2 1 = 3/10*						
Sys BP MEWS	**3**	**2**	**1**	**0**	**1**	**2**	**3**
	≤70	71-80	81-100	101-149	150-169	170-179	>180

Ranking: 20%	0 1 2 3 4 5 6 7 8 9 *1 1 = 2/10*						
Sys BP MEWS	**3**	**2**	**1**	**0**	**1**	**2**	**3**
	≤70	71-80	81-100	101-179	180-200	>200	>250

Ranking: 20%	0 1 2 3 4 5 6 7 8 9 *2 = 2/10*						
Sys BP MEWS	**3**	**2**	**1**	**0**	**1**	**2**	**3**
	≤80	81-85	86-100	101-140	141-160	161-190	>190

Ranking: 20%	0 1 2 3 4 5 6 7 8 9 *1 1 = 2/10*						
Sys BP MEWS	**3**	**2**	**1**	**0**	**1**	**2**	**3**
	≤80	81-90	91-100	101-140	141-160	161-180	>180

Ranking: 10%	0 1 2 3 4 5 6 7 8 9 *1 = 1/10*						
Sys BP MEWS	**3**	**2**	**1**	**0**	**1**	**2**	**3**
	≤75	76-85	86-100	101-159	160-180	181-200	>200

Range of values generated for a TEMPERATURE MEWS

Ranking: 40%	0 1 2 3 4 5 6 7 8 9 *2 2 = 4/10*						
Temp MEWS	**3**	**2**	**1**	**0**	**1**	**2**	**3**
	<33°C	33-35°C	35.1-35.9°C	36-37.7°C	37.8-38.5°C	>38.6-39.5°C	>39.6°C

Ranking: 20%	0 1 2 3 4 5 6 7 8 9 *1 1 = 2/10*						
Temp MEWS	**3**	**2**	**1**	**0**	**1**	**2**	**3**
	<33°C	33-35°C		35-38°C	38-39 °C	>39 °C	

Ranking: 30%	0 1 2 3 4 5 6 7 8 9 *1 1 1 = 3/10*						
Temp MEWS	**3**	**2**	**1**	**0**	**1**	**2**	**3**
	<33°C	33-35°C		36-37.5°C	37.6-38°C	>38.1-39.5°C	>39.6°C

Ranking: 10%	0 1 2 3 4 5 6 7 8 9 *1 = 1/10*						
Temp MEWS	**3**	**2**	**1**	**0**	**1**	**2**	**3**
	<35°C	35-36°C		36.1-38°C		>38°C	

Range of values generated for a NEUROLOGICAL STATUS/CONSCIOUS LEVEL MEWS*

Ranking: 44.4%	0 1 2 3 4 5 6 7 8 9 *1* 3 1 = 4/9 *excluded*						
Conscious MEWS	**3**	**2**	**1**	**0**	**1**	**2**	**3**
				ALERT (A)	RESPONDS TO VOICE (V)	RESPONDS TO PAIN (P)	UNRESPONSIVE (U)

Ranking: 55.6%	0 1 2 3 4 5 6 7 8 9 *1 1 3 = 5/9*						
Conscious MEWS	**3**	**2**	**1**	**0**	**1**	**2**	**3**
				ALERT (A) (≅GCS 15)	RESPONDS TO VOICE (V) (≅GCS 14)	RESPONDS TO PAIN (P) (≅GCS 13-9) Confused	UNRESPONSIVE (U) (≅GCS <8)

***The close tie for conscious level MEWS rankings resulted in a further round by Delphi to clarify rankings only for this variable, resulting in the following ranges (only 8 members responded):**

Ranking: 37.5%	0 1 2 3 4 5 6 7 8 9 *2 1 = 3/8*						
Conscious MEWS	**3**	**2**	**1**	**0**	**1**	**2**	**3**
				ALERT (A)	RESPONDS TO VOICE (V)	RESPONDS TO PAIN (P)	UNRESPONSIVE (U)

Ranking: 62.5%	0 1 2 3 4 5 6 7 8 9 *1 1 3 = 5/8*						
Conscious MEWS	**3**	**2**	**1**	**0**	**1**	**2**	**3**
				ALERT (A) (≅GCS 15)	RESPONDS TO VOICE (V) (≅GCS 14)	RESPONDS TO PAIN (P) (≅GCS 13-9) Confused	UNRESPONSIVE (U) (≅GCS <8)

Range of value sets generated for a URINE OUTPUT MEWS

Ranking: 50%	0 1 2 3 4 5 6 7 8 9 *1 2 2 = 5/10*						
UO MEWS	**3**	**2**	**1**	**0**	**1**	**2**	**3**
	<20 ml/hr	<30 ml/hr or less	50 ml/hr or less	60ml/hr If normally anuric score 0	150 ml/hr or more		

Ranking: 10%	0 1 2 3 4 5 6 7 8 9 *1 =1/10*						
UO MEWS	**3**	**2**	**1**	**0**	**1**	**2**	**3**
	<0.3 ml/kg/hr	0.3- 0.5 ml/kg/hr	0.5-1 ml/kg/hr	60ml/hr If normally anuric score 0	3ml/kg/hr or more		

Ranking: 0%	0 1 2 3 4 5 6 7 8 9 *1* *Excluded*						
UO MEWS	**3**	**2**	**1**	**0**	**1**	**2**	**3**
	<30 ml/hr *Or no urine for 6 hours*	30 ml/hr		60ml/hr If normally anuric score 0			>200 ml/hr

Ranking: 20%	0 1 2 3 4 5 6 7 8 9 *1 1 = 2/10*						
UO MEWS	**3**	**2**	**1**	**0**	**1**	**2**	**3**
	≤30 ml/hr	≤40 ml/hr	<50 ml/hr	50-60ml/hr If normally anuric score 0	150 ml/hr or more		>200 ml/hr

Round 3 results: Consensus for 5* parameters within the high tertile scores (7-9)

Range of value sets generated for a RESPIRATORY RATE (RR) MEWS

Agreement: 90%	0 1 2 3 4 5 6 7 8 9 3 *6 = 9/10*			Ranking key: Total disagreement: 0 1 2 3 4 5 6 7 8 9 Total agreement			
RR MEWS	**3**	**2**	**1**	**0**	**1**	**2**	**3**
	<8	≤9	10-11	12-14	15-20	21-29	≥30

Range of value sets generated for a SYSTOLIC BP MEWS

Agreement: 100%	0 1 2 3 4 5 6 7 8 9 5 *5 = 10/10*						
Sys BP MEWS	**3**	**2**	**1**	**0**	**1**	**2**	**3**
	≤70	71-80	81-100	101-149	150-169	170-179	>180

Range of values generated for a TEMPERATURE MEWS

Agreement: 100%	0 1 2 3 4 5 6 7 8 9 3 *7 = 10/10*						
Temp MEWS	**3**	**2**	**1**	**0**	**1**	**2**	**3**
	<33°C	33-35°C	35.1-35.9°C	36-37.7°C	37.8-38.5°C	>38.6-39.5°C	>39.6°C

Range of value sets generated for a URINE OUTPUT MEWS

Agreement: 90%	0 1 2 3 4 5 6 7 8 9 *1 4 4 = 9/10*						
UO MEWS	**3**	**2**	**1**	**0**	**1**	**2**	**3**
	<20 ml/hr	<30 ml/hr or less	50 ml/hr or less	60ml/hr If normally anuric score 0	150 ml/hr or more		

***Range of values generated for a NEUROLOGICAL STATUS/CONSCIOUS LEVEL MEWS** (Although this range did not achieve a 70% ranking there was consensus by e-mail and personal interview to accept this range to make the transition from the GCS to the AVPU easier for ward staff)

Agreement: 62.5%	0 1 2 3 4 5 6 7 8 9 *1 1 3 = 5/8*						
Conscious MEWS	**3**	**2**	**1**	**0**	**1**	**2**	**3**
				ALERT (A) (≅GCS 15)	RESPONDS TO VOICE (V) (≅GCS 14)	RESPONDS TO PAIN (P) (≅GCS 13-9) Confused	UNRESPONSIVE (U) (≅GCS <8)

CONSENSUS RANKING (70%) was **not achieved** for two MEWS parameters

Range of value sets generated for a HEART RATE (HR) MEWS

Agreement: 50%	0 1 2 3 4 5 6 7 8 9 *1 4 = 5/10*						
HR MEWS	**3**	**2**	**1**	**0**	**1**	**2**	**3**
	<40	40-50	51-59	60-100	101-110	111-129	≥130

Range of value sets generated for a SpO_2 %MEWS

Agreement: 50%	0 1 2 3 4 5 6 7 8 9 *1 1 3 = 5/10*						
SpO_2 % MEWS	**3**	**2**	**1**	**0**	**1**	**2**	**3**
	<85%	85-89%	90-93%	94%+			

Appendix 4.1

APPENDIX 4.1

Review No.	Folder No.	SAE 1=YES 0=NO	Death	ICU	CardArrest	Ward	Intervention=1 Comparator=0	Speciality	Age	1=Female	Prescribed vital signs monitoring 1=Yes 0=No	Specific parameters 1=yes	No. parameters	Frequency 1=yes	Cut-point 1=yes
Ordered other monitoring 1=yes	MEWS CHART (study 3) 1=yes	RR Admission 0 = not recorded	adm RRMEWS	RR Freq (Hrs) prescribed 0=no 1=yes	RR Freq POST-OP recordings first 8 hrs	Postop normal MEWS=0	Post-op MEWS RRh 1,2,3, 4=absent	Post-op MEWS RRL 1,2,3, 4=absent	RR Triggered response 1=YES 0=NO 2=N/A 3=not recorded	SATS Freq prescribed 0=no 1=yes	SATS Freq POST-OP recordings first 8 hrs	MEWS SATS normal=0	Post-op MEWS SATSL 1,2,3, 4=absent	Triggered response 1=YES 0=NO 2=N/A 3=not recorded	HR Admission 0 = not recorded
MEWS HR adm	HR Freq prescribed 0=no 1=yes	HR Freq POST-OP recordings in first 8 hrs	MEWS HR normal=0	Post-op MEWS HRh 1,2,3 4=absent	Post-op MEWS HRL 1,2,3 4=absent	HR Triggered response 1=YES 0=NO 2=N/A 3=not recorded	BP (syst) Admission 0=not recorded	Adm MEWS SBP	BP Freq prescribed 0=no 1=yes	Freqof POST-OP BP recordings in first 8 hrs	MEWS SPB normal=0	Post-op MEWSBPh 1,2,3 4=absent	Post-op MEWSBPL 1,2,3 4=absent	BP Triggered response 1=YES 0=NO 2=N/A 3=not recorded	Temp Admission
Adm MEWS temp	TOTAL MEWS on adm	Temp Freq prescribed 0=no 1=yes	Temp Freq POST-OP temp recordings in first 8 hrs	MEWS temp normal=0	Post-op MEWS TEMPh 1,2,3 4=absent	Post-op MEWS TEMPL 1,2,3 4=absent	Temp Triggered response 1=YES 0=NO 2=N/A 3=Not Documented	LOC freq prescribed 0=no 1=yes	LOC Freq recordings in first 8 hrs POST-OP	MEWS loc normal=0	LOC MEWS L 1,2,3 4=absent	LOC Triggered response 1=YES 0=NO 2=N/A 3=Not Documented	UO Freq prescribed 0=no 1=yes	Freq of POST-OP U/O recordings in first 8 hrs	
MEWS UO normal=0	UO MEWS L 0,1,2,3 4=absent	UO Triggered response 1=YES 0=NO 2=N/A 3=Not Documented	Co-morbidity 1=yes 0=no	No. Comorbid	HPT	MI	DM	Carcinomas	CVAHyper Chol	Respiratory	Renal	OthercoMorbid	No. of days in hospital (Clinicom)		

Total MEWS for recoded vital sign recordings on admission for individual patients (0=normal, +=upper value, -=lower value)

	Respiratory rate	MEWS	Heart rate	MEWS	Systolic blood pressure	MEWS	Temperature °C	MEWS	Total MEWS
SAE n=11									
1	20	+1	70	0	206	+3	36.6	0	4
2									
3			89	0	142	0	36.4	0	0
4			97	0	164	+1	36.2	0	1
5			100	0					0
6	20	+1	67	0	186	+3	36	0	4
7					100	-1	36	0	1
8									
9	18	+1	61	0	116	0	36.3	0	1
10			97	0	58	-3	36	0	3
11	20	+1	84	0	130	0	36.8	0	1
									Total MEWS Median=1, minimum-maximum=0-4
No SAE (n=44)									
1									
2			78	0	175	+2			2
3	22	+2	85	0	115	0	36	0	2
4	18	+1	83	0	100	-1	36.2	0	2
5	18	+1	123	+2	120	0	38.7	+2	5
6	18	+1	93	0	145	0	36.6	0	1
7			53	-1	110	0	35.6	-1	2
8			106	+1	197	+3	36.5	0	4
9			96	0	143	0	35.9	-1	1
10	18	+1	60	0	130	0	36	0	1
11			111	+2	133	0	36.1	0	2
12	18	+1	90	0	116	0			1
13			91	0	132	0	36.7	0	0
14			108	+1	111	0	36.4	0	1
15	16	+1	96	0	110	0	37	0	1
16			119	+2	133	0	38.2	+1	3
17			80	0	130	0	36	0	0
18			75	0	116	0	37.3	0	0
19			63	0	141	0	36.8	0	0
20			96	0	141	0	36.5	0	0
21	18	+1	103	+1			36.7	0	2
22					150	+1	36	0	1

No SAE 23	21	+2	89	0	219	+3	36.5	0	5
24	18	+1	81	0	118	0	36.3	0	1
25	18	+1	86	0	144	0	36.3	0	1
26	18	+1	76	0	117	0	36.2	0	1
27			72	0	98	-1	36.1	0	1
28	20	+1	87	0			36.6	0	1
29			78	0	191	+3	36.2	0	3
30	18	+1	94	0	137	0	36.1	0	1
31	20	+1	69	0	130	0	36.6	0	1
32			66	0	115	0	36.5	0	0
33	16	+1	106	+1	140	0	36.8	0	2
34			91	0	132	0	36	0	0
35	16	+1	87	0	128	0	36	0	1
36			95	0	119	0	36.4	0	0
37			65	0	124	0	36.2	0	0
38			76	0	140	0	35.6	-1	1
39	20	+1	74	0	136	0	36.3	0	1
40	22	+2	58	-1	130	0	36.1	0	3
41			90	0	130	0	36.3	0	0
42			96	0	113	0	36.2	0	0
43			88	0	120	0	37	0	0
44					140	0	37.4	0	0
									Total MEWS Median=1, minimum-maximum=0-5

Note on Table 4-11:

Shaded areas denote no recordings.

Record review showed that not all patients had recordings of all four parameters on admission. Two patients who died and one from the comparator group had no recordings. Respiratory rate was recorded the least often for all patients (23/55, 41.8%) and was recorded for four (36.4%) patients who died following surgery.

On admission the majority of patients in both groups scored 0 ('normal') on the MEWS for single parameters (systolic BP, heart rate and temperature). However, six (N=55, 10.9%) patients should have triggered the call-out algorithm by scoring 3 on the MEWS for systolic BP, three of whom died following surgery. All patients had a rapid respiratory rate (15-29, MEWS upper 1 and 2). Eight patients had seriously disturbed physiology (MEWS of 2 for single parameters) but none died. The median total MEWS for both groups was 1 (SAE=range 0-4; No SAE=range 0-5).

To fully understand Aiken et al.'s (1997) model, the primary author (LA) provided a conceptual framework depicting, in this instance, the comparative cost-effectiveness of nursing delivery system strategies[1] presented in Figure 5-1.

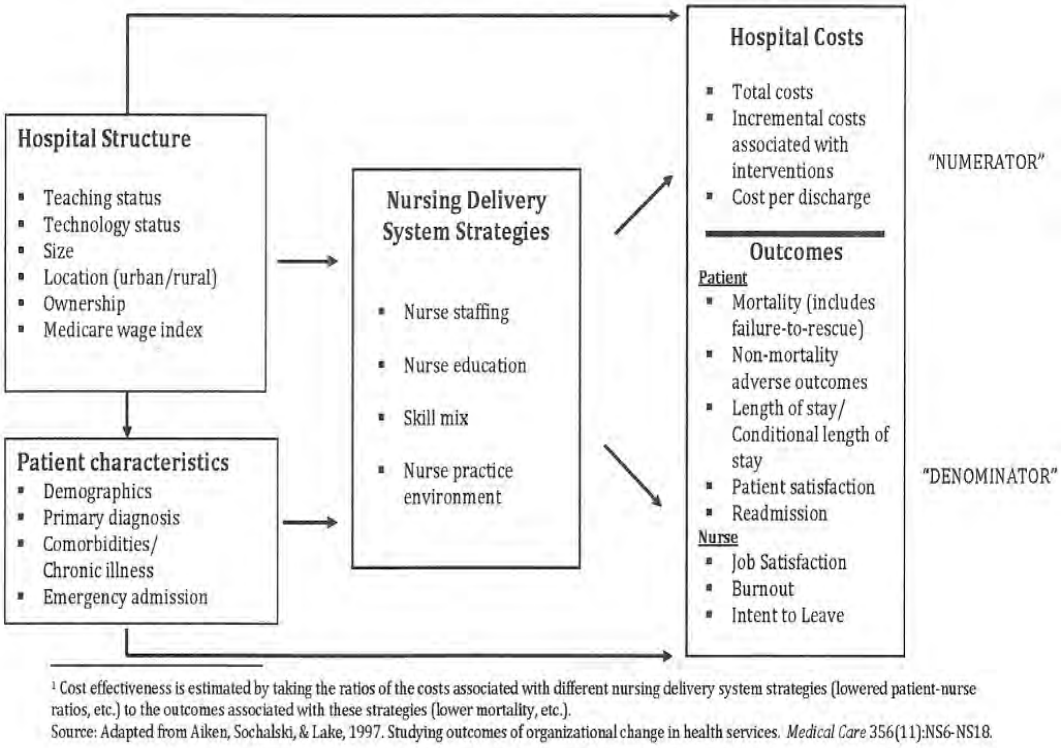


Figure 1: Conceptual Framework of the Comparative Cost-Effectiveness of Nursing Delivery System Strategies[1] (provided by the author)

Reference

1. Aiken LH, Sochalski J, Lake ET. Studying Outcomes of Organizational Change in Health Services. *Medical care* 1997;35(11):NS6-NS18.

SAMPLE SIZE DETERMINATION FOR RECORD REVIEW (STUDY 3)

Mean 1 (exp): 0.02

Mean 2 (obs): 0.2

SD1 or Tolerance: 0

SD2: 0

Allocation Ratio: 1

Power: 80

Alpha: 5

Method: Two Sample

Analysis with continuity correction

---

z for 1-power=0.84
z for alpha double sided=1.96
z for alpha single sided=1.64

TWO SAMPLE ANALYSIS
RESULTS for double sided
The sample size required for group1=n1=57. The sample size required for group 2=n1*allocation ratio=57*1=57. The total sample size required N=n1+n2=57+57=114.
RESULTS for single sided
The sample size required for group1=n1=47. The sample size required for group2=n1*allocation ratio=47*1=47. The total sample size required N=n1+n2=47+47=94.
Optimum allocation ratio= 2.86

Reference:
Uitenbroek DG. "SISA-Binomial" (SISA (Simple Interactive Statistical Analysis), 1997. Available online at: http://www.quantitativeskills.com/sisa/distributions/binomial.htm

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26 February 2010

Dear colleague

Invitation to validate instruments

I am registered for a PhD in Nursing comprising a 3-part study. Part 1 was to design an observation chart with a scoring system to be used by nurses for the early recognition of physiological and clinical deterioration. This has been completed with medical and nursing experts.

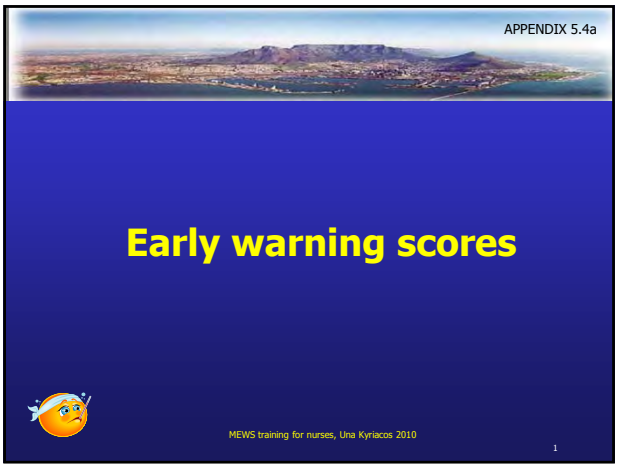
Part 3 involves ward teaching and testing the chart. To get to this I would like to test nurses' knowledge of basic vital sign monitoring and associated physiology, then to implement the chart in 3 experimental wards (having 3 control wards as well) and then administer the same test afterwards to establish if the training and new chart has changed scores. Because of staffing constraints I will have a skill-mix of nurse categories in each group as staff will be released for training as the ward situation allows. I will make allowance for this in the marking – even if only to note trends in knowledge base amongst the various categories of nurses. It is not about the mark achieved, rather, it is about improvement, if any.

I have invited you to evaluate both the test and the PowerPoint training programme using the CVI form attached.

I would be most grateful to have this back by Wednesday 3 March. Please let me know if you need more time (0761422676) as I am on sabbatical and not in office at regular times.

Yours sincerely

Una Kyriacos



Objectives of training programme

To improve nurses':

- ✓ competence in recognising early warning signs of physiological deterioration
- ✓ competence in recognising early warning signs of clinical deterioration
- ✓ confidence in summoning skilled clinical assistance in appropriate circumstances
- ✓ confidence in reporting abnormal vital signs using the SBAR communication aid
- ✓ clinical decision-making skills
- ✓ record keeping of vital sign monitoring

MEWS training for nurses, Una Kyriacos 2010 2

How do you know when patients are so ill that it's time to act?
(Baines, E. & Kanagasundaram, N. S. 2008)

MEWS training for nurses, Una Kyriacos 2010 3

Patient data:

Mrs Dlomo, a widowed 65 year old woman, is admitted to your general surgical ward. She lives with her married daughter.

Medical history: Hypertension, schizophrenia. She is on medication for each of these.

Her admission vital sign recordings were:

Respiratory rate:	22 breaths a minute
BP:	219/92 mm Hg
Heart rate:	90 beats a minute
Temperature:	36.8ºC
Finger prick Hb:	13 g/dL

Mrs Dlomo has had a general anaesthetic for a laparotomy and total gastrectomy.

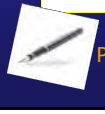
Her vital sign recordings when discharged from the recovery room were:

Respiratory rate:	14 breaths a minute
O_2 Sat:	99%
BP:	180/88 mm Hg
Heart rate:	72 beats a minute
Temperature:	36.2ºC
Conscious level:	Awake and responding to voice
Pain:	Morphine 10mg given intramuscularly
Finger prick Hb:	13 g/dL

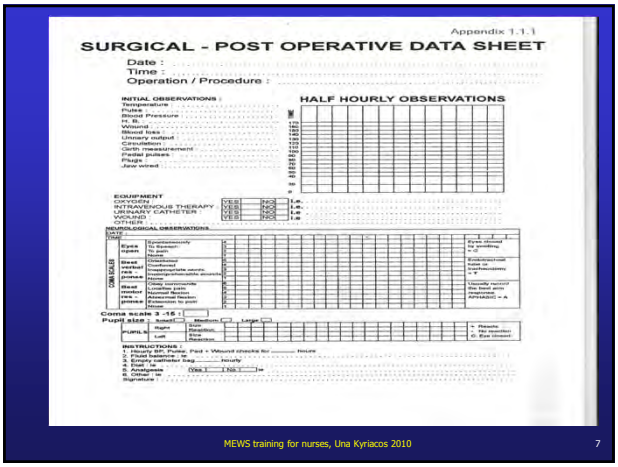
Post-operative instructions: RR, HR, BP ½ hourly until stable

Mrs Dlomo's post-operative vital sign recordings are taken immediately she returns to the ward:

	10h30	11h00	11h30
RR:	26 p/m	27 p/m	31 p/m
O_2 Sat:	96%	97%	94%
BP:	100/75 mm Hg	96/65 mm Hg	92/63 mm Hg
HR:	115 bpm	120 bpm	135 bpm
Temperature:	36ºC	35.8ºC	35.6ºC
Conscious level : Responds to voice (V)		V	V
Urine output (bedpan):		0	30 ml



Plot the data on the blank observation chart


Appendix 1.1.1

SURGICAL - POST OPERATIVE DATA SHEET

Date :
Time :
Operation / Procedure :

INITIAL OBSERVATIONS :
Temperature
Pulse
Blood Pressure
R. R.
Volume
Blood loss
Urine output
Circulation
Girth measurement
Pedal pulses
Plugs
Jaw wired

HALF HOURLY OBSERVATIONS

EQUIPMENT
OXYGEN
INTRAVENOUS THERAPY
URINARY CATHETER
WOUND
OTHER

NEUROLOGICAL OBSERVATIONS

Coma scale 3 -15 :
Pupil size

INSTRUCTIONS :
1. Hourly BP, Pulse, Pad = Wound checks for _____ hours
2. Fluid balance : to _____
3. Catheter bag _____ hourly
4. Gel : to
5. Analgesia
Signature :

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Clinical picture at 11h30:

- Mrs Dlomo says she feels cold – you confirm peripheral coldness
- She looks pale
- and complains of severe abdominal pain at a score of 3
- appears anxious and does not look well

Plot the data on the same blank ward observation chart

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QUESTIONS

What would you have to know about vital sign monitoring to respond appropriately in this situation?	Revision of test questions using diagrams to elicit responses
How does the chart help you decide how ill the patient is and when to call for more skilled assistance?	Group work and feedback
Explain what you would do in this situation	Group work and feedback

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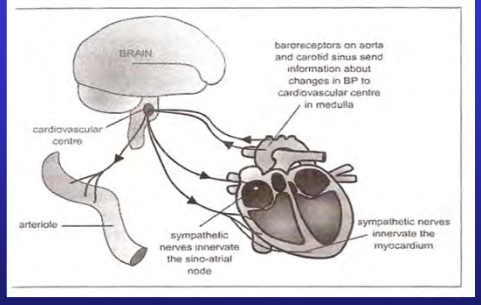
igure 1. Sympathetic and parasympathetic nervous system.
eproduced with the kind permission of Roger McFadden, University
f Central England.



Kiesel & Perkins, 2006

Other diagrams on separate pages

An Early Warning Score (EWS) is:

- used by nurses on general wards
- to monitor patients' bedside observations
- to prevent cardio-respiratory arrests and other serious adverse events

These EWS have been modified and are also known as Modified Early Warning Scores (MEWS)

Modified Early Warning Scoring System (MEWS) for 7 physiological parameters

	3	2	1	0	1	2	3
Respiratory rate/min	<8	8-9	10-11	12-14	15-20	21-29	30 or more
SpO_2	<85	85-89	90-94	95+			
Heart rate/min	<40	40-50	51-59	60-100	101-110	111-129	130 or more
BP systolic	≤70	71-80	81-100	101-149	150-169	170-179	>180
Temperature °C	<34	34-35	35.1-35.9	36-37.7	37.8-38.5	38.6-39.5	>39.6
*** Glasgow Coma Scale**				GCS 15	Change in Mental status/ GCS 14	GCS 13-9	GCS ≤ 8 or unresponsive
OR AVPU NEUROLOGICAL STATUS *				Alert	Reacting to voice	Reacting to pain	Unresponsive
**** Urine mls/kg/hr**	<20 ml/hr	≤30 ml/hr	50 ml/hr	60 ml/hr If normally anuric score 0			>300 ml/hr for 2 hrs

Aggregated score =

Interpretation: Aggregated MEWS: 3 = critical score

13

How well does the next chart tell

you

how ill the patient is?

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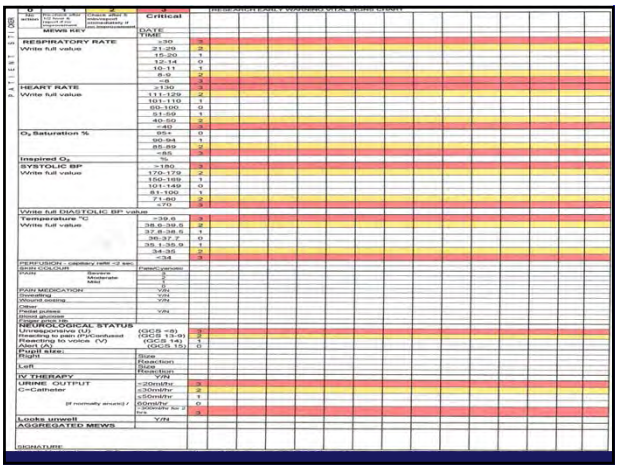
14



- What must the score be when you summon skilled assistance for a deteriorating patient?
- How will you know what to do?
- Let's see if the next chart tells you what to do ...

CALLING CRITERIA FOR INITIATION OF AN EMERGENCY RESPONSE

if any one of these is present call the Sister, if not available, the Medical Officer:

- ❑ Staff member is worried about the patient
- ❑ Acute change in heart rate to <50 or >120 beats/min
- ❑ Acute change in systolic blood pressure to <80 or >170 mmHg
- ❑ Acute change in respiratory rate to <10 or >20 breaths/min
- ❑ Acute change in pulse oximetry saturation to <90%, despite oxygen administration
- ❑ Acute deterioration in conscious state
- ❑ Acute change in urine output to <30ml/hr or >300ml/hour for 2 hours

Still puzzled?

Not to worry, there is more help ...

The SBAR communication tool for uniform reporting in the hospital

The SBAR communication aid:

report the following concerning the deteriorating patient

S = Situation

B = Background

A = (your) Assessment

R = (your) Recommendation/request

Now you know exactly what to do:

You have the -

- ✓ MEWS observation chart
- ✓ Calling criteria and
- ✓ SBAR communication tool

Let's try using our new tools …

Mrs Dlomo's post-operative vital sign recordings are taken immediately she returns to the ward:

	10h30	11h00	11h30
RR:	26 p/m	27 p/m	31 p/m
O_2 Sat:	96%	97%	94%
BP:	100/75 mm Hg	96/65 mm Hg	92/63 mm Hg
HR:	115 bpm	120 bpm	135 bpm
Temperature:	36°C	35.8°C	35.6°C
Conscious level : Responds to voice (V)		V	V
Urine output (bedpan):		0	30 ml

Plot the data on the MEWS observation chart

Clinical picture at 11h30:

- Mrs Dlomo says she feels cold – you confirm peripheral coldness
- She looks pale
- and complains of severe abdominal pain at a score of 3
- appears anxious and does not look well

Plot the data on the same blank MEWS observation chart

Let's compare charts

Read the scoring instructions on the MEWS chart

Now score Mrs Dlomo's vital signs

QUESTIONS

Compared to the current chart how does the MEWS chart help you decide how ill the patient is?	Group work and feedback
Compared to the current chart how does the MEWS chart help you decide when to call for more skilled assistance?	Group work and feedback
Explain what you would do in this situation and why you would take this action	Group work and feedback

The end .... (are you discouraged)?
Or
the beginning...(are you excited)?

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SBAR report to Doctor about a critical situation **APPENDIX 5.4b**

Time Dr alerted:_____

Time Dr responded: _____ **Date**

Time

S	**Situation** **I am calling about <patient name and location>.** **The patient's resuscitation status is < For Resus ? Not For Resus ?** **The problem I am calling about is** ☐ I am afraid the patient is going to arrest. **I have just assessed the patient personally:** **Observations are:** Blood pressure _____ /_____, Pulse _____, Respiration _____and temperature_____ **I am concerned about the sudden change in observations:** in the red or yellow bands on the observation chart ☐ Systolic blood pressure because it is ☐ over 170 or ☐ less than☐ or 30 mmHg below / above usual ☐ Pulse because it is ☐ over 120 or ☐ less than 50 ☐ Respiration because it is ☐ less than 10 or ☐ over 20. ☐ Temperature because it is ☐ less than 35 or☐ over 38.6^{0}C ☐ Conscious level is deteriorating ☐ General condition is deteriorating Urine Output =
B	**Background** **The patient's mental status is:** ☐ Alert and oriented to person place and time. ☐ Confused and ☐ cooperative or ☐ non-cooperative ☐ Agitated or combative ☐ Lethargic but conversant and able to swallow ☐ Drowsy and not talking clearly and possibly not able to swallow ☐ Comatose. Eyes closed. Not responding to stimulation. **The skin is:** ☐ Warm and dry ☐ Pale ☐ Sweaty ☐ Extremities are cold ☐ Extremities are warm **The patient ☐ is not or ☐ is on oxygen**. ☐ The patient has been on _____(l/min) or (%) oxygen for _____ minutes (hours) ☐ The oximeter is reading _____% ☐ The oximeter does not detect a good pulse and is giving erratic readings.
A	**Assessment** ☐ **I think the problem is …….** ☐ **I don't know what the problem is but patient is deteriorating**
R	**Recommendation** ☐ I would like you to see the patient within the next 30 minutes ☐ I would like you to see the patient now ☐ I would like approval of my course of action which is …….. **Are any tests needed:** ☐ Do you need any tests? **If a change in treatment is ordered then ask:** ☐ How often do you want observations done? ☐ If the patient does not qet better when would you want us to call aqain?

Adapted from Kaiser Foundation Health Plan, Inc. 2004 by Una Kyriacos, March 2010

How to measure and record vital signs to ensure detection of deteriorating patients

Nursing Times 30 November, 2009

Staff need to recognise and act appropriately when patients deteriorate. This article gives practical advice on using basic observations to monitor patients

Authors

Carole Boulanger, MSc, BSc, is consultant nurse, critical care, Royal Devon and Exeter Foundation Trust, and core adviser to Patient Safety First; **Marie Toghill, PGDip, BN,** is sister, intensive care unit, Royal Devon and Exeter Foundation Trust.

Abstract

Boulanger C, Toghill M (2009) Ensuring best practice in observation to detect and report on patient deterioration. *Nursing Times*; 105: 47, early online publication.

This article aims to provide knowledge, skills and practical advice for registered nurses, to improve the assessment, recording and reporting of patient observations. Using guidance from Patient Safety First's intervention on reducing harm from deterioration, common issues for ward staff are illustrated and practical advice is given.

Keywords: Patient safety, Deterioration, Patient observations, Vital signs

- This article has been double-blind peer reviewed

Patient Safety First
Patient Safety First aims to make sustainable change to the way NHS staff approach patient safety, making it everyone's highest priority. The campaign focuses on five key clinical and leadership interventions known to make a difference, including reducing harm from deterioration. For more information and resources see www.patientsafetyfirst.nhs.uk.

Practice points

- Senior nurses should encourage all staff to take pulses manually while recording respiratory rates, as much more clinical information can be gathered in the same amount of time.
- It is good practice to write patients' normal blood pressure reading on the top of their observation chart; this makes it easier to quickly detect deterioration in individual patients.

Background
It is well recognised that hospitals may not consistently be the place of safety that patients and their families expect. Indeed, some literature suggests that patients may receive suboptimal care and early recognition of deterioration can be inconsistent (The National Confidential Enquiry into Patient Outcome and Death, 2005). This is supported by research on cardio-respiratory arrest in hospital, where one study showed 60% of cardiac arrests, deaths and unplanned admission to ICU had detectable deterioration in vital signs (Hillman et al, 2001).

Serious incidents reported to the National Patient Safety Agency (2007) identified that 11% of deaths were due to patient deterioration not being recognised or acted on appropriately. Key areas for improvement were regular observations, early recognition of deterioration, improved communication and effective response to concerns.

Nurses are pivotal to influencing improvements in observations management and ultimately patient safety. Patient Safety First's reducing harm from deterioration intervention provides guidance to help. It is designed to reduce avoidable harm and reduce in-hospital cardiac arrest and mortality rates through earlier recognition and treatment of deteriorating adult patients.

Tackling deterioration
The national patient safety agenda and occasionally individual trust agendas can sometimes feel removed from busy clinical areas where there are multiple clinical, organisational and managerial challenges to prioritise on a shift-to-shift basis. Drawing from clinical cases and taking practical advice from Patient Safety First will help provide solutions.

Nurses play an essential role in influencing patient safety every day. However, taking observations or measuring vital signs is increasingly seen as a task based activity rather than the gathering of clinical information. This poses a real danger for patients. Without effective leadership from nurses in senior roles, there is the potential for patient observations not to be seen as a serious responsibility.

Observations should form part of nurses' core skill set and provide the best early information on a patient at risk of deterioration: taking and recording of observations should be seen as pieces in a clinical jigsaw to illustrate how patients are progressing and demonstrate areas of potential concern.

The most important vital signs are:

- **Heart rate:** registered and non registered staff are formally trained to feel patients' pulse. However, once in a clinical setting, the culture reverts to recording the heart rate from an automated machine, a Dinamap or equivalent. While this is accepted practice, as it is quick and easy and in theory removes some of the potential for human error, it is not the most effective method of gaining clinical information about patients' cardiovascular

status. Important clinical information such as pulse volume, rate and rhythm, together with patients' peripheral temperature picked up on touch, are all lost if equipment alone is used;

- **Blood pressure:** currently most BP recording is undertaken with automated machines. There are benefits as it removes some of the variability which may exist between operators. However, issues such as cuff size often feature in concerns over accuracy. Moreover, skills in manual auscultation of BP using a sphygmomanometer are lost. It is important to remember that using the incorrect cuff size in manual BP measurement can also make this unreliable.
- **Respiratory rate:** many hospitals involved in monitoring their reliability in recording physiological observations, such as the Safer Patients Initiative or Productive Ward sites, have noted that recording of respiratory rate is frequently absent, despite its importance in alerting staff to deterioration in a patient's condition. There are many suggestions about why this might be the case, including a lack of mechanical equipment capable of recording respiratory rate and variability between observers;
- **Level of consciousness** - there are a number of ways this is detected, such as AVPU (Alert, responds to Voice, responds to Pain, Unresponsive). This quick and easy tool gives a clear guide on patients' level of consciousness; patients are identified as being at risk if they respond only to pain or are unresponsive. This would equate to a Glasgow Coma Scale (GCS) score of 8-9 and therefore the patient would require an urgent review as their airway may be at risk. The GCS has been widely used for many years to assess consciousness level and is scored from 3 to 15, 3 being the worst, and 15 the best. It consists of three parameters: best eye response, best verbal response and best motor response;
- **Pulse oximetry:** an observation of pulse oximetry can often be used to confirm practitioners' clinical view. However, this can be misleading and inaccurate in some patients, such as those with anaemia, arrhythmias, poor peripheral perfusion and those who have been exposed to carbon monoxide. Used with appropriate clinical judgement, pulse oximetry, together with respiratory rate, signs of increased work in breathing, colour and "new" patient confusion all have the potential to consistently provide valuable information;
- **Urine output:** this is used in many trusts with some merit as oliguria is a sensitive indicator of poor perfusion, a reduced cardiac output and early indicator of acute renal failure. This parameter often causes problems in general ward areas as many patients will not be on hourly urine measurements or may not be on fluid management charts. Getting into the habit of asking even mobile patients about urine output is not a waste of time as it can be an early indicator of causes for concern.

Box 1and Box 2 outline case studies showing signs of patient deterioration that were not detected or acted on.

Box 1. Case study 1

Tom Brown*, aged 68, was admitted to the intensive care unit following successful resuscitation for a pulseless electrical activity (PEA) arrest. His past medical history included hypertension and atrial fibrillation controlled with digoxin. He had been admitted to an acute medical ward five days earlier with a lower respiratory tract infection and started on IV antibiotics and chest physiotherapy.

His observations had been recorded six hourly as per ward protocol since admission. While these triggered an alert on the early warning score (EWS) system, the results had been added up incorrectly.

Review of his observation charts in intensive care revealed that in the two days before his arrest:

- His respiratory rate was slowly increasing;
- His BP was falling from his baseline of 165/80 to 110/65;
- Heart rate had risen from 98 and being irregular on admission to 130;
- The fluid balance chart showed increasing oliguria and poor oral intake secondary to nausea and vomiting;
- His early warning score had been incorrectly calculated and repeated.

*The patient's name has been changed.

Commentary on case study 1

This is not an unusual case and illustrates some of the pitfalls of both vital signs recording and track and trigger systems. Non shockable cardiac arrests, that is, asystolic or those with pulseless electrical activity, form the majority of in-hospital cardiac arrests and also carry the highest mortality. The primary cause of the event is not always cardiac in origin and therefore the underlying cause has to be determined and addressed for a successful outcome. In this case the following questions should be asked:

Who is taking observations?

In many ward areas observations are taken by a range of staff, both registered and non registered members of the team. It is worth reviewing the education and competency packages in use. The Department of Health (2009) has developed a framework of core competencies and skills that teams need if they are caring for acutely ill patients;

Can you be sure all staff undertaking observations have the necessary knowledge and skills?

It is easy to become complacent about vital signs when their recording is seen very much as a task to be undertaken rather than a key clinical skill in putting patient safety first;

What provision is there for regular updates and checking accuracy?

In reality this is difficult to achieve but nonetheless necessary. Ensure your ward area participates fully in measuring compliance with observations. Plotting and tracking observations will help motivate staff to see this as important.

For example, nurses can use the Patient Safety First "check your charts template" at tinyurl.com/check-charts-template. This is a good way of getting all staff involved and maintaining standards.

Mr Brown's pre existing cardiac problems caused confusion with observations that could have been perceived as normal. Patients with atrial fibrillation and hypertension can cause confusion with track and trigger systems such as EWS and modified early warning scores (MEWS), as there can be a tendency to accept parameters as "the norm" and therefore miss subtle changes in patients' condition.

In Mr Brown's case, his BP would have been considered normal. However, for him this pressure constituted hypotension; it contributed to his poor urine output and accelerated his clinical deterioration.

There are no quick and easy solutions to this problem. Track and trigger tools, by definition, are broad and not patient specific. Solutions need to be trust wide and could include "acceptable heart rate or blood pressure" parameters on observation charts. Patients would then not trigger above or below this rate.

This has the potential to reduce false triggering, which in itself causes de-sensitisation to the tool. However, decisions to accept vital signs outside normally accepted parameters need to be reviewed carefully. A consultant or senior registrar would be best placed to make this judgement based on a thorough review of the patient and clear documentation in the medical notes. Clear guidance and training for this would be essential. It is a method used successfully in some trusts with the requisite safety systems in place for specifying who, what grade, and in which circumstances it should - and importantly should not - be used.

In this case Mr Brown's condition was detected and reported eventually, but to a junior doctor who may not have the experience or skills to make the appropriate judgement about their condition. NICE (2007) suggested that the response to a trigger should be a doctor with sufficient experience to manage the patient in question.

Not all patients at risk will be moved to a higher care area. Recognition and awareness of those at risk in the clinical area can be a significant challenge in rapidly changing ward cultures. Consider using the patient location/ward whiteboard to provide an instant visual reminder of the location of those at risk, not only for all nursing staff but medical/allied health professionals as well. For example, the Royal Devon and Exeter Foundation Trust uses an alarm icon on the physical and electronic patient administration system to denote patients at risk, which:

- Provides a visual trigger of those at risk;
- Allows the nurse in charge to ask questions about clinical management plans, providing clinical leadership and support for more junior team members;
- Prompts discussion about placing patients at risk together to facilitate nursing and appropriate observation;
- Allows a trust wide view of acuity, which is important for staff allocation.

Box 2. Case study 2

Jenny Armitage*, aged 76, has long standing COPD, and was admitted with an infective exacerbation onto a respiratory ward. Mrs Armitage has chronic respiratory problems which limit both her exercise tolerance and activity. She normally has a respiratory rate of 30.

On admission she had a respiratory rate of 32 which was thought to be normal for her. Observations continued on a six hourly basis, which was the norm for that ward. Two days after admission her oxygen saturations were noted to be 78% on a 28% Venturi mask.

On closer examination, Mrs Armitage had had a slowly increasing respiratory rate since admission to a rate of 44. She was using all her accessory muscles and was both peripherally and centrally cyanosed. She was tachycardic at 110bpm regular and hypertensive at 168/95mmHg.

Her EWS had been recorded over the last few days but no score had been entered for respiratory rate as she is normally tachypnoeic.

*The patient's name has been changed.

Commentary on case study 2

Increasing respiratory rate and increased effort by patients to breathe are well recognised as robust indicators for physiological decline. While this applies to all patients, staff often seem to be more concerned about the percentage of oxygen saturation.

The second case study further illustrates the dangers of assuming a parameter is normal. In this situation being tachypnoiec was "normal" for Mrs Armitage; what was abnormal, and a clinical indicator of deterioration, was the steady increase of her respiratory rate.

Issues surrounding desensitisation to parameters and early warning scores are always a risk in busy clinical areas. The solutions are not always clear; leadership has a key part to play:

- Consider short patient safety briefings at one or two points during the shift. These need only take a few minutes, with staff members reviewing early warning scores and areas of concern. This provides a defined forum for nurses

to challenge all scores and triggers, allowing clinical support for escalation and a review of the trend of patients' progress;

- Review handover processes - try to put patient safety at the centre of the handover with early warning scores handed over as part of patient details;
- Ensure escalation is appropriately documented and that all staff caring for specific patients are clear about the next steps;
- Improve communication - handover all patients using a communication tool such as SBAR (situation-background-assessment-recommendation, see Changing Practice) or RSVP (reason-story-vital-signs-plan) (Featherstone et al, 2008). This enables all staff to become familiar with the process and also gives confidence to more junior staff and helps them coordinate their thoughts and escalation of patients appropriately.

In summary, observations, often perceived as basic and routine, are a vital part of the information gained to ensure safer patient care and early recognition of deterioration.

Patient safety can, and should, be influenced at ward level on a daily basis. Without the active involvement of all nurses, it will not be seen as a priority. Patient safety is everyone's responsibility and should be at the forefront in everyday practice.

The Patient Safety First website, www.patientsafetyfirst.nhs.uk, features a "how to guide" on reducing harm from deterioration, provides access to a network of trusts taking similar steps to achieve safer healthcare and further practical advice on care of deteriorating patients.

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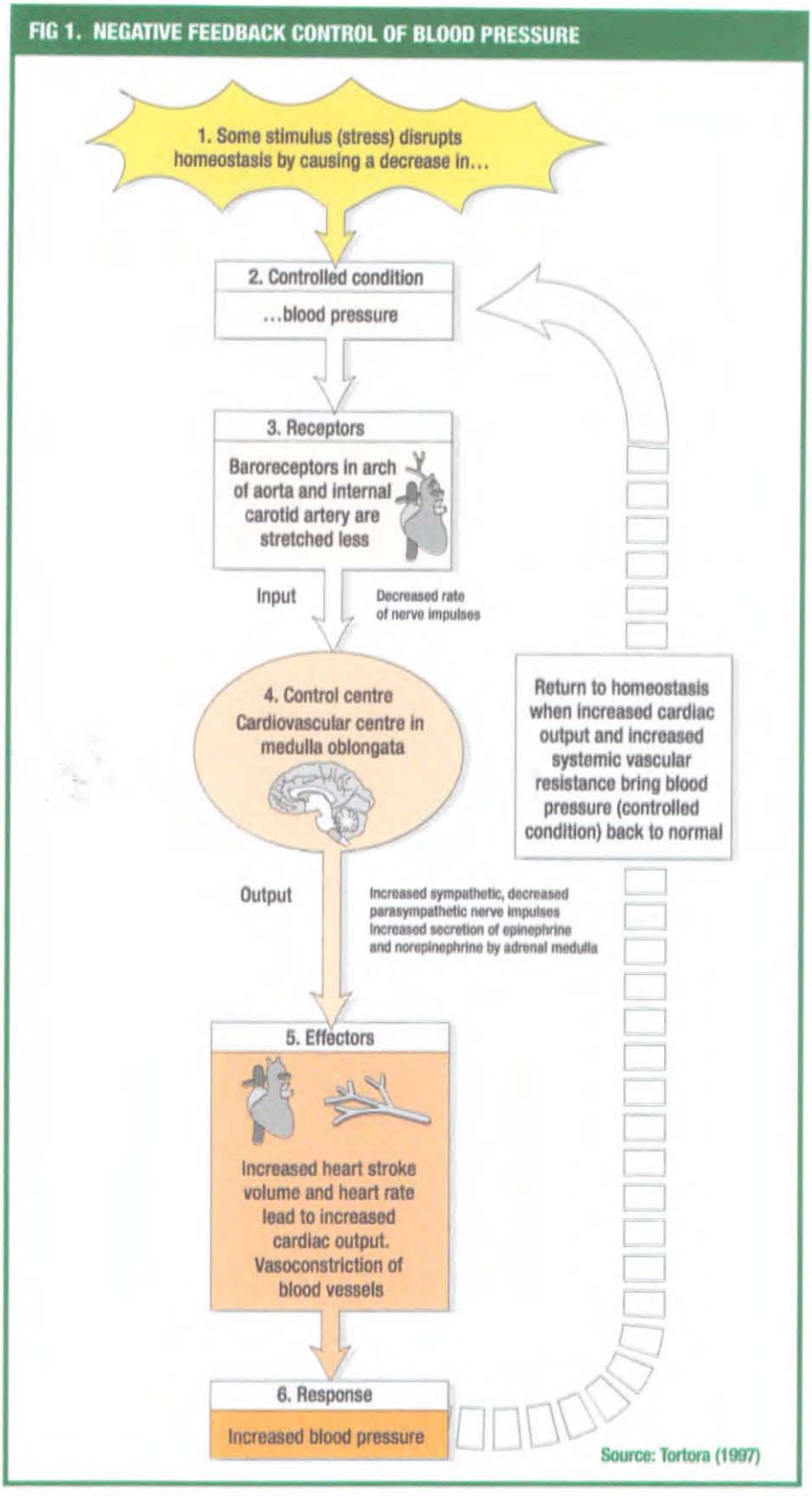
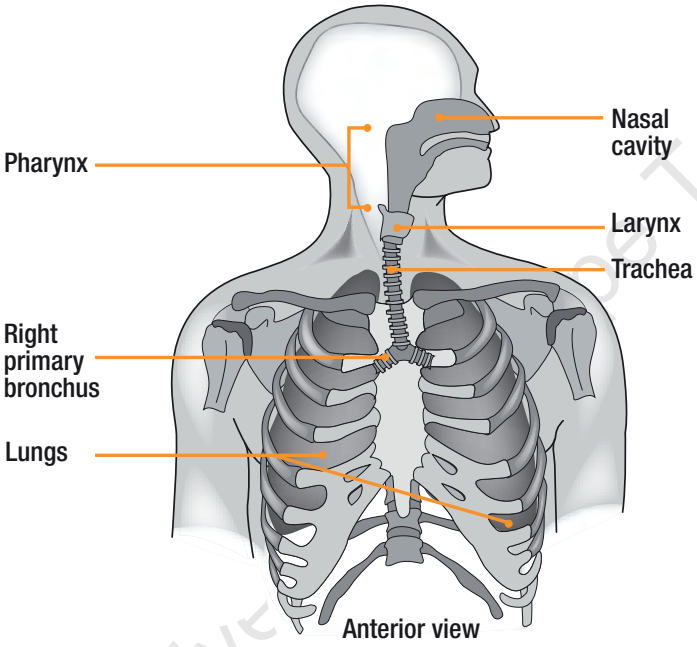


FIG 1. NEGATIVE FEEDBACK CONTROL OF BLOOD PRESSURE
1. Some stimulus (stress) disrupts homeostasis by causing a decrease in...
2. Controlled condition
...blood pressure
3. Receptors
Baroreceptors in arch of aorta and internal carotid artery are stretched less
Input
Decreased rate of nerve impulses
4. Control centre
Cardiovascular centre in medulla oblongata
Return to homeostasis when increased cardiac output and increased systemic vascular resistance bring blood pressure (controlled condition) back to normal
Output
Increased sympathetic, decreased parasympathetic nerve impulses
Increased secretion of epinephrine and norepinephrine by adrenal medulla
5. Effectors
Increased heart stroke volume and heart rate lead to increased cardiac output. Vasoconstriction of blood vessels
6. Response
Increased blood pressure
Source: Tortora (1997)

FIG 1. THE STRUCTURE OF THE RESPIRATORY SYSTEM



Functions of the respiratory system

1. Provide for gas exchange intake of O_2 for delivery to body cells and elimination of CO_2, produced by body cells.

2. Contains receptors for the sense of smell, filters inspired air, produces sounds, and helps eliminate waste.

3. Respiration takes place in three basic steps – pulmonary ventilation, external (pulmonary) respiration, and internal (tissue) respiration.

Source: Tortora (1997)

THE FORMATION OF URINE

FIGURATION, REABSORPTION, AND SECRETION

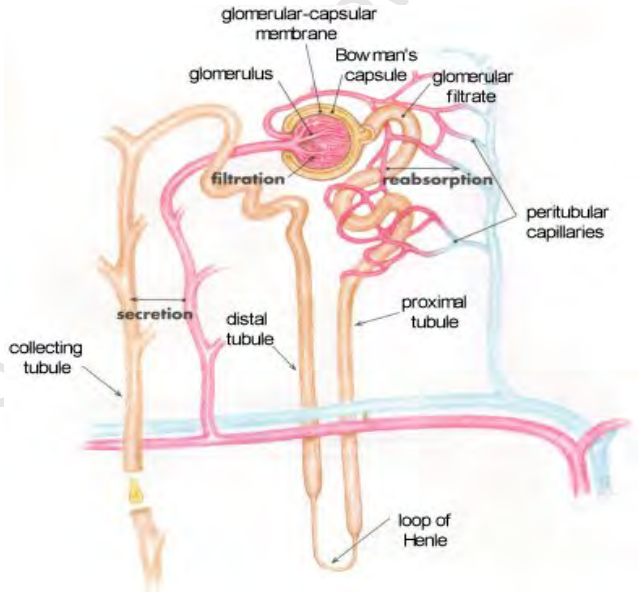
Every one of us depends on the process of urination for the removal of certain waste products in the body. The production of urine is vital to the health of the body. Most of us have probably never thought of urine as valuable, but we could not survive if we did not produce it and eliminate it. Urine is composed of water, certain electrolytes, and various waste products that are filtered out of the blood system. Remember, as the blood flows through the body, wastes resulting from the metabolism of foodstuffs in the body cells are deposited into the bloodstream, and this waste must be disposed of in some way. A major part of this "cleaning" of the blood takes place in the kidneys and, in particular, in the nephrons, where the blood is filtered to produce the urine. Both kidneys in the body carry out this essential blood cleansing function. Normally, about 20% of the total blood pumped by the heart each minute will enter the kidneys to undergo filtration. This is called the **filtration fraction**. The rest of the blood (about 80%) does not go through the filtering portion of the kidney, but flows through the rest of the body to service the various nutritional, respiratory, and other needs that are always present.

For the production of urine, the kidneys do not simply pick waste products out of the bloodstream and send them along for final disposal. The kidneys' 2 million or more nephrons (about a million in each kidney) form urine by three precisely regulated processes: filtration, reabsorption, and secretion.

Filtration

Urine formation begins with the process of **filtration**, which goes on continually in the renal corpuscles (Figure 3). As blood courses through the glomeruli, much of its fluid, containing both useful chemicals and dissolved waste materials, soaks out of the blood through the membranes (by osmosis and diffusion) where it is filtered and then flows into the Bowman's capsule. This process is called **glomerular filtration**. The water, waste products, salt, glucose, and other chemicals that have been filtered out of the blood are known collectively as glomerular filtrate. The glomerular filtrate consists primarily of water, excess salts (primarily Na^+ and K^+), glucose, and a waste product of the body called **urea**. Urea is formed in the body to eliminate the very toxic ammonia products that are formed in the liver from amino acids. Since humans cannot excrete ammonia, it is converted to the less dangerous urea and then filtered out of the blood. Urea is the most abundant of the waste products that must be excreted by the kidneys. The total rate of glomerular filtration (**glomerular filtration rate** or **GFR**) for the whole body (i.e., for all of the nephrons in both kidneys) is normally about 125 ml per minute. That is, about 125 ml of water and dissolved substances are filtered out of the blood per minute. The following calculations may help you visualize how enormous this volume is. The GFR per hour is:

Figure 3. Urine formation takes place in the nephron.



125 ml/min X 60min/hr= 7500 ml/hr.

The GFR per day is:
7500 ml/hr X 24 hr/day = 180,000 ml/day or 180 liters/day.

Now, what we have just calculated is the **amount of water** that is removed from the blood each day - about 180 liters per day. (Actually it also includes other chemicals, but the vast majority of this glomerular filtrate is water.) Imagine the size of a 2-liter bottle of soda pop. About 90 of those bottles equals 180 liters! Obviously no one ever excretes anywhere near 180 liters of urine per day! Why? Because almost all of the estimated 43 gallons of water (which is about the same as 180 liters - did you get the right answer?) that leaves the blood by glomerular filtration, the first process in urine formation, returns to the blood by the second process - reabsorption.

Reabsorption

Reabsorption, by definition, is the movement of substances out of the renal tubules back into the blood capillaries located around the tubules (called the **peritubular copillaries**). Substances reabsorbed are water, glucose and other nutrients, and sodium (Na^+) and other ions. Reabsorption begins in the proximal convoluted tubules and continues in the loop of Henle,

distal convoluted tubules, and collecting tubules (Figure 3). Let's discuss for a moment the three main substances that are reabsorbed back into the bloodstream.

Large amounts of water - more than 178 liters per day - are reabsorbed back into the bloodstream from the proximal tubules because the physical forces acting on the water in these tubules actually push most of the water back into the blood capillaries. In other words, about 99% of the 180 liters of water that leave the blood each day by glomerular filtration returns to the blood from the proximal tubule through the process of **passive reabsorption**.

The nutrient glucose (blood sugar) is **entirely** reabsorbed back into the blood from the proximal tubules. In fact, it is **actively transported** out of the tubules and into the peritubular capillary blood. None of this valuable nutrient is wasted by being lost in the urine. However, even when the kidneys are operating at peak efficiency, the nephrons can reabsorb only so much sugar and water. Their limitations are dramatically illustrated in cases of diabetes mellitus, a disease which causes the amount of sugar in the blood to rise far above normal. As already mentioned, in ordinary cases all the glucose that seeps out through the glomeruli into the tubules is reabsorbed into the blood. But if too much is present, the tubules reach the limit of their ability to pass the sugar back into the bloodstream, and the tubules retain some of it. It is then carried along in the urine, often providing a doctor with her first clue that a patient has diabetes mellitus. The value of urine as a diagnostic aid has been known to the world of medicine since as far back as the time of Hippocrates. Since then, examination of the urine has become a regular procedure for physicians as well as scientists.

Sodium ions (Na^+) and other ions are only partially reabsorbed from the renal tubules back into the blood. For the most part, however, sodium ions are **actively transported** back into blood from the tubular fluid. The amount of sodium reabsorbed varies from time to time; it depends largely on how much salt we take in from the foods that we eat. (As stated earlier, sodium is a major component of table salt, known chemically as sodium chloride.) As a person increases the amount of salt taken into the body, that person's kidneys decrease the amount of sodium reabsorption back into the blood. That is, more sodium is retained in the tubules. Therefore, the amount of salt excreted in the urine increases. The process works the other way as well. The less the salt intake, the greater the amount of sodium reabsorbed back into the blood, and the amount of salt excreted in the urine decreases.

Secretion

Now, let's describe the third important process in the formation of urine. **Secretion** is the process by which substances move into the distal and collecting tubules from blood in the capillaries around these tubules (Figure 3). In this respect, secretion is reabsorption in reverse. Whereas reabsorption moves substances out of the tubules and into the blood, secretion moves substances out of the blood and into the tubules where they mix with the water and other wastes and are converted into urine. These substances are secreted through either an **active transport** mechanism or as a result of **diffusion** across the membrane. Substances secreted are hydrogen ions (H+), potassium ions (K+), ammonia (NH3), and certain drugs. Kidney tubule secretion plays a crucial role in maintaining the body's acid-base balance, another example of an important body function that the kidney participates in.

Summary

In summary, three processes occurring in successive portions of the nephron accomplish the function of urine formation:

1. Filtration of water and dissolved substances out of the blood in the glomeruli and into Bowman's capsule;
2. Reabsorption of water and dissolved substances out of the kidney tubules back into the blood (note that this process prevents substances needed by the body from being lost in the urine);
3. Secretion of hydrogen ions (H^+), potassium ions (K^+), ammonia (NH_3), and certain drugs out of the blood and into the kidney tubules, where they are eventually eliminated in the urine.

Appendix 5.5

Participant Code Number …..……

RPN	RSN	RNA	SN

PRE- and POST-INTERVENTION TEST

Title of study: **The development, validation and testing of a vital signs monitoring tool for early identification of deterioration in adult surgical patients**

Researcher: Una Kyriacos
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OBSERVATORY 7925

Supervisor: Professor J Jelsma

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Thank you for agreeing to participate in this study. An information sheet is provided for you to keep. Please sign the attached consent form.

Please answer all the questions on this sheet:

Office use

1. How would you recognize respiratory arrest? (one sign) | 1 |

1.1

2. There is a sudden change in a patients' condition: circle the 2 respiratory rate readings in the list below for which you will summon more skilled assistance (help): in other words draw a circle around one group of slow rate readings and one group of fast rate readings. | 2 |

Less than 8	8-9	10-11	12-14	15-20	21-29	30 or more

3. How would you recognize signs of inadequate breathing in a patient in your ward? Give 3 signs. | 3 |

3.1

3.2

3.3

4. Do you personally measure and record oxygen saturation (SAT/SpO_2) on your ward? Circle your answer.

YES	NO

5. There is a sudden change in a patients' condition: circle the one SAT/SpO_2 reading in the list below for which you will summon more skilled assistance (help): in other words draw a circle around one group of readings.

Less than 85% 85-89% 90-94% 95+%

6. List 3 common causes of breathlessness (shortness of breath) in a post-operative patient: | | 1 |

6.1

6.2

6.3 | | 3 |

7. How would you recognize cardiac arrest? (one sign) | | 1 |

7.1

8. There is a sudden change in a patients' condition: circle the 2 heart rate values in the list below for which you will summon more skilled assistance (help): in other words draw a circle around one group of slow rate readings and one group of fast rate readings. | | 2 |

Less than 40 bpm	40-50	51-59	60-100	101-110	111-129	130 or more

9. There is a sudden change in a patients' condition: circle the 2 systolic blood pressure values in the list below for which you will summon more skilled assistance (help): in other words draw a circle around one group of low readings and one group of high readings. | | 2 |

70 or less	71-80	81-100	101-149	150-169	170-179	180 or more

10. List 3 causes of low blood pressure: | | 3 |

10.1

10.2

10.3

11. List 3 causes of high blood pressure: | | 3 |

11.1

11.2

11.3

12. List 4 factors responsible for maintaining a normal blood pressure (how does the body maintain a normal blood pressure)?

12.1

12.2

12.3

12.4 | | 4 |

13. List 5 factors that could help you assess cardiac output clinically [in other words, by looking at or examining the patient without using equipment, how would you know that the heart was pumping adequately]?

13.1 | | 5 |

13.2

13.3

13.4

13.5

14. Circle the one group of temperature readings in the list below for which you will take no action:

	1

Less than 34° C	34-35	35.1-35.9	36-37.7	37.8-38.5	38.6-39.5	39.6 or more

15. Circle one response in the list below for a sudden deterioration in a patients' conscious level that will alert you to call for more skilled assistance (in other words, when will you call for help?):

	1

ALERT (A)	RESPONDS TO VOICE (V)	RESPONDS TO PAIN (P) / Confused	UNRESPONSIVE (U)
(same as GCS 15)	(same as GCS 14)	(same as GCS 13-9)	(same as GCS <8)

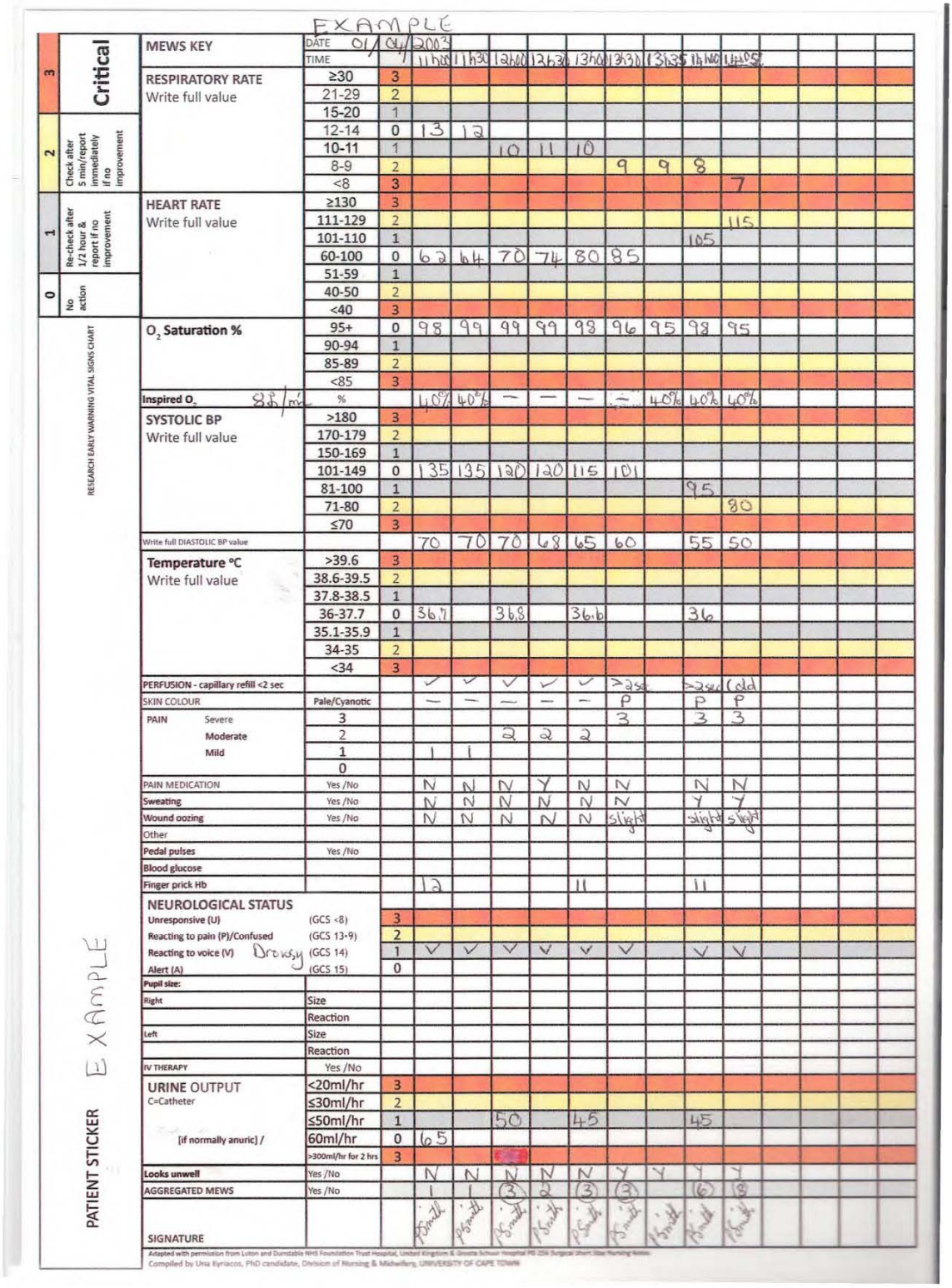
16. Circle the 2 values for urine output in the list below for which you would seek more skilled assistance (help):

	2

20 ml/hr or less	30 ml/hr or less	50 ml/hr or less	60 ml/hr	>300 ml/hr for 2 hrs

	34	

THANK YOU



EXAMPLE

3	Critical	MEWS KEY	DATE 01/04/2003															
			TIME	7	11h00	11h30	12h00	12h30	13h00	13h30	13h35	14h00	14h05					
		RESPIRATORY RATE Write full value	≥30	3														
			21-29	2														
			15-20	1														
2	Check after 5 min/report immediately if no improvement		12-14	0	13	12												
			10-11	1			10	11	10									
			8-9	2						9	9	8						
			<8	3									7					
1	Re-check after 1/2 hour & report if no improvement	HEART RATE Write full value	≥130	3														
			111-129	2									115					
			101-110	1								105						
			60-100	0	62	64	70	74	80	85								
			51-59	1														
0	No action		40-50	2														
			<40	3														
		O_2 Saturation %	95+	0	98	99	99	99	98	96	95	98	95					
			90-94	1														
			85-89	2														
			<85	3														
		Inspired O_2 8L/min	%		40%	40%	—	—	—	—	40%	40%	40%					
		SYSTOLIC BP Write full value	>180	3														
			170-179	2														
			150-169	1														
			101-149	0	135	135	120	120	115	101								
			81-100	1								95						
			71-80	2									80					
			≤70	3														
		Write full DIASTOLIC BP value			70	70	70	68	65	60		55	50					
		Temperature °C Write full value	>39.6	3														
			38.6-39.5	2														
			37.8-38.5	1														
			36-37.7	0	36.7		36.8		36.6			36						
			35.1-35.9	1														
			34-35	2														
			<34	3														
		PERFUSION - capillary refill <2 sec			✓	✓	✓	✓	✓	>2sec		>2sec	(cold					
		SKIN COLOUR	Pale/Cyanotic		—	—	—	—	—	P		P	P					
		PAIN Severe	3							3		3	3					
		Moderate	2				2	2	2									
		Mild	1		1	1												
			0															
		PAIN MEDICATION	Yes /No		N	N	N	Y	N	N		N	N					
		Sweating	Yes /No		N	N	N	N	N	N		Y	Y					
		Wound oozing	Yes /No		N	N	N	N	N	slight		slight	slight					
		Other																
		Pedal pulses	Yes /No															
		Blood glucose																
		Finger prick Hb			12				11			11						
		NEUROLOGICAL STATUS																
		Unresponsive (U)	(GCS <8)	3														
		Reacting to pain (P)/Confused	(GCS 13-9)	2														
		Reacting to voice (V) Drowsy	(GCS 14)	1	✓	✓	✓	✓	✓	✓		✓	✓					
		Alert (A)	(GCS 15)	0														
		Pupil size:																
		Right	Size															
			Reaction															
		Left	Size															
			Reaction															
		IV THERAPY	Yes /No															
		URINE OUTPUT C=Catheter	<20ml/hr	3														
			≤30ml/hr	2														
			≤50ml/hr	1			50		45			45						
		[if normally anuric] /	60ml/hr	0	65													
			>300ml/hr for 2 hrs	3														
		Looks unwell	Yes /No		N	N	N	N	N	Y	Y	Y	Y					
		AGGREGATED MEWS	Yes /No		1	1	(3)	2	(3)	(3)		(6)	(8)					
		SIGNATURE			PSmith	PSmith	PSmith	PSmith	PSmith	PSmith	PSmith	PSmith	PSmith					

RESEARCH EARLY WARNING VITAL SIGNS CHART

PATIENT STICKER EXAMPLE

Adapted with permission from Luton and Dunstable NHS Foundation Trust Hospital, United Kingdom & Groote Schuur Hospital PD 2256 Surgical Short Stay Nursing Notes

Compiled by Una Kyriacos, PhD candidate, Division of Nursing & Midwifery, UNIVERSITY OF CAPE TOWN

Participant Code Number…….

CONSENT TO PARTICIPATE IN RESEARCH

Researcher: Una Kyriacos
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OBSERVATORY 7925

Telephone Number: (021)406 6410

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Supervisor: Professor J Jelsma

(021) 406 6595

Title of study: **The development, validation and testing of a vital signs monitoring tool for early identification of deterioration in adult surgical patients**

INFORMATION:

What is the study about?

The **purpose** of this study is to discover how registered professional nurses (RPNs) use the current vital signs chart/'observation chart' to identify and manage post-operative adult patients who show early warning signs of deterioration. Based on these findings, the researcher will revise or design a new vital signs chart and an educational programme to improve nurses' competence in early identification and management of patients at risk of serious adverse events (SAE) such as avoidable hospital deaths, cardiac arrest and intensive care admissions.

You have been selected to participate in the study because you are a nurse on one of the three intervention wards that has been randomly selected for the implementation and evaluation of a new 'observation chart' that has been designed for early recognition and management of patients at risk of serious adverse events (SAE) such as avoidable hospital deaths, cardiac arrest and intensive care admissions.

The study will be conducted in this surgical ward over approximately a 3-month period. If you are moved out of this ward you will no longer participate in the study unless you are moved to a ward that is included in the study and in that instance your participation will again be voluntary. All the research activities will take place during on-duty time, whether on day or night shift.

Does the study have ethics approval?

The study has been approved by the Faculty of Health Sciences Research Ethics Committee (REC/REF 192/2009). Dr B Patel, Senior Medical Superintendent Groote Schuur Hospital, Provincial Government of the Western Cape has approved the study (Ref: Research 24 June 2009), as well as the Director of Nursing at the hospital (Ref: F/9/2 20 July 2009). Your voluntary participation in this study is requested by signing this consent form once you are satisfied that you have been fully informed of all aspects of the study.

What is required of you?

If you agree to participate in the study you will be asked to complete a short multiple choice test that is based on clinical scenarios recorded on the nurses' observation chart. The test paper will have a code number for you that will be known only to the researcher. The test will be repeated after three months. No one in the hospital, except the researcher, will know the score you achieved for the test. Your name will not be linked to any results that are published at the completion of the study. Your participation in the study will not in any way affect your employment at the hospital.

After the first test you will be given a training programme on the new 'observation chart' for early identification of patients who may be at risk of cardiac arrest, spread over a few days because the training will take place on the ward in small groups or individually at times that suit the ward and yourself. The training programme will also include revision of basic anatomy and mechanisms that control heart rate and blood pressure, respiration and urine production. Clinical scenarios will be used in the form of 'paper patients'. Nursing Management is fully aware of the study and you should feel free to notify me or the Surgical Nurse Manager if you experience problems. Every effort will be made by the researcher not to disrupt your work by being around for at least four hours during the day shift and at night at pre-arranged times. My contact details are available should you have any difficulty you wish to discuss.

The new observation chart will then be used for all patients who have had a general anaesthetic for surgery. The researcher will evaluate the effectiveness of the new chart for early recognition of warning signs of deterioration in post-operative adult patients.

CONSENT FORM:

CONFIDENTIALITY/ANONYMITY: The researcher has explained that all information is confidential and that my name will not appear on the data emerging from the study. The researcher has also explained that she is the only person who will have a copy of my name and the number assigned to my data.

RISKS: The researcher has explained that there are no physical risks involved. Information offered by me is confidential and protected. There are no known or anticipated risks.

BENEFITS: The researcher has explained that the new observation chart and the staff training programme should help nurses to identify patients at risk of an adverse clinical outcome and help nurses to gain improved competence and confidence in patient monitoring to reduce avoidable hospital deaths, cardiac arrests and intensive care admissions.

AUTONOMY/RIGHT TO WITHDRAW: The researcher has explained that participation is voluntary and that I have the right to withdraw from the study at any stage without penalties. All my questions will be answered by the researcher.

I agree to participate in the study on the terms specified above.

_____	_____
Date	Participant's Signature
_____	_____
Date	Researcher's Signature
_____	_____
Date	Witness

Participant Code Number…….

CONSENT TO PARTICIPATE IN RESEARCH

Researcher: Una Kyriacos
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Supervisor: Professor J Jelsma

(021) 406 6595

Title of study: **The development, validation and testing of a vital signs monitoring tool for early identification of deterioration in adult surgical patients**

INFORMATION:

What is the study about?

The **purpose** of this study is to discover how nurses use the current vital signs chart/'observation chart' to identify and manage post-operative adult patients who show early warning signs of deterioration. Based on these findings, the researcher will revise or design a new vital signs chart and an educational programme to improve nurses' competence in early identification and management of patients at risk of serious adverse events (SAE) such as avoidable hospital deaths, cardiac arrest and intensive care admissions.

You have been selected to participate in the study because you are a nurse on one of the wards that has been randomly selected.

Does the study have ethics approval?

The study has been approved by the Faculty of Health Sciences Research Ethics Committee (REC/REF 192/2009). Dr B Patel, Senior Medical Superintendent Groote Schuur Hospital, Provincial Government of the Western Cape has approved the study (Ref: Research 24 June 2009), as well as the Director of Nursing at the hospital (Ref: F/9/2 20 July 2009). Your voluntary participation in this study is requested by signing this consent form once you are satisfied that you have been fully informed of all aspects of the study.

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If you agree to participate in the study you will be asked to complete a short multiple choice test that is based on clinical scenarios recorded on the nurses' observation chart. The test paper will have a code number for you that will be known only to the researcher. The test will be repeated after three months. No one in the hospital, except the researcher, will know the score you achieved for the test. Your name will not be linked to any results that are published at the completion of the study. Your participation in the study will not in any way affect your employment at the hospital.

CONSENT FORM:

CONFIDENTIALITY/ANONYMITY: The researcher has explained that all information is confidential and that my name will not appear on the data emerging from the study. The researcher has also explained that she is the only person who will have a copy of my name and the number assigned to my data.

RISKS: The researcher has explained that there are no physical risks involved. Information offered by me is confidential and protected. There are no known or anticipated risks.

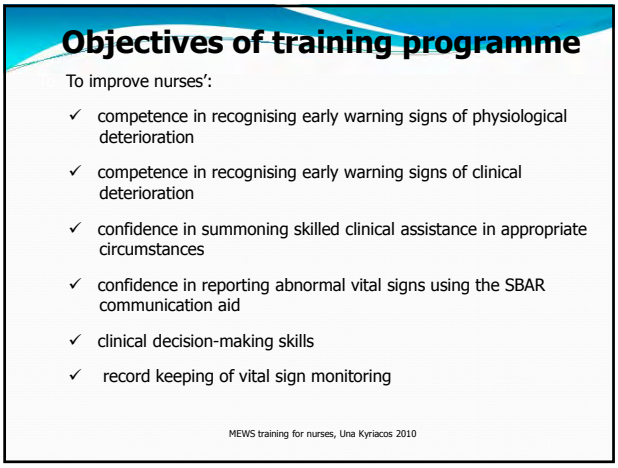
BENEFITS: The researcher has explained the importance of identifying patients at risk of an adverse clinical outcome to reduce avoidable hospital deaths, cardiac arrests and intensive care admissions.

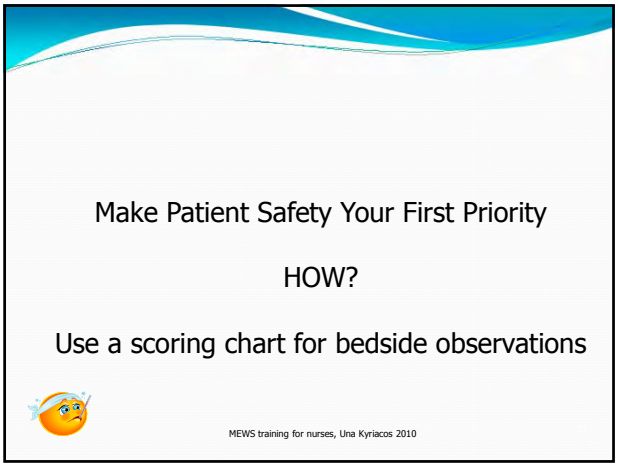
AUTONOMY/RIGHT TO WITHDRAW: The researcher has explained that participation is voluntary and that I have the right to withdraw from the study at any stage without penalties. All my questions will be answered by the researcher.

I agree to participate in the study on the terms specified above.

_____	_____
Date	Participant's Signature
_____	_____
Date	Researcher's Signature
_____	_____
Date	Witness


Appendix 5.9
Early warning scores for bedside monitoring of vital signs
MEWS training for nurses, Una Kyriacos 2010


Objectives of training programme
To improve nurses':
✓ competence in recognising early warning signs of physiological deterioration
✓ competence in recognising early warning signs of clinical deterioration
✓ confidence in summoning skilled clinical assistance in appropriate circumstances
✓ confidence in reporting abnormal vital signs using the SBAR communication aid
✓ clinical decision-making skills
✓ record keeping of vital sign monitoring
MEWS training for nurses, Una Kyriacos 2010


Make Patient Safety Your First Priority
HOW?
Use a scoring chart for bedside observations
MEWS training for nurses, Una Kyriacos 2010

Learn about an Early Warning Scoring (EWS) chart for vital signs ('observations'):

- used by nurses on general wards
- to monitor patients' bedside observations
- to alert you when you need to call for help
- to prevent cardio-respiratory arrests and other serious adverse events

These Early Warning Scores

are also known as

Modified Early Warning Scores (MEWS)

How would you recognize respiratory arrest?

ANSWER:

- *no breathing*
- *no chest movement*

How would you recognize signs of inadequate breathing in a patient in your ward?

ANSWER:

- *a change in respiratory rate*
- *a change in SpO_2 (SAT)*
- *a change in the pattern of breathing*

List 3 common causes of breathlessness in a post-operative patient

ANSWER:

- *pre-existing lung condition*
- *poor physical condition*
- *obesity*
- *hyperventilation*
- *anxiety*
- *pyrexia*
- *pain*

How would you recognize cardiac arrest?

ANSWER:

- *no pulse felt*
- *No heart beat heard*

List 3 causes of low blood pressure:

ANSWER:

- *bleeding*
- *dehydration over a prolonged period*
- *pre-existing condition*
- *not taking medication*
- *incorrect dose of medication taken*
- *wrong reading*

List 3 causes of high blood pressure:

ANSWER:

- *pre-existing condition*
- *not taking medication*
- *incorrect dose of medication taken*
- *overhydration over a prolonged period*
- *anxiety*
- *wrong reading*

List 4 factors responsible for maintaining a normal blood pressure:

ANSWER:

- *cardiac output*
- *intravascular volume*
- *peripheral vascular resistance*
- *viscosity of blood*

List 5 factors that could help you assess cardiac output clinically [by looking at/examining the patient]

ANSWER:

- *colour of skin*
- *capillary refill*
- *skin temperature*
- *presence of sweating*
- *level of consciousness*

How do you know when patients are so ill that it's time to act?

(Baines, E. & Kanagasundaram, N. S. 2008)

Introduction to the Early Warning Scoring System for observation charts

It is estimated that, in the UK, 23 000 in-hospital cardiac arrests[1] and in England, Wales and Northern Ireland 20 000 unexpected ICU admissions[2] can be prevented with better care.[3-6] One in ten patients may experience an adverse event. Clinical negligence claims following adverse events occurring within the United Kingdom National Health Service costs the Department of Health hundreds of millions of pounds per year. These findings are not unique to the UK and similar findings are reported in the USA, New South Wales and Australia. Patient safety, and in particular avoidable in-hospital morbidity and mortality, is an unexplored research area in developing countries that demands attention at this time in South Africa's history, a period characterized by an increased public awareness of patients' rights and escalating litigation in a health care system with shrinking resources.

My PhD thesis will examine three serious adverse events (SAE) that hospitalized adult surgical patients may experience in the wards, defined operationally as **avoidable**: 1) in-hospital cardiac arrest, 2) urgent and unanticipated admission to an intensive care unit (ICU) and 3) death[2], caused by human error of omission, that is, failure to monitor patients' vital signs and/or failure recognise, decide and/or act on available information as adapted.[7]

Vital sign monitoring in the wards is only one aspect of patient safety but it is the focus of my study. In the literature there is particular concern about infrequent and incomplete monitoring and recording, misinterpretation of clinical data by nurses, delays in reporting and little convincing evidence of appropriate interventions being carried out for patients at risk of an adverse event in general wards. Studies have shown that abnormal physiology is common on general hospital wards[8] and that there is documented evidence of clinical and physiological deterioration within six[9] to eight hours[10] of cardiopulmonary arrest. In these cases, arrest often occurs after a period of slow and progressive physiological deterioration that was not recognized or when hypoxaemia and hypotension were not treated adequately.[11] However, many surgical deaths occur several days after an operation.[12]

The five most important prognostic variables for catastrophic deterioration are respiratory rate, systolic blood pressure, pulse rate, temperature and central nervous system status; in addition, urine output[13] is an early indicator of vascular compromise.[14] Skin tone, sweating, nausea and other clinical signs such as 'looking unwell' or nurses' intuitive assessment of the patient being 'just not right'[15] are also important signs which need to be monitored regularly in patients to reduce avoidable, serious adverse events (SAE) such as cardiac arrest, urgent

and unexpected admission to an ICU or even death. A number of studies have examined combinations of early signs for association with in-hospital death.[14 16-19] Adverse clinical outcomes can be reduced and even prevented if abnormal signs of clinical and physiological deterioration are identified early, particularly in the acutely ill patient on a general ward. Vital signs charts in certain countries in the developed world incorporate early warning systems (EWSs) to 'track' signs of physiological deterioration in adult patients and 'trigger' a rapid response.[20 21]

For early warning scoring systems, points are allocated to abnormal physiological values. The higher the score, the more urgent nurses need to intervene or call for assistance. For my chart nurses should respond to each abnormal vital sign reading AS WELL AS for a total score (at the bottom of the chart) of 3.

MEWS system:

- 0 = normal value
- 1 (upper or lower) = early sign of deterioration
- 2 (upper or lower) = serious sign of deterioration
- 3 = critical condition requiring urgent attention.

Mrs Dlomo, a widowed 65 year old woman, is admitted to your general surgical ward. Medical history: Hypertension, schizophrenia. She is on medication for each of these.
She has had a general anaesthetic for a laparotomy and total gastrectomy and her post-operative vital sign recordings are taken immediately she returns to the ward:

	10h30	11h00	11h30
RR:	26 p/m	27 p/m	31 p/m
O_2 Sat:	96%	97%	94%
BP:	100/75 mm Hg	96/65 mm Hg	92/63 mm Hg
HR:	115 bpm	120 bpm	135 bpm
Temperature:	36°C	35.8°C	35.6°C
Conscious level : Responds to voice (V)		V	V
Urine output (bedpan):		0	30 ml

Record the data on the blank observation chart

Clinical picture at 11h30:

- Mrs Dlomo says she feels cold – you confirm peripheral coldness
- She looks pale
- and complains of severe abdominal pain at a score of 3
- appears anxious and does not look well

Plot the data on the same blank ward observation chart

QUESTIONS

How does the MEWS chart help you decide how ill the patient is and when to call for more skilled assistance?	Group work and feedback

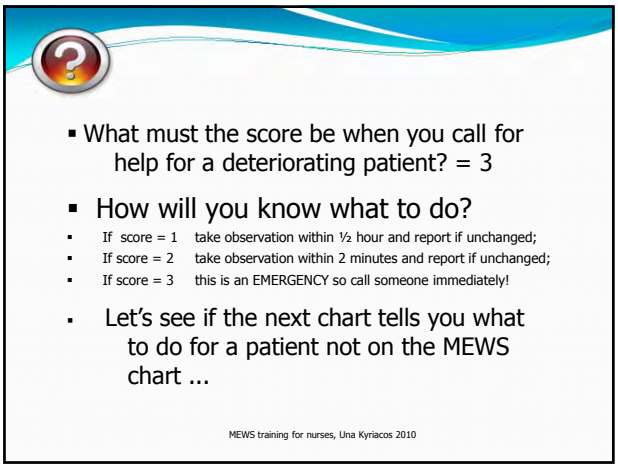
The next slide shows us

how the all MEWS scores

can be shown when they are not on a chart

Modified Early Warning Scoring System (MEWS) for 7 physiological parameters

	3	2	1	0	1	2	3
Respiratory rate/min	<8	8-9	10-11	12-14	15-20	21-29	30 or more
SpO_2	<85	85-89	90-94	95+			
Heart rate/min	<40	40-50	51-59	60-100	101-110	111-129	130 or more
BP systolic	≤70	71-80	81-100	101-149	150-169	170-179	>180
Temperature °C	<34	34-35	35.1-35.9	36-37.7	37.8-38.5	38.6-39.5	>39.6
* Glasgow Coma Scale				GCS 15	Change in Mental status/ GCS 14	GCS 13-9	GCS ≤ 8 or unresponsive
OR AVPU NEUROLOGICAL STATUS *				Alert	Reacting to voice	Reacting to pain	Unresponsive
** Urine mls/kg/hr	<20 ml/hr	≤30 ml/hr	50 ml/hr	60 ml/hr If normally anuric score 0			>300 ml/hr for 2 hrs



- What must the score be when you call for help for a deteriorating patient? = 3
- How will you know what to do?
  - If score = 1 take observation within ½ hour and report if unchanged;
  - If score = 2 take observation within 2 minutes and report if unchanged;
  - If score = 3 this is an EMERGENCY so call someone immediately!
- Let's see if the next chart tells you what to do for a patient not on the MEWS chart ...

MEWS training for nurses, Una Kyriacos 2010

CALLING CRITERIA FOR INITIATION OF AN EMERGENCY RESPONSE

if any one of these is present call the Sister, if not available, the Medical Officer:

- ❑ Staff member is worried about the patient
- ❑ Acute change in heart rate to <50 or >120 beats/min
- ❑ Acute change in systolic blood pressure to <80 or >170 mmHg
- ❑ Acute change in respiratory rate to <10 or >20 breaths/min
- ❑ Acute change in pulse oximetry saturation to <90%, despite oxygen administration
- ❑ Acute deterioration in conscious state
- ❑ Acute change in urine output to <30ml/hr or >300ml/hour for 2 hours

MEWS training for nurses, Una Kyriacos 2010 17

Now you know exactly what to do to improve Patient Safety:

You have the -

- ✓ MEWS observation chart for patients who have had a general anaesthetic (for my study)
- ✓ Calling criteria for patients not on the MEWS chart who you are worried about

Please teach all the nurses

in your ward

HOW

to use the new tools …

This is the first step towards improved

PATIENT SAFETY

References

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Thank you
Dankie
Ndiyabulela

Explore

[DataSet3] F:\Una PhD\iFolder Una PhD\Data Analysis\Study 3 analysis\Record review\Final 9 May\FINAL combined data 9 May_adjusted4surgery.sav

Intervention=1 Comparator=0

Case Processing Summary

	Intervention=1 Comparator=0	Cases					
		Valid		Missing		Total	
		N	Percent	N	Percent	N	Percent
Age	comparator ward	57	100.0%	0	.0%	57	100.0%
	intervention ward	57	100.0%	0	.0%	57	100.0%
No. of days in hospital (Clinicom)	comparator ward	57	100.0%	0	.0%	57	100.0%
	intervention ward	57	100.0%	0	.0%	57	100.0%

Descriptives

	Intervention=1 Comparator=0			Statistic	Std. Error
Age	comparator ward	Mean		45.61	2.178
		95% Confidence Interval for Mean	Lower Bound	41.25	
			Upper Bound	49.98	
		5% Trimmed Mean		45.37	
		Median		45.00	
		Variance		270.348	
		Std. Deviation		16.442	
		Minimum		14	
		Maximum		84	
		Range		70	
		Interquartile Range		26	
		Skewness		.229	.316
		Kurtosis		-.585	.623
	intervention ward	Mean		44.95	2.464
		95% Confidence Interval for Mean	Lower Bound	40.01	
			Upper Bound	49.88	
		5% Trimmed Mean		44.92	
		Median		49.00	
		Variance		345.944	
		Std. Deviation		18.600	
		Minimum		14	
		Maximum		76	
		Range		62	
		Interquartile Range		29	
		Skewness		-.029	.316
		Kurtosis		-1.176	.623
No. of days in hospital (Clinicom)	comparator ward	Mean		7.23	.855
		95% Confidence Interval for Mean	Lower Bound	5.52	
			Upper Bound	8.94	
		5% Trimmed Mean		6.69	
		Median		4.00	
		Variance		41.679	
		Std. Deviation		6.456	
		Minimum		2	
		Maximum		23	
		Range		21	
		Interquartile Range		7	
		Skewness		1.292	.316
		Kurtosis		.366	.623
	intervention ward	Mean		6.44	.918
		95% Confidence Interval for Mean	Lower Bound	4.60	
			Upper Bound	8.28	
		5% Trimmed Mean		5.42	

Nurses' raw pre- and post-intervention knowledge test scores (mark out of 23) at cluster and individual level

Cluster	Category of nurse 1=RPN 2=RSN 3=RNA	Pre-intervention knowledge test score (%)	Post-intervention knowledge test score (%)	Mean %	Mean difference %	Wilcoxon Signed Ranks Test			
						Mean Rank	Sum of Ranks	Z-value	Significance p-value
1	1	12 (52.2)	12 (52.2)	52.2	0	1.50 3.90	1.50 19.50	-1.892	p=0.058
1	2	10 (43.5)	8 (34.8)	39.1	-8.7				
1	1	10 (43.5)	20 (87.0)	65.2	+43.5				
1	2	7 (30.4)	17 (73.9)	52.2	+43.5				
1	1	14 (60.9)	16 (69.6)	65.2	+9.0				
1	1	14 (60.9)	14 (60.9)	60.9	0				
1	3	10 (43.5)	23 (100.0)	71.7	+56.5				
1	1	8 (34.8)	21 (91.3)	63.0	+56.5				
2	1	12 (52.2)	13 (56.5)	54.3	+3.0	3.00 4.17	3.00 25.00	-1.863	p=0.063
2	2	14 (60.9)	16 (69.6)	65.2	+9.0				
2	1	9 (39.1)	10 (43.5)	41.3	+4.4				
2	3	4 (17.4)	23 (100.0)	58.7	+82.6				
2	1	8 (34.8)	17 (73.9)	54.3	+39.1				
2	3	9 (39.1)	10 (43.5)	41.3	+4.4				
2	1	7 (30.4)	6 (26.1)	28.3	-4.3				
3	1	10 (43.5)	13 (56.5)	50.0	+13.0	4.00 4.57	4.00 32.00	-1.963	p=0.050
3	3	6 (26.1)	6 (26.1)	26.1	0				
3	1	15 (65.2)	23 (100.0)	82.6	+34.8				
3	2	10 (43.5)	23 (100.0)	71.7	+56.5				
3	3	10 (43.5)	12 (52.2)	47.8	+8.7				
3	1	13 (56.5)	22 (95.7)	76.1	+39.2				
3	3	8 (34.8)	5 (21.7)	28.3	-13.1				
3	1	14 (60.9)	15 (65.2)	63.0	+4.3				
3	2	4 (17.4)	5 (21.7)	19.6	+4.3				
3	3	3 (13.0)	3 (13.0)	13.0	0				
Mean		9.6 (41.9)	14.1 (61.4)	51.6	+19.5				

WILCOXON SIGNED RANKS TEST **CLUSTER 1**

Descriptive Statistics

	N	Mean	Std. Deviation	Minimum	Maximum	Percentiles		
						25th	50th (Median)	75th
Pre-intervention knowledge test%	8	46.19565	11.130410	30.435	60.870	36.95652	43.47826	58.69565
Post-intervention knowledge test%	8	71.19565	21.669142	34.783	100.000	54.34783	71.73913	90.21739

Ranks

		N	Mean Rank	Sum of Ranks
Post-intervention knowledge test% - Pre-intervention knowledge test%	Negative Ranks	1[a]	1.50	1.50
	Positive Ranks	5[b]	3.90	19.50
	Ties	2[c]		
	Total	8		

a. Post-intervention knowledge test% < Pre-intervention knowledge test%
b. Post-intervention knowledge test% > Pre-intervention knowledge test%
c. Post-intervention knowledge test% = Pre-intervention knowledge test%

Test Statistics[b]

	Post-intervention knowledge test% - Pre-intervention knowledge test%
Z	-1.892[a]
Asymp. Sig. (2-tailed)	.058

CLUSTER 2
Descriptive Statistics

	N	Mean	Std. Deviation	Minimum	Maximum	Percentiles 25th	50th (Median)	75th
Pre-intervention knowledge test%	7	39.13043457	14.199940254	17.391304	60.869564	30.43478200	39.13043600	52.17391200
Post-intervention knowledge test%	7	59.00621029	24.448181065	26.086956	100.000000	43.47826000	56.52174000	73.91304000

Ranks

		N	Mean Rank	Sum of Ranks
Post-intervention knowledge test% - Pre-intervention knowledge test%	Negative Ranks	1[a]	3.00	3.00
	Positive Ranks	6[b]	4.17	25.00
	Ties	0[c]		
	Total	7		

a. Post-intervention knowledge test% < Pre-intervention knowledge test%
b. Post-intervention knowledge test% > Pre-intervention knowledge test%
c. Post-intervention knowledge test% = Pre-intervention knowledge test%

Test Statistics[b]

	Post-intervention knowledge test% - Pre-intervention knowledge test%
Z	-1.863[a]
Asymp. Sig. (2-tailed)	.063

a. Based on negative ranks.
b. Wilcoxon Signed Ranks Test

CLUSTER 3
Descriptive Statistics

	N	Mean	Std. Deviation	Minimum	Maximum	Percentiles 25th	50th (Median)	75th
Pre-intervention knowledge test%	10	40.43478200	17.755841175	13.043478	65.217390	23.91304300	43.47826000	57.60869600
Post-intervention knowledge test%	10	55.21739120	34.360360150	13.043478	100.000000	21.73913000	54.34782600	96.73913200

Ranks

		N	Mean Rank	Sum of Ranks
Post-intervention knowledge test% - Pre-intervention knowledge test%	Negative Ranks	1[a]	4.00	4.00
	Positive Ranks	7[b]	4.57	32.00
	Ties	2[c]		
	Total	10		

a. Post-intervention knowledge test% < Pre-intervention knowledge test%
b. Post-intervention knowledge test% > Pre-intervention knowledge test%
c. Post-intervention knowledge test% = Pre-intervention knowledge test%

Test Statistics[b]

	Post-intervention knowledge test% - Pre-intervention knowledge test%
Z	-1.963[a]
Asymp. Sig. (2-tailed)	.050

Nurses' raw pre- and post-intervention knowledge test scores (mark out of 23) at individual level

Cluster	Category of nurse 1=RPN 2=RSN 3=RNA	Pre-intervention knowledge test mark (%)	Post-intervention knowledge test mark (%)	Overall mean % score	Mean difference % score	Wilcoxon Signed Ranks Test (see output below)
4	1	(10) 43.5	(11) 47.8	45.7	4.3	
4	1	(8) 34.8	(7) 30.4	32.6	-4.3	
4	3	(5) 21.7	(8) 34.8	28.3	13.0	
4	3	(4) 17.4	(8) 34.8	26.1	17.4	
4	1	(11) 47.8	(14) 60.9	54.3	13.0	p=0.021
4	2	(5) 21.7	(12) 52.2	37.0	30.4	
4	3	(7) 30.4	(10) 43.5	37.0	13.0	
4	3	(4) 17.4	(3) 13.0	15.2	-4.3	
4	1	(9) 39.1	(11) 47.8	43.5	8.7	
5	1	(7) 30.4	(7) 30.4	30.4	0.0	
5	3	(7) 30.4	(8) 34.8	32.6	4.3	
5	1	(16) 69.6	(15) 65.2	67.4	-4.3	
5	2	(2) 8.7	(6) 26.1	17.4	17.4	
5	1	(7) 30.4	(8) 34.8	32.6	4.3	p=0.931
5	3	(5) 21.7	(6) 26.1	23.9	4.3	
5	1	(13) 56.5	(10) 43.5	50.0	-13.0	
5	1	(15) 65.2	(15) 65.2	65.2	0.0	
5	3	(9) 39.1	(5) 21.7	30.4	-17.4	
6	1	(12) 52.2	(15) 65.2	58.7	13.0	
6	2	(14) 60.9	(10) 43.5	52.2	-17.4	
6	1	(12) 52.2	(15) 65.2	58.7	13.0	
6	1	(15) 65.2	(15) 65.2	65.2	0.0	p=0.916
6	2	(3) 13.0	(5) 21.7	17.4	8.7	
6	1	(3) 13.0	(8) 34.8	23.9	21.7	
6	3	(11) 47.8	(5) 21.7	34.8	-26.1	
Mean		8.6 (37.2)	9.5 (41.2)	39.2	4.0	

CONTROL GROUP (CLUSTERS 4-6 = MEAN)

```
DESCRIPTIVES VARIABLES=Preinterventionknowledgetest Postinterventionknowledgetest
  /STATISTICS=MEAN STDDEV MIN MAX.
```

Descriptive Statistics

	N	Minimum	Maximum	Mean	Std. Deviation
Pre-intervention knowledge test%	25	8.695652	69.565216	37.21547808	18.198233858
Post-intervention knowledge test%	25	13.043478	65.217390	41.21373872	16.225956248
Valid N (listwise)	25				

OVERALL MEAN (COMPARATOR GROUP = CLUSTERS 4-6)

```
GET DATA /TYPE=XLSX
FREQUENCIES VARIABLES=Mean
  /STATISTICS=MEAN
  /ORDER=ANALYSIS.
```

Statistics

Mean

N	Valid	26
	Missing	0
Mean		39.22

```
DESCRIPTIVES VARIABLES=MeanDifference
  /STATISTICS=MEAN STDDEV MIN MAX.
```

[DataSet3] F:\Una PhD\iFolder Una PhD\Data Analysis\Study 3 analysis\Training\Final 9 May\cluster4-6 Mean Diffs2gps.sav

Descriptive Statistics

	N	Minimum	Maximum	Mean	Std. Deviation
Mean Difference	25	-26.08696	30.43478	4.0000000	13.21863076
Valid N (listwise)	25				

WILCOXON SIGNED RANK TESTS

CLUSTER 4

Descriptive Statistics

	N	Mean	Std. Deviation	Minimum	Maximum	Percentiles 25th	50th (Median)	75th
Pre-intervention knowledge test%	9	30.43478244	11.503266907	17.391304	47.826088	19.56521700	30.43478200	41.30434800
Post-intervention knowledge test%	9	40.57970978	14.088566711	13.043478	60.869564	32.60869500	43.47826000	50.00000000

Ranks

		N	Mean Rank	Sum of Ranks
Post-intervention knowledge test% - Pre-intervention knowledge test%	Negative Ranks	2[a]	1.50	3.00
	Positive Ranks	7[b]	6.00	42.00
	Ties	0[c]		
	Total	9		

a. Post-intervention knowledge test% < Pre-intervention knowledge test%
b. Post-intervention knowledge test% > Pre-intervention knowledge test%
c. Post-intervention knowledge test% = Pre-intervention knowledge test%

Test Statistics[b]

	Post-intervention knowledge test% - Pre-intervention knowledge test%
Z	-2.314[a]
Asymp. Sig. (2-tailed)	.021

a. Based on negative ranks.
b. Wilcoxon Signed Ranks Test

CLUSTER 5

Descriptive Statistics

	N	Mean	Std. Deviation	Minimum	Maximum	Percentiles 25th	50th (Median)	75th
Pre-intervention knowledge test%	9	39.13043444	20.508654437	8.695652	69.565216	26.08695600	30.43478200	60.86956500
Post-intervention knowledge test%	9	38.64734222	16.332503542	21.739130	65.217390	26.08695600	34.78260800	54.34782500

Ranks

		N	Mean Rank	Sum of Ranks
Post-intervention knowledge test% - Pre-intervention knowledge test%	Negative Ranks	3[a]	4.83	14.50
	Positive Ranks	4[b]	3.38	13.50
	Ties	2[c]		
	Total	9		

a. Post-intervention knowledge test% < Pre-intervention knowledge test%
b. Post-intervention knowledge test% > Pre-intervention knowledge test%
c. Post-intervention knowledge test% = Pre-intervention knowledge test%

Test Statistics[b]

	Post-intervention knowledge test% - Pre-intervention knowledge test%
Z	-.086[a]
Asymp. Sig. (2-tailed)	.931

a. Based on positive ranks.
b. Wilcoxon Signed Ranks Test

CLUSTER 6

Descriptive Statistics

	N	Mean	Std. Deviation	Minimum	Maximum	Percentiles 25th	50th (Median)	75th
Pre-intervention knowledge test%	7	43.47826029	21.593716194	13.043478	65.217390	13.04347800	52.17391200	60.86956400
Post-intervention knowledge test%	7	45.34161400	20.059322906	21.739130	65.217390	21.73913000	43.47826000	65.21739000

Ranks

		N	Mean Rank	Sum of Ranks
Post-intervention knowledge test% - Pre-intervention knowledge test%	Negative Ranks	2[a]	5.00	10.00
	Positive Ranks	4[b]	2.75	11.00
	Ties	1[c]		
	Total	7		

a. Post-intervention knowledge test% < Pre-intervention knowledge test%
b. Post-intervention knowledge test% > Pre-intervention knowledge test%
c. Post-intervention knowledge test% = Pre-intervention knowledge test%

Test Statistics[b]

	Post-intervention knowledge test% - Pre-intervention knowledge test%
Z	-.105[a]
Asymp. Sig. (2-tailed)	.916

a. Based on negative ranks.
b. Wilcoxon Signed Ranks Test

- **Pre-intervention test scores by professional categories *within trial arms* are presented in Table 5.1A.**

Table 5.1A: Pre-intervention test scores by professional categories within trial arms

Intervention arm (N=25)		ANOVA			
Professional category	***Within Group*** Mean % score [95% CI]	Mean % score by trial arm (SD)	p-value	df	F-test statistic
Registered Professional Nurses (n=13)	48.8 [41.702-55.956]	41.9 (14.63)	p=0.023	2	F=4.48
Registered Staff Nurses (n=5)	39.1 [18.930-59.329]				
Registered Nursing Auxiliaries (n=7)	31.1 [19.581-42.530]				
Control arm (N=25)					
Registered Professional Nurses (n=13)	46.2 [36.228-56.077]	37.2 (18.19)	p=0.030	2	F=4.15
Registered Staff Nurses (n=5)	39.1 [-11.845-64.013]				
Registered Nursing Auxiliaries (n=7)	31.1 [19.150-37.365]				

Within the intervention and control trial arms, RPNs achieved the highest scores (48.8% and 46.2%) respectively, followed by RSNs (39.1%) and RNAs (31.1%) and these differences achieved statistical significance (p=0.023) and (p=0.030) respectively.

- **Nurses' post-intervention test scores by professional categories *within clusters* in trial arms are presented in Table 5.2B.**

Table 0.2B: Post-intervention knowledge test scores by category of nurse *in clusters* within trial arms

Intervention arm (N=25)				
Cluster 1	Mean % score by category [95% CI]	SD	Mean % score by cluster	***Within cluster*** Between categories p value (df)
RPN (n=5)	72.2 [51.40-92.94]	16.72	71.2	p=0.249, (2)
RSN (n=2)	54.3 [-194.25-302.94]	27.66		
RNA (n=1)	100.0	Not computed		
Cluster 2				
RPN (n=4)	50.0 [17.79-82.20]	20.23	59.0	p=0.621, (2)
RSN (n=1)	69.57	Not computed		
RNA (n=2)	71.7 [-287.34-430.82]	39.96		
Cluster 3				
RPN (n=4)	79.3 [44.81-113.88]	21.70	55.2	p=0.089, (2)
RSN (n=2)	60.9 [-436.32-558.06]	55.33		
RNA (n=4)	28.3 [1.46-55.05]	16.83		
Cluster 4				
RPN (n=4)	46.7 [26.86-66.61]	12.48	40.6	p=0.230, (2)
RSN (n=1)	52.2	Not computed.		
RNA (n=4)	31.5 [10.86-52.18]	12.98		
Cluster 5				
RPN (n=5)	47.8 [27.26-68.38]	16.55	38.6	p=0.171, (2)
RSN (n=1)	26.1	Not computed.		
RNA (n=3)	27.5 [11.03-44.03]	6.64		
Cluster 6				
RPN (n=4)	57.6 [33.39-81.82]	15.21	45.3	p=0.149, (2)
RSN (n=2)	32.6 [-105.50-170.71]	15.37		
RNA (n=1)	21.7	Not computed		

Differences in post-intervention test scores between professional categories within clusters did not achieve statistical significance in either of the trial arms.

- **Analysis of pre- and post-intervention test scores by cluster and arm**

Data for intervention arm clusters (1, 2, 3) and control arm clusters (4, 5, 6) are shown in Table 5.3A.

Table 5.3A: Nurses' pre- and post-intervention test scores by cluster and arm

	Pre-test Mean % score	Post-test Mean % score	Mean differences (se)	Median differences (IQR)	Wilcoxon Signed-Ranks test p-value
Cluster ward 1	46.2	71.2	25.0 (9.747)	26.09 (0-50)	0.076
Cluster ward 2	39.1	59.0	19.9 (11.685)	4.35 (4.35-39.13)	0.034
Cluster ward 3	40.4	55.2	14.8 (6.840)	6.52 (0-34.78)	0.051
Control arm					
Cluster ward 4	30.4	40.6	10.1 (3.637)	13.04 (4.35-13.04)	0.038
Cluster ward 5	39.1	38.6	-0.5 (3.435)	0 (-4.35-4.35)	1.000
Cluster ward 6	43.5	45.3	1.9 (6.634)	8.70 (-17.40-13.04)	0.799
					0.0004

With the exception of Cluster ward 5 (control arm), mean post-test scores in all the clusters in both arms were higher than pre-scores. A Wilcoxon Signed-Ranks Test (STATA) showed that the training programme significantly improved post-test scores in Clusters 2 (p=0.034) and 3 (p=0.051) in the intervention arm but also in Cluster 4 (0.038) in the control arm where nurses had no training. The difference between pre- and post-intervention test scores was statistically significant (p<0.001) with a median score difference of 4.35 for all participants. A cluster effect on test scores is evident.

- **Nurses' pre-intervention test scores by professional categories *within clusters* in trial arms are presented in Table 5.1B.**

Table 0.1B: Pre-intervention knowledge test scores by category of nurse *in clusters* within trial arms

Intervention arm (N=25)				
Cluster 1	Mean % score by category [95% CI]	SE mean	Mean % score by cluster	***Within cluster*** Between categories p value (df)
RPN (n=5)	50.4 [36.35-64.51]	5.07	46.2	p=0.397 (2)
RSN (n=2)	37.0 [-45.91-119.82]	6.52		
RNA (n=1)	43.5			
Cluster 2				
RPN (n=4)	39.1 [24.18-54.07]	4.70	39.1	p=0.171 (2)
RSN (n=1)	60.9			
RNA (n=2)	28.3 [-109.85-166.37]	10.87		
Cluster 3				
RPN (n=4)	56.2 [41.58-71.47]	4.70	40.4	p=0.038 (2)
RSN (n=2)	30.4 [-135.30-196.17]	13.04		
RNA (n=4)	29.3 [8.69-50.00]	6.50		
RPN (n=4)	41.3 [32.37-50.23]	2.80	30.4	p=0.008 (2)
RSN (n=1)	21.7			
RNA (n=4)	21.7 [11.96-31.52]	3.07		
Cluster 5				
RPN (n=5)	50.4 [27.02-73.84]	8.43	39.1	p=0.102 (2)
RSN (n=1)	8.7			
RNA (n=3)	30.4 [8.83-52.03]	5.02		
Cluster 6				
RPN (n=4)	45.7 [9.70-81.60]	11.29	43.5	p=0.914 (2)
RSN (n=2)	37.0 [-266.89-340.80]	23.91		
RNA (n=1)	47.8			

Within Cluster 3 of the intervention arm the Scheffe post hoc test showed that mean difference in scores between RPNs and RNAs was statistically significant (p=0.052, 95% CI -.241-54.59).

Within Cluster 4 of the control arm the mean difference in scores between categories was statistically significant (p=0.008) but the Scheffe post hoc test was not performed because one cluster had fewer than two cases.

Post-intervention test scores by professional categories *within trial arms* were not normally distributed for RNAs (Shapiro-Wilk p=0.002, df=15) and for cluster 1 (Shapiro-Wilk p=0.019, df=26) and nonparametric tests were used as presented in Table 5.2A.

- **Post-intervention test scores by professional categories *within trial arms***

Table 5.2A: Post-intervention test scores by professional categories *within trial arms*

Intervention arm (N=25)			**KRUSKAL-WALLIS test**			
Professional category	***Within Group*** Mean % score	Mean % score by trial arm (SD)	Mean Rank	Chi-Square test statistic	Significance p-value	df
Registered Professional Nurses (n=13)	67.6	61.4 (27.90)	14.46	1.474	0.478	2
Registered Staff Nurses (n=5)	60.0		13.00			
Registered Nursing Auxiliaries (n=7)	50.9		10.29			
Control arm (N=25)						
Registered Professional Nurses (n=13)	50.5	41.2 (16.22)	17.15	9.259	0.010	2
Registered Staff Nurses (n=4)	35.9		10.75			
Registered Nursing Auxiliaries (n=8)	28.8		7.38			

Within the intervention and control trial arms, RPNs achieved the highest scores (67.6% and 50.5%) respectively, followed by RSNs (60.0%, 35.9%) and RNAs (50.9%, 28.8%) respectively and these differences achieved statistical significance (p=0.010) in the control arm but not in the intervention arm.

- **Proportion of incremental, decremental and no change in nurses' post-intervention test scores by category and cluster within trial arms**

Data are shown in Table 5.3B (see Appendix 5.8.a and b for Wilcoxon Signed-Rank test results).

Table 5.3B: Number of nurses by performance in the post-intervention knowledge test by category, cluster and trial arm

Cluster	Post-test score higher than pre-score Category (Number)	Post-test score lower than pre-test score Category (Number)	No change in scores
Intervention Arm			
1	RPN (3), RSN (1), RNA (1)	RSN (1)	RPN (2)
2	RPN (3), RSN (1), RNA (2)	RPN (1)	0
3	RPN (4), RSN (2), RNA (1)	RNA (1)	RNA (2)
Control Arm			
4	RPN (3/4), RSN (1/1), RNA (3/4)	RPN (1), RNA(1)	0
5	RPN (1/5), RSN (1/1), RNA (2/3)	RPN (2), RNA (1)	RPN (2)
6	RPN (3/4), RSN (1/2)	RSN (1), RNA (1/1)	RPN (1), RSN (1)

In cluster 1 of the intervention arm, three of the five RPNs had improved post-test scores, as for one of the two RSNs and the only RNA. In cluster 2, three of four RPNs had improved post-test scores, as for the only RSN and both RNAs. In cluster 3, all RPNs and RSNs had better scores following training, whereas one of the four RNAs did better. However, in each cluster one nurse had poorer results for the post-test than for the pre-test and this included a RPN. Two RPNs and RNAs had no change in scores following training.

In cluster 4 of the control arm, three of the four RPNs had improved post-test scores, as for the only RSN and three of four RNAs despite having no training; one RPN and RNA had poorer results for the post-test than for the pre-test. In cluster 5, one of five RPNs had improved post-test scores, as for the only RSN and two of three RNAs; two RPNs and one RNA had poorer results for the post-test than for the pre-test. In cluster 6, three of four RPNs and one of two RSNs had better scores for the post-test than for the pre-test; one RSN and RNA had poorer results for the post-test, whereas one RPN and RSN had no change in scores.

Summary of nurses' responses to disturbed single vital sign parameters (MEWS) weighted trigger points (0-3) during the first 8 post-operative hours

Vital signs	Frequency of weighted trigger point[1] for all observation time-points Response Yes=√, No=X (number)						
	Recoded MEWS weighted trigger points						
	Lower			Normal		Upper	
Intervention group (N=57)	**3**	**2**	**1**	**0**	**1**	**2**	**3**
Respiratory rate			1 x	52	14 x	6 x	
Pulse oximetry[2]		1 x		9	//	//	//
Heart rate		1 x	6 x	166	5 x	5 x 1 √	1 x
Blood pressure		2 x	5 x 1 √	300	5 x	5 x	5x 2 √
Temperature		5 x	14 x	105	6 x 2 √	2 x	
Conscious level			9 x	125	//	//	//
Urine output	6 x 1 √	6 x	11 x	69	//	//	//
	Lower			**Normal**			
Comparator group (n=57)	**3**	**2**	**1**	**0**	**1**	**2**	**3**
Respiratory rate				2			
Pulse oximetry			1 x	1	//	//	//
Heart rate		3 x	5 x	327	8 x	3 x	
Blood pressure		2 x	8 x	387	12 x	2 x	2 x 1 √
Temperature	1 x	2 x	17 x	90	1 x	2 x	
Conscious level			7 x	31	//	//	//
Urine output	6 x 1 √	4 x	5 x	71	//	//	//

Notes on table:

There were no recordings for some parameters.

Some patients had high and low MEWS for a single parameter recorded at different times.

// denotes no MEWS range.

SURGICAL - POST OPERATIVE DATA SHEET

Date : ....

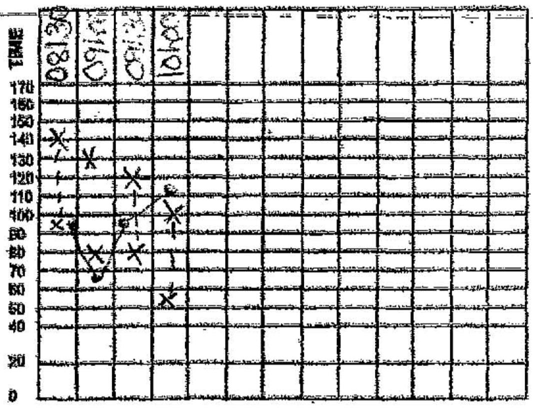
Time : ....

Operation / Procedure : ....

INITIAL OBSERVATIONS :

Temperature : ....
Pulse : ....
Blood Pressure : ....
H. B. : ....
Wound : ....
Blood loss : ....
Urinary output : ....
Circulation : ....
Girth measurement : ....
Pedal pulses : ....
Plugs : ....
Jaw wired : ....

HALF HOURLY OBSERVATIONS



EQUIPMENT

OXYGEN :	YES	NO	i.e. ....
INTRAVENOUS THERAPY :	YES	NO	i.e. ....
URINARY CATHETER :	YES	NO	i.e ....
WOUND :	YES	NO	i.e ....

OTHER : ....

NEUROLOGICAL OBSERVATIONS

DATE :

TIME :

COMA SCALES				
Eyes open	Spontaneously	4		Eyes closed by swelling = C
	To Speech	3		
	To pain	2		
	None	1		
Best verbal res - ponse	Orientated	5		Endotracheal tube or tracheostomy = T
	Confused	4		
	Inappropriate words	3		
	Incomprehensible sounds	2		
	None	1		
Best motor res - ponse	Obey commands	6		Usually record the best arm response APHASIC = A
	Localise pain	5		
	Normal flexion	4		
	Abnormal flexion	3		
	Extension to pain	2		
	None	1		

Coma scale 3 -15 : ☐

Pupil size : Small ☐ Medium ☐ Large ☐

PUPILS	Right	Size		+ Reacts
		Reaction		- No reaction
	Left	Size		C. Eye closed
		Reaction		

INSTRUCTIONS :

1. Hourly BP, Pulse, Pad + Wound checks for ______ hours
2. Fluid balance : ie ....
3. Empty catheter bag ______ hourly
4. Diet : ie ....
5. Analgesia : Yes ☐ No ☐ ie ....
6. Other : ie ....

Signature : ....