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PO Box 117
221 00 Lund
+46 46-222 00 00

The National Early Warning Score (NEWS)

Testing and evaluation in a Swedish setting

MARTIN SPÅNGFORS

FACULTY OF MEDICINE | LUND UNIVERSITY





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MEDICINE**

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Section of Anesthesiology and Intensive Care

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The National Early Warning Score (NEWS)

Testing and evaluation in a Swedish setting

Martin Spångfors



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DOCTORAL DISSERTATION

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Faculty opponent

Professor Lars Simon Rasmussen

Department of Anaesthesia, Centre of Head and Orthopaedics, Rigshospitalet,
University of Copenhagen, Copenhagen, Denmark

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Abstract <p>Background Deviating vital signs have been known to precede Serious Adverse Events (SAEs) like In-Hospital Cardiac Arrest (IHCA), unplanned Intensive Care Unit (ICU) admission or unexpected death for more than a decade but still the recognition of these deteriorating patients is poor. The British National Early Warning Score (NEWS) is a "track and trigger" scale designed to assess in-hospital patients' vital signs and detect clinical deterioration.</p> <p>Aim Translate, test and evaluate the NEWS in a Swedish hospital setting.</p> <p>Methods Study I: The NEWS was translated and culturally adapted into Swedish and its association with the need of intensive care was investigated by a review of the rapid response teams (RRT) medical records in a university hospital. Study II: The associations between in-hospital or 30-day mortality and the NEWS risk categories low, medium and high was analyzed in a vital signs database. Study III: The 24 hours preceding an in-hospital cardiac arrest were divided into four timespans and the NEWS was analyzed by a medical record review of 127:254 matched case-control patients. Study IV: A web-based questionnaire was designed to describe Registered Nurses (RN) perceptions and experiences of and barriers for using the NEWS in relation to their work experience and medical affiliation.</p> <p>Results The Swedish translated NEWS had an excellent inter-rater reliability and the median score for patients admitted to the ICU were higher than for those who were not. AUC for discriminating admittance to the ICU was fair. Patients classified as medium or high risk by the NEWS experienced a two- or threefold increase, respectively, in odds of in-hospital death or 30-day mortality compared to low-risk patients. Patients suffering an IHCA had higher NEWS than their matched controls. The NEWS high-risk category was associated with a three- to fourfold increase in odds of IHCA compared to low-risk. In general, RNs perceived the NEWS as a useful tool, supporting their gut feelings about an unstable patient. Barriers to the NEWS were found in doctors and the most experienced RNs.</p> <p>Conclusion The Swedish translated NEWS is a sound "track and trigger" scale to identify high-risk patients at risk of SAEs in Swedish hospital settings.</p>		
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The National Early Warning Score (NEWS)

Testing and evaluation in a Swedish setting

Martin Spångfors



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MADE IN SWEDEN 

I would like to dedicate this thesis to all the patients I have encountered that suffered an in-hospital cardiac arrest or unplanned intensive care unit admission from a hospital ward.

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List of publications

This thesis is based on the following studies, referred to in the text by their Roman numbers (I-IV):

- I. Spångfors M, Arvidsson L, Karlsson V & Samuelson K. The National Early Warning Score: Translation, testing and prediction in a Swedish setting. *Intensive Crit Care Nurs.* 2016;37: 62-67. <https://doi.org/10.1016/j.iccn.2016.05.007>.
- II. Spångfors M, Bunkenborg G, Molt M & Samuelson K. The National Early Warning Score predicts mortality in hospital ward patients with deviating vital signs: A retrospective medical record review study. *J Clin Nurs.* 2018;28: 1216-1222. <https://doi.org/10.1111/jocn.14728>.
- III. Spångfors M, Molt M & Samuelson K. In-hospital cardiac arrest and preceding National Early Warning Score (NEWS): A retrospective case-control study. *Clinical Medicine Journal.* 2020;20: 55-60. <https://doi.org/10.7861/clinmed.2019-0137>.
- IV. Spångfors M, Molt M & Samuelson K. National Early Warning Score (NEWS): A questionnaire study of nurses' perceptions, experiences and barriers. *J Clin Nurs.* 2019. [Epub ahead of print]. <https://doi.org/10.1111/jocn.15167>.

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Abbreviations

α	Alpha
ACCI	Age adjusted Charlson Comorbidity Index
AUC	Area Under the Curve
BP	Blood Pressure
CCI	Charlson Comorbidity Index
CCOT	Critical Care Outreach Team
CHDU	Cardiac High Dependency Unit
CI	Confidence Interval
COPD	Chronic Obstructive Pulmonary Disease
DNR	Do-Not-Resuscitate
ED	Emergency Department
EWS	Early Warning Score
HDU	High Dependency Unit
ICD-10	International Classification of Diseases 10th revision
ICU	Intensive Care Unit
IHCA	In-hospital cardiac arrest
IQR	Interquartile range
κ	Kappa
md	Median
*MET	Medical Emergency Team
MEWS	Modified Early Warning Score
n	Number
NEWS	National Early Warning Score

NICE	National Institute for Health and Clinical Excellence
OR	Odds ratio
OT	Operating Theater
p	Probability
RETTS	Rapid Emergency Triage and Treatment System
RN	Registered Nurse
RR	Respiratory Rate
RRS	Rapid Response System
RRT	Rapid Response Team
SAE	Serious Adverse Events
SIR	Swedish Intensive care Registry
TCA	Trans Cultural Adaptation
UK	United Kingdom
IEWS	VitalPAC Early Warning Score
WHO	World Health Organization (WHO)

*In this thesis the abbreviation MET will be used to refer to any type of teams not distinguishing between the different team compositions.

**"Vital signs" is an umbrella term for physiological parameters like respiratory rate, oxygen saturation of the hemoglobin, pulse rate, blood pressure, temperature and level of consciousness. These parameters are all vital to our survival and involved in the oxygen delivery to the cells.

Abstract

Background

Deviating vital signs have been known to precede Serious Adverse Events (SAEs) like In-Hospital Cardiac Arrest (IHCA), unplanned Intensive Care Unit (ICU) admission or unexpected death for more than a decade but still the recognition of these deteriorating patients is poor.

The British National Early Warning Score (NEWS) is a “track and trigger” scale designed to assess in-hospital patients’ vital signs and detect clinical deterioration.

Aim

Translate, test and evaluate the NEWS in a Swedish hospital setting.

Methods

Study I: The NEWS was translated and culturally adapted into Swedish and its association with the need for intensive care was investigated by a review of the rapid response team’s (RRT) medical records in a university hospital.

Study II: The associations between in-hospital or 30-day mortality and the NEWS risk categories low, medium and high were analyzed in a vital signs database.

Study III: The 24 hours preceding an in-hospital cardiac arrest were divided into four timespans and the NEWS was analyzed by a medical record review of 127:254 matched case-control patients.

Study IV: A web-based questionnaire was designed to describe Registered Nurses’ (RN) perceptions and experiences of and barriers for using the NEWS in relation to their work experience and medical affiliation.

Results

The Swedish translated NEWS had an excellent inter-rater reliability and the median score for patients admitted to the ICU were higher than for those who were not. AUC for discriminating admittance to the ICU was fair.

Patients classified as medium or high risk by the NEWS experienced a two- or threefold increase, respectively, in odds of in-hospital death or 30-day mortality compared to low-risk patients.

Patients suffering an IHCA had higher NEWS than their matched controls. The NEWS high-risk category was associated with a three- to fourfold increase in odds of IHCA compared to low-risk.

In general, RNs perceived the NEWS as a useful tool, supporting their gut feelings about an unstable patient. Barriers to the NEWS were found in doctors and the most experienced RNs.

Conclusion

The Swedish translated NEWS is a sound “track and trigger” scale to identify high-risk patients at risk of SAEs in Swedish hospital settings.

Introduction

Patient safety is a broad term which covers a large spectrum that affects the patients both directly and indirectly. This thesis focuses on three serious adverse events (SAEs) occurring in somatic hospital wards; In-hospital Cardiac Arrest (IHCA), unplanned Intensive Care Unit (ICU) admission and unexpected death.

These SAEs have been linked to suboptimal care preceding the event (1-5). Lack of basic assessment and documentation of our most important vital functions - breathing, circulation, and consciousness - have been suggested as plausible causes of the suboptimal care (1-4).

Deviating vital signs have been known to precede SAEs like IHCA, unplanned ICU-admission or unexpected death for more than a decade but still the recognition of these deteriorating patients are poor (1, 6-11).

As a result, the Rapid Response System (RRS) emerged (12). The RRS consists of an afferent limb for the early identification of patients at risk of SAEs by a “track and trigger” scale and the efferent limb of a Medical Emergency Team (MET), also named Critical Care Outreach Team (CCOT), which is a team with competence in handling the acutely ill patient (12).

A crucial component of the RRS is the afferent limb of the system, the “track and trigger” scale. There have been several attempts throughout the years to improve the early identification of deteriorating patients by introducing different “track and trigger” scales with various results (10, 13-15). However, most of these scales were locally produced in small samples with poor validation and generalizability as a result. Further, some of them lacked clear cut off values related to the patient’s risk of critical illness and instructions of what actions should be taken at the different levels of risk.

In 2012 in the UK, an attempt was made to improve the assessment and documentation of vital signs in hospitals by introducing a unified standardized concept on a national basis (16). This concept was named the National Early Warning Score (NEWS) and was better validated than the earlier concepts and showed better discriminative abilities than the previously used “track and trigger” scales (15, 16). Further, the NEWS also

classifies the risk of critical illness and offers a clinical decision support as well as a standardized documentation.

In conclusion, the literature supports the NEWS as the currently best validated “track and trigger” scale. However, although the NEWS is a promising tool it was designed for the British healthcare system and no Swedish evaluation studies of the NEWS exist. If the NEWS is to be used in Swedish healthcare settings it needs not only translation and adaptation into Swedish but also testing and evaluation in a Swedish setting.

Background

Patient safety in hospitals

Patient safety is a major global health issue. The incidence of patients dying due to a preventable medical error is estimated to be 1 in 300 (17). In comparison, there is a 1 in 3 000 000 risk of death when you travel by airplane. The aviation industry, just like the nuclear industry, has a higher perceived risk and consequently has a more developed safety protocol than healthcare (17).

According to the World Health Organization (WHO) patient safety is defined as:

“The absence of preventable harm to a patient during the process of health care and reduction of risk of unnecessary harm associated with health care to an acceptable minimum. An acceptable minimum refers to the collective notions of given current knowledge, resources available and the context in which care was delivered weighed against the risk of non-treatment or other treatment (WHO, Patient Safety, 2019, para. 3. Retrieved from: <https://www.who.int/patientsafety/about/en/>)”.

Studies from high-income countries have shown that about 10 % of the hospitalized patients are injured while receiving care (17). About 50 % of these injuries are considered to be preventable (17).

In Sweden, it is estimated that 8 % of the hospitalized patients are injured while receiving care (18). Annually this corresponds to 110 000 patients being injured while receiving care and of these, about 1400 patients die as a direct result of this injury (18).

Consequently, it is of key importance for all healthcare staff to avoid injuring patients with their care and if they do injure a patient it is imperative that they take action to prevent future patients from being injured.

SAEs have been linked to suboptimal care preceding the event and it is most often not an expensive blood biomarker or an advanced radiographic investigation that is lacking but the basic assessment, documentation and management of our most important vital functions - breathing, circulation and consciousness (1-5).

According to a multicenter study in 2004 called the “SOCCER” study, the prevalence of deviating physiological variables in hospital ward patients was more than 50 % and of these, 16 % were considered late signs of deviation (11). In another multicenter study in 2004 called the “ACADEMIA” study, SAEs occurring during three study days in 90 hospitals were reviewed and the researchers found that 60 % of the SAEs were preceded by identifiable antecedents (8).

Thus, the association between deviating vital signs and SAEs seems to be strong and the relationship has been known for more than a decade. However, reports about low adherence in the assessment and documentation of vital signs are frequent (19-23). Hence, adherence of all healthcare staff is essential for the safety of the deteriorating patient and therefore an illustrative “Chain of prevention” has been proposed (Figure 1) (24).

Chain of prevention



Figure 1. The chain of prevention. © Reproduced with permission of Professor Gary B Smith.

Serious adverse events in hospitals

In this thesis SAEs are defined as IHCA, unplanned ICU-admission, or unexpected death. These events are all associated with a high mortality rate but they also have something else in common: they are all associated with preceding deviating vital signs (1, 3, 8). This feature is the key to detect and intervene which might ultimately prevent some of these SAEs.

In-hospital cardiac arrest (IHCA)

The overall incidence of IHCA is estimated to be 0.8-2.9/1000 admissions and the survival rates are low at around 15-25 % (25-28).

Cardiac arrest is a life-threatening condition that can occur both in-hospital (IHCA) or out of hospital. An international consensus group first published a uniform definition of out of hospital cardiac arrest in 1991, called “The Utstein style” (29). In 1997 separate Utstein style guidelines were published for IHCA and ultimately in 2004 the guidelines were conformed to the current guidelines for cardiac arrest (30, 31). According to these guidelines a cardiac arrest is defined as “the cessation of cardiac mechanical activity as confirmed by the absence of signs of circulation” (31).

In most cases IHCA differs significantly from out of hospital cardiac arrest where the primary cause is predominantly cardiac with a rapid onset (1, 32-35). On the other hand, IHCA seems to be the end result of a process of deterioration where the cause is not predominantly cardiac and should pose a window of opportunity to detect patients at risk of IHCA (1, 8, 32, 36).

A majority of the IHCAs occur in the hospital wards where the survival rates unfortunately are the lowest (5, 27, 32). It has also been shown that IHCAs in the hospital wards are more than five times as likely to be preventable compared to IHCAs in critical care areas with a higher level of monitoring (5).

Already in the 1990s Schein et al. showed that deviations in the level of consciousness, heart rate and respiratory rate preceded a majority of the included IHCAs (1). These deviations were documented for up to 8 hours before the IHCAs occurred.

A later British review in 2012 of patients who underwent cardiopulmonary resuscitation as a result of an IHCA concluded that a majority of the events were preceded by deviating vital signs up to 6 hours before the IHCA and in some cases for more than 24 hours. A large proportion of the events were considered preventable (37).

Unplanned ICU-admission

According to the Swedish ICU-register (SIR) unplanned admission to the ICU from a hospital ward was associated with a higher 30-day mortality (25 %) compared to the Emergency Department (ED) (14 %) or the Operating Theatre (OT) (15 %) in 2008-2018 (38). During that time period 31 % of the unplanned admissions to the ICU originated from the hospital wards (38).

Patients admitted from the hospital wards have shown greater severity of illness and a greater number of serious physiological abnormalities than those admitted from the OT or the ED (39).

Deviating vital signs are known to be strongly associated with unplanned ICU-admission (40). Recognition and response to these deviating vital signs can be challenging. Two seminal studies were published in the late 1990s by Mquillan et al. (1998) and McGloin et al. (1999) showing that the management of airway, breathing, circulation, oxygen therapy and monitoring in severely ill patients before admission to the ICU was frequently suboptimal (3, 4).

In a study by Hillman et al. (2002) more than 60 % of the patients admitted to the ICU had potentially life-threatening abnormalities documented up to 8 h before admission (39).

Unexpected death

The incidence of unexpected deaths is relatively unreported. However, two Australian studies reported 1-2 unexpected deaths/1000 hospital admissions (41, 42).

A patient is considered to die unexpectedly in hospital if the patient is dying without a “Do Not Resuscitate” (DNR) order.

Unexpected deaths are in a way the end stage of deviating vital signs and might start out as an IHCA that fails to be resuscitated. With this reasoning in mind, the first description of deviating vital signs preceding unexpected deaths was published in the early 1990s by Schein et al. whose aim was to study IHCAs (1). However, associations of deviating vital signs and unexpected death in a prospective study were first described in the early 2000s where a deviating vital sign was associated with a more than six-fold increase in risk of unexpected death (43).

Serious adverse events in Sweden

Corresponding figures for SAEs in Swedish hospital settings are largely unreported. Yet, a total of 2460 IHCAs were reported to the Swedish national cardiac arrest registry in 2016 and during this time there were approximately 1 397 749 hospital admissions in Sweden (44). By combining these numbers, the incidence of IHCA in Sweden in 2016 is estimated to 2/1000 admissions (44).

The evolution of “track and trigger”

The knowledge of deviating vital signs preceding SAEs has led to the development of two methodologically different concepts, the MET-calling criteria and the Early Warning Score (EWS), to improve the detection of patients at risk of SAEs. However different, they are both structured ways to detect abnormal vital signs by “tracking” them and “triggering” a response when the abnormality is considered to be relevant to the risk of developing SAEs. These “track and trigger” scales have been developed during more than two decades and are presented in a historical way (Figure 2).

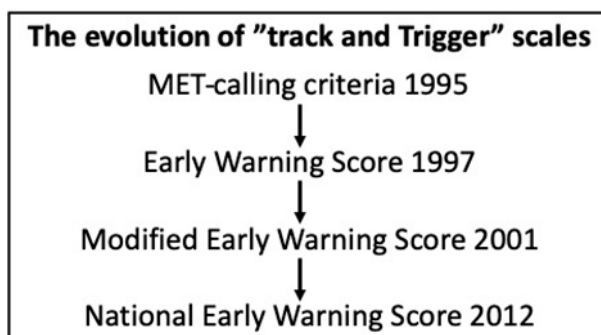


Figure 2. The evolution of “track and trigger” scales.

MET-calling criteria 1995

More than two decades ago in Australia, Lee et al. (1995) published the MET-calling criteria consisting of six calling criteria (Table 1) (10). If one or more of them were fulfilled the patient “triggered” and the healthcare staff was to call a responding team called the MET. Since then numerous different calling criteria have been published (45). The MET-calling criteria are also referred to as a single-parameter “track and trigger” system.

Table 1.

The MET-calling criteria		
Temperature	<35,5° C	>39,5° C
Systolic blood pressure	<100 mmHg	>200 mmHg
Respiratory rate/min	<10	>30
Pulse rate/min	<40	>120
Urine output (24 h)	<500	
Level of consciousness	Decreased	Altered

The single-parameter cut-off points are easier to use than the more complex EWS but on the downside they lose a lot of valuable information since they do not aggregate deviations in more than one parameter and can only trigger or not trigger. Furthermore, subtle changes in one or more vital signs will not be noticed and thus not lead to a triggered response.

In a review, 30 different single-parameter “track and trigger” systems were assessed in predicting in-hospital mortality (45). Specificities (true negative rate i.e. the proportion of patients without suffering an SAE who test negative) were generally high but sensitivities (true positive rate i.e. the proportion of patients who suffer an SAE who test positive) were low, meaning that a lot of patients will be missed.

Early Warning Score 1997 & Modified Early Warning Score 2001

The EWS was first published in 1997 by Morgan et al. and was closely followed by the more familiar Modified Early Warning Score (MEWS) in 2001 (46, 47). These concepts originating from the UK are also called aggregated weighted “track and trigger” systems and differ from the MET-calling criteria in that each parameter is assigned different points, correlating to the divergence from the expected normal value and then summed up to a total score. This total score can then be related to the patients risk of SAEs.

The aggregate weighted “track and trigger” systems are more complex than the single parameter “track and trigger” system and are more prone to human error both when assigning the correct points to the measured vital sign and in summing them up (20, 48, 49). On the other hand, they contain more information and give a wider view of the patient’s physiological state. Furthermore, changes in more than one vital sign will be aggregated and have been shown to be more predictive for SAEs than a single deviating vital sign (21, 50).

Many of the aggregate weighted “track and trigger” systems were produced locally in small samples with poor validation as a result. A review in 2008 of 33 aggregate weighted “track and trigger” systems showed that the performance of most of them was poor when used to discriminate patients at risk of in-hospital mortality. The results suggested that deviating vital signs could be used to predict outcome but further work was required to improve the “track and trigger” systems (51).

National Early Warning Score 2012

In response to a report on the acutely ill patients in hospital, covering the recognition of and response to acute illness in adults from the National Institute for Health and Clinical Excellence (NICE) in 2007 the Royal College of Physicians commissioned a working group to develop a National Early Warning Score (NEWS) for the UK (16, 52). The result was a concept in part derived from a database analysis in the UK and an expert panel's clinical reasoning. The NEWS represents a balanced assessment of the available evidence, experienced clinical and professional judgement, patient and user opinion, evaluation, validation, and pragmatism (16).

Rapid response system

The medical emergency team (MET) was first described in 1995 but it took until 2006 before the Rapid Response System (RRS) was first described (12). The RRS was then described at an international consensus conference by a panel comprising of experts in patient safety, hospital medicine, critical care and METs as a hospital wide system designed to detect deterioration in patients, trigger an alert and deliver a response by competent personnel to prevent further deterioration and death (12).

The afferent limb of the RRS consists of a single-parameter or aggregated weighted “track and trigger” scale and the efferent limb consists of a MET (Figure 3). The MET, also called CCOT, consists of a team with competence in handling the acutely ill patient. The composition of the team varies, and it is led by a physician or RN.

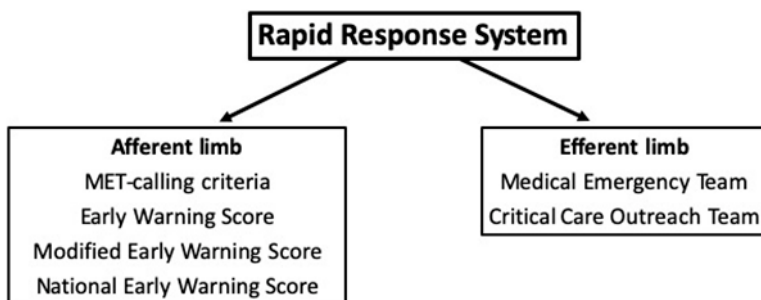


Figure 3. The Rapid Response System.

There has been a lot of debate concerning the effectiveness of the RRS in actually decreasing deterioration and preventing death. High grade evidence from well-designed randomized clinical trials is lacking. The Cochrane network made a review of CCOT and EWS for the prevention of ICU-admission and death in 2007 and concluded that the current evidence of MET and EWS systems was inconclusive due to poor study design (53). More than a decade has now passed since that review was made and some studies are worth mentioning. The following studies display the development of the RRS from a historical perspective.

In 2002, a single centre 12 months before the introduction of the MET system to 12 months after study was performed in Australia with the primary outcome of incidence and outcome of IHCA (54). More than 53 000 hospital admissions were included. The incidence of IHCA was reduced from 3.77 to 2.05 per 1000 hospital admissions with a corresponding reduction in mortality from 77 % to 55 %. After adjustment for case mix, the intervention was associated with a 50 % reduction in the incidence of IHCA (54).

A note of caution is that there was a two-year implementation period between the two study periods and during this time, hospital admissions and planned admissions increased as well as some differences in the case mix of patients. Furthermore, medical progressions during this time period are not described. The reporting of the frequency of DNR pre-MET is also missing.

In 2003, Bellomo et al. conducted a single centre four month before to four month after study in Australia, introducing the MET-system with the primary outcome as the incidence of IHCA, patients dying after IHCA, number of postcardiac-arrest bed-days and number of in-hospital deaths. (55). More than 42 000 patients were included. There was a relative risk reduction in the incidence of IHCA of 65 % and 56 % for IHCA related death post-MET introduction. Survivors of IHCA pre-MET required 163 ICU bed-days versus 33 in the post-MET period and 1353 hospital bed-days versus 159 respectively. There was a relative risk reduction of 26 % for in-hospital deaths post-MET introduction (55).

These findings should be interpreted with caution due to the single centre before-after study design which is prone to bias and the relatively short study period.

In 2003, in the UK, Subbe et al. performed a one month before to three months after study, evaluating the effectiveness of the MEWS and CCOT in patients admitted to one acute medical unit in reducing the rates of IHCA, ICU-admission or high dependency unit admission (14). More than 2300 patients were included. No significant reductions in the outcome variables were shown.

A note of caution is that data for the control group was obtained from a previous study validating the MEWS which might have raised the awareness and possibly increased the interventions to prevent the outcome variables already in the control period. Factors that might affect these findings, other than the study design, may be lack of power or seasonal variation.

In 2004, DeVita et al. performed a retrospective analysis of more than 199 000 hospital admissions with 3200 MET-responses and 1200 IHCAs over seven years in a US hospital (56). During the study period there was an increase in MET-responses from 13.7 to 25.8 per 1000 hospital admissions with a coincident 17 % decrease in the incidence of IHCA (6.5 to 5.4 per 1000 admissions) (56).

There was no reporting on DNR and the observational design does not allow for any causal inferences to be drawn.

In 2005, the first large seminal study of the effectiveness of RRS was made by the MERIT-study investigators where 23 hospitals in Australia were cluster randomized in two arms to continue usual care or to introduce the MET-system (42). The primary outcome was the composite of cardiac arrest, unexpected death, or unplanned ICU-admission. More than 125 000 hospital admissions were included. During the six-month study period the overall calling incidence for the MET increased but the composite primary outcome in the control and MET hospitals was non-significant. However, a reduction in the rate of cardiac arrests and unexpected deaths was seen from baseline to the study period for both groups combined which clouds the results (42).

It might be an indication of bias or contamination of the usual care hospitals and the results should be interpreted with caution. Furthermore, a study period of only six months post MET-system activation might not be representative for the evaluation of its effectiveness since saturation and maturation of the system might not be complete.

In 2007, a large ICU registry study was performed in the UK with a multicentre interrupted time-series analysis of the impact of RRS (57). More

than 350 000 ICU-admissions to 172 ICUs between 1996 and 2004 were audited. There were 109 ICUs included of which 79 had a formal RRS. In ICU-admissions from the hospital ward, RRSs were associated with significant decreases in the proportion of admissions receiving cardiopulmonary resuscitation in the 24 hours before ICU-admission (OR 0.84, 95 % confidence interval 0.73 to 0.96). Admissions out of hours and mean Intensive Care National Audit & Research Centre physiology score decreased but there was no significant change in ICU mortality (57).

There are many pitfalls and uncontrolled confounders in this study and it only associates the RRS with the patients that are admitted to the ICU which means that there are no data on all the patients not admitted to the ICU.

In 2010, in Sweden, Jäderling et al. performed a single centre five years before to two years after study on the effects of implementing a MET-system on rates of IHCA and hospital mortality (28). More than 277 000 patients were included and the rates of IHCA decreased from 1.12 to 0.83 per 1,000 admissions. Furthermore, hospital mortality was reduced by 10 % when adjusting for confounding variables (28).

A note of caution is that the patients in the post-MET group were younger and more were electively admitted. Furthermore, the DNR amongst patients seen by the MET increased from 5 % to 26 % which might impact the rates of IHCA in the post-MET group.

In 2011, Moon et al. performed a before-after study in a UK hospital to determine whether IHCA-calls, proportion of adult patients admitted to the ICU post-CPR in the hospital and their associated mortalities were reduced, in a four-year period after the introduction of a CCOT and the MEWS (58). More than 440 000 hospital admissions were included. There was a 50 % decrease in the number of IHCA-calls relative to the adult hospital admissions and a 30 % decrease in the proportion of patients admitted to the ICU post-IHCA. Furthermore, the in-hospital mortality of these patients was reduced from 52 % to 42 % and the total hospital mortality was reduced by 7 % (58).

An obvious risk of bias in this study is that the researchers used records of a switchboard's cardiac arrest calls as an outcome measure where the number of "true" cardiac arrests is unknown. Furthermore, the frequency of DNR is not reported.

In 2014, in a Danish study by Bunkenborg et al. with a pre – post design including more than 4000 patients admitted to a medical or surgical hospital ward, a significant reduction in IHCAs from 61 to 17/100 adjusted patient years was seen after a clinical intervention comprising education of the healthcare staff, introduction of the MEWS and algorithms for bedside actions (13).

This was a small single centre before-after study comprising of only a few hospital wards with the constant presence of one of the investigators and the healthcare staff attending a very intense education programme in the acutely ill. From this study we cannot draw any isolated conclusions about the RRS since we do not know how much of the effect is due to the educational programme. Furthermore, this approach might not be feasible in a large hospital setting.

In 2015, the Dutch COMET-study was a five months before to five months after the introduction of the MEWS and RRT study, including two surgical and two nonsurgical wards at 12 hospitals. More than 57 000 hospital ward admissions were analysed (59). A 15 % adjusted risk reduction of SAEs, constituting of IHCAs, unplanned ICU admissions, and in-hospital deaths, was found. Incidence of IHCA was reduced from 1.94 (1.43–2.46) to 1.22 (0.82–1.61) and in-hospital mortality from 20.4 (18.7–22.0) to 17.7 (16.2–19.2) per 1000 admissions. Unplanned ICU-admissions were reduced from 19.8 (18.1–21.6) to 17.1 (15.5–18.6) per 1000 admissions (59).

The study period of only five months pre and post RRS activation might not be representative for the evaluation of its effectiveness since seasonal variations can inflict bias. Furthermore, selection bias must be considered when interpreting the study results since only four hospital wards at each hospital were included which in turn impacts the generalisability of the results.

In 2018, in Belgium a stepped wedge cluster randomised controlled trial including 14 hospitals with two medical and two surgical wards each was performed (60). The intervention comprised of the introduction of the NEWS and an RRT. There were more than 69 000 admissions included but the study failed to show any significant effect on the incidence of IHCA, unplanned ICU-admission or unexpected death (60).

However, there was a large drop out of included centres and an unexpected low baseline incidence of IHCA and unexpected mortality contributing to a largely underpowered study.

In 2019, Hogan et al. published an interesting study with a mixed-methods approach where a systematic literature review and interviews with healthcare staff was used to design an organisational survey on RRS which was conducted in 171 British hospitals (61). The survey was followed by an interrupted time series and analyses of 106 hospitals to determine how interventions had been implemented in practice and across time between 2009-2015, allowing associations between variations in services, IHCA rates and survival to be drawn. Introduction of the NEWS was associated with an 8.4 % drop in IHCA rates in addition to the pre-existing trends. The RRT was not associated with a change in IHCA survival or hospital mortality but the intensity of RRTs were associated with increased ward-based IHCA survival (61).

The observational design does not allow for causal relationships to be drawn.

There have been a couple of systematic reviews with and without meta-analysis with the aim of assessing the effect of RRS on IHCA, unplanned ICU-admission, unexpected death or in-hospital mortality (62-66). The majority of these reviews concluded a positive effect of the RRS on the outcome measures (62-66).

However, they all reported difficulties in heterogenous study designs, interventions and unstandardized EWS or MET-calling criteria. Furthermore, most study designs were unblinded before-after studies without a contemporaneous control.

Generally, when reflecting on these studies one must bear in mind that due to the relatively low rate of SAEs most studies are probably underpowered, and the study designs are prone to biased results. Furthermore, the effectiveness of the RRS cannot be isolated from other confounding factors like changes in DNR policies, new drugs, routines, diagnostic procedures or the simple effect of education of the staff or a general increased awareness. Likewise, hospital cultures, delayed responses, shortage of staff, shortage of ICU-beds, faulty assessment and diagnosis of disease severity or inadequate response or treatment might also have affected the study results.

In conclusion, despite the lack of high-grade evidence of the effectiveness of RRS in reducing SAEs, studies are accumulating, and a majority of the studies reports a positive effect.

National Early Warning Score

The NEWS is an aggregated weighted “track and trigger” scale designed to be an afferent limb of an RRS. The six physiological parameters, respiratory rate, oxygen saturations, body temperature, systolic blood pressure, heart rate and level of consciousness, were suggested as core components of an EWS by the NICE clinical guideline 50 in 2007 (52). The NEWS working group agreed with the recommendations to use the six core components and decided to use a previously published EWS called the VitalPAC Early Warning Score (VIEWS), which contained the six physiological parameters as a template (67). Further, the VIEWS also consisted of the assessment of supplemental oxygen which was adopted by the NEWS working group. The VIEWS was derived from a database consisting of 198,755 data sets from 35,585 admissions to an acute medical assessment unit in the UK. This database was used for the further development of the NEWS and consisted of consecutive completed admissions to the unit between 2006-2008. This unit was the common entry point for all medical emergency patients ≥ 16 years of age that were not directly transferred to the ICU from the ED. Patients that were discharged from the hospital before midnight on the day of admission were excluded from the database. Thus, the database consisted of complete vital signs documented by hospital staff in an electronic interface that were combined with demographic variables and the status at discharge from the hospital as either alive or dead (67).

The template for the NEWS was circulated to the working group members and the weightings given to the different parameters were based on a systematic review of other EWSs and group discussions by the members (16). It was decided that deviations in physiological parameters were more common to occur in multiple parameters and an aggregate score would be a more robust measure of the severity of acute critical illness (16).

The key changes to the NEWS template were the addition to assign a “Red score” for the extreme isolated values in the physiological parameters rather than basing it on an aggregated score of 3 and to assign 2 points for supplemental oxygen instead of 3 points (16).

The database was then used to evaluate the NEWS template against other EWSs and to evaluate the NEWS performance in discriminating patients dying before hospital discharge within 24 hours of the assessment. The NEWS outperformed the older EWSs and showed excellent discriminative capabilities (16).

The final NEWS physiological parameters consist of measures of respiratory rate, oxygen saturations, body temperature, systolic blood pressure, heart rate and level of consciousness and are rated from 0 to 3, correlating with their divergence from the expected normal values (Figure 4) (16).

PHYSIOLOGICAL PARAMETERS	3	2	1	0	1	2	3
Respiration Rate	≤8		9 - 11	12 - 20		21 - 24	≥25
Oxygen Saturations	≤91	92 - 93	94 - 95	≥96			
Any Supplemental Oxygen		Yes		No			
Temperature	≤35.0		35.1 - 36.0	36.1 - 38.0	38.1 - 39.0	≥39.1	
Systolic BP	≤90	91 - 100	101 - 110	111 - 219			≥220
Heart Rate	≤40		41 - 50	51 - 90	91 - 110	111 - 130	≥131
Level of Consciousness				A			V, P, or U

Figure 4. The NEWS physiological parameters. © Royal College of Physicians.

The level of consciousness is assessed by the A-V-P-U concept as follows: A = alert, V = verbal, P = pain, U = unresponsive. Any alteration in level of consciousness is rated as three points. The individual parameter scores are then summed, and supplemental oxygen increases the score by two points (16).

The sum of points can then be related to the level of risk for the patient: low risk = 0–4 points, medium risk = 5–6 points or three points in one individual parameter and high risk = ≥7 points (Figure 5) (16). These trigger thresholds were set by an analysis of another database from the same hospital that was not used to form the NEWS physiological parameters. This database was obtained in the same way and contained the same data as the previously used database and comprised three clinical settings: an acute medical unit (81,010 observation sets from 12,476 patients), medical wards (283,288 observation sets from 8,937 patients) and surgical wards (197,715 observations sets from 7,801 patients) in the UK (16). The trigger thresholds were set by a sensitivity analysis with regards to the frequency of alerts and the specificity in relation

to other EWSs’ predictive capabilities regarding patients dying before hospital discharge. A NEWS trigger threshold of 5 points triggered 20 % of the datasets in the medical wards and 10 % in the surgical wards which meant a higher sensitivity and specificity than older EWSs. In contrast, a trigger threshold of 7 points triggered 10 % of the datasets in the medical wards and 4 % in the surgical wards (16).

NEWS scores	Clinical risk
0	Low
Aggregate 1–4	
RED score* (Individual parameter scoring 3)	Medium
Aggregate 5–6	
Aggregate 7 or more	High

Figure 5. The NEWS Clinical risk scale. © Royal College of Physicians.

In addition to the NEWS physiological parameters and the clinical risk scale, an outline clinical response scale serves as a clinical decision support for the healthcare staff (Figure 6). The decision support consists of recommendations on levels of expertise required for the situation, assessment interval and level of care. An activation of the rapid response team (RRT), as the efferent limb of the rapid response system, is thus also implied in the outline clinical response scale (16).

NEWS SCORE	FREQUENCY OF MONITORING	CLINICAL RESPONSE
0	Minimum 12 hourly	<ul style="list-style-type: none"> • Continue routine NEWS monitoring with every set of observations
Total: 1-4	Minimum 4-6 hourly	<ul style="list-style-type: none"> • Inform registered nurse who must assess the patient; • Registered nurse to decide if increased frequency of monitoring and/ or escalation of clinical care is required;
Total: 5 or more or 3 in one parameter	Increased frequency to a minimum of 1 hourly	<ul style="list-style-type: none"> • Registered nurse to urgently inform the medical team caring for the patient; • Urgent assessment by a clinician with core competencies to assess acutely ill patients; • Clinical care in an environment with monitoring facilities;
Total: 7 or more	Continuous monitoring of vital signs	<ul style="list-style-type: none"> • Registered nurse to immediately inform the medical team caring for the patient – this should be at least at Specialist Registrar level; • Emergency assessment by a clinical team with critical care competencies, which also includes a practitioner/s with advanced airway skills; • Consider transfer of Clinical care to a level 2 or 3 care facility,

Figure 6. The NEWS Clinical response scale. © Royal College of Physicians.

The following three studies highlights the ability of the NEWS to predict and discriminate patients at risk of SAEs.

In 2013, in the UK a comparison of the NEWS with 32 other widely used “track and trigger” scales was performed. This study used the same database from which the NEWS physiological parameters were derived and had also been used in a previous review of older “track and trigger” scales in 2008. NEWS showed the highest ability to discriminate patients at risk of cardiac arrest, unplanned ICU admission or death within 24 hours (15). In this retrospective study, conducted on a vital signs database, more than 35 000 patients in an acute medical setting were included. The AUROC for the NEWS for IHCA was 0.72, unplanned ICU admission 0.86, unexpected death 0.89 and the combined outcome of all SAEs 0.87 (15).

In 2014, in a Finnish prospective point prevalence study by Tirkkonen et al., the NEWS was calculated on more than 600 patients and compared with the hospital's MET-calling criteria (68). A NEWS of seven or more was associated with a more than sevenfold increase in odds of SAEs, defined as MET-activation, IHCA, unplanned ICU-admission or death. A more than elevenfold increase in odds of 30-day mortality was also found. The authors concluded that the NEWS, unlike the MET-calling criteria, had the ability to discriminate high-risk patients in a heterogeneous general ward population (68).

In 2016, in a large mixed patient population database study comprising almost 104 000 admissions with more than 2 000 000 sets of vital signs, different MET-calling criteria were compared to a NEWS ≥ 7 for prediction of SAEs (69). Some MET-calling criteria had higher sensitivity than NEWS, but in turn, all of these had a lower specificity and would generate greater workloads. The AUROC for the NEWS for cardiac arrest was 0.78, unplanned ICU admission 0.86, unexpected death 0.91 and the combined outcome 0.88 (69).

In summary the NEWS currently seems to be the best performing and validated “track and trigger” system available for prediction of IHCA, unplanned ICU-admission or unexpected death. Furthermore, the NEWS consists of commonly known and easily measured vital signs with a logical physiological rationale (Figure 7).

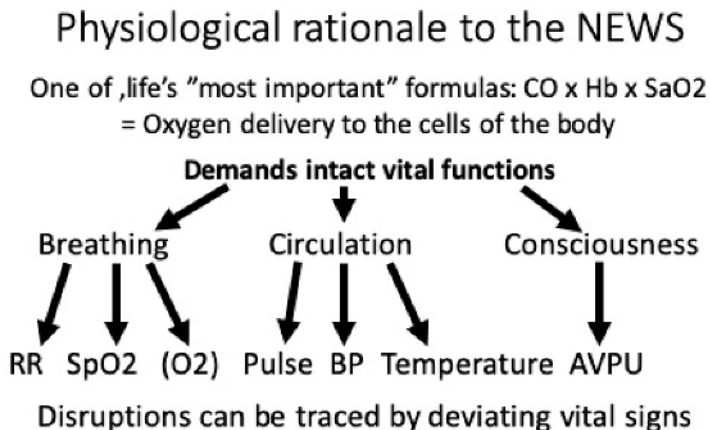


Figure 7. Physiological rationale to the NEWS.

Aims

These main findings from the literature indicate a positive effect on reducing SAEs with the use of an RRS. A crucial component of the RRS is the afferent limb of the system, the “track and trigger” scale. The literature supports the NEWS as the currently best validated “track and trigger” scale. However, the NEWS is designed for the British healthcare system and no Swedish validation studies exist. If the NEWS is to be widely used in Swedish healthcare settings it needs translation into Swedish, adaption, testing and evaluation in a Swedish setting.

The overall aim of this thesis was to test and evaluate the NEWS in a Swedish hospital setting.

Specific aims of the different research projects were:

- To translate the NEWS concept into Swedish, test the Swedish version and to investigate the association of NEWS values with ICU admission.
- To investigate if the NEWS clinical risk scale assessed on the hospital ward could be a predictor of in-hospital and 30-day mortality amongst a mixed patient population with deviating vital signs.
- To describe the NEWS in different timespans in the 24 hours preceding an IHCA and evaluate the discriminative ability of the NEWS among general somatic ward patients, using the clinical risk classification.
- To describe Swedish RNs’ perceptions, experiences and barriers in using the NEWS in relation to their work experience and medical affiliation.

Methods

Designs and settings

Studies I-III were, except study I's translation and cultural adaptation, primarily focused on SAEs (ICU-admission, mortality and IHCA) (Figure 8). During this work, we found indications of inconsistencies in adherence to the NEWS guidelines. As a result, we chose to design study IV to describe RNs' perceptions and experiences of and barriers for using the NEWS (Figure 8).

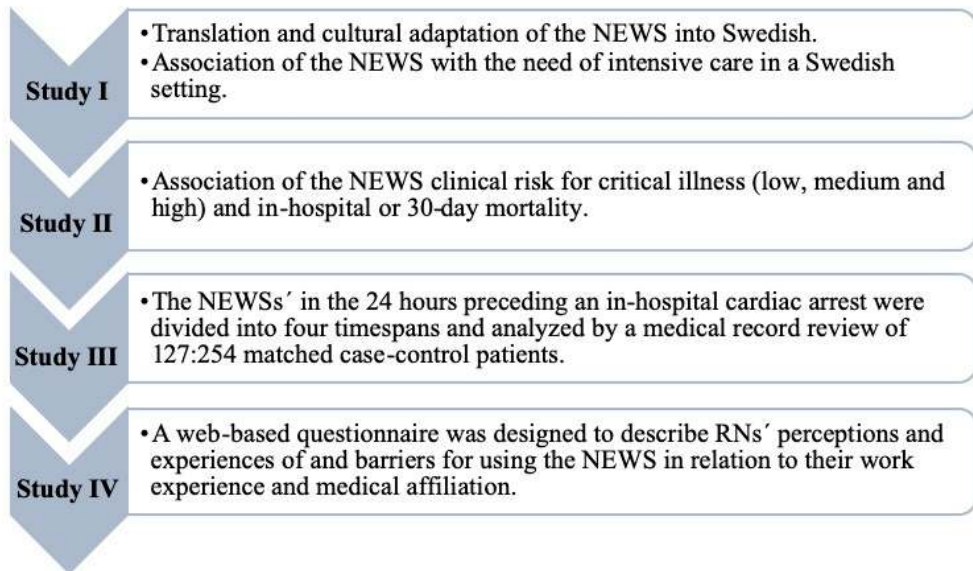


Figure 8. Flowchart of the studies.

Study I

The study was carried out in 2014-2015 at a Swedish university hospital with 500 adult beds, and conducted in three phases; scale translation, scale testing and evaluation in relation to ICU admission. The MET at the study hospital consisted of an anesthesiologist and an ICU-nurse and this MET service was available to all hospital wards around the clock. At that time, the “track and trigger” scale MEWS was used by the entire hospital and the MET activation criteria was MEWS >4.

The forward translation of the NEWS concept was inspired by the Translation and Cultural Adaptation (TCA) process and conducted by three of the authors by comparison of their independent versions (70). The TCA process offers a step-by-step approach in translating and adapting an instrument to a different language and setting in order to maintain the validity of the original instrument. A Swedish ICU-nurse originating from Great Britain made the back-translation into English without knowledge of the original version. The authors and the British nurse then had a cognitive debriefing and reviewed the two English and the Swedish versions making minor linguistic or cultural adaptations when necessary.

In the next two steps all MET-charts at a university hospital in Sweden from 2013 and 2014 ($n = 868$) were reviewed. These charts consisted of the calculated MEWS and all the data needed to calculate the NEWS, a brief medical history, actions taken by the MET and if the patient was admitted to the ICU. Adults, ≥ 18 years of age, were eligible for inclusion in the study. Vital parameters necessary to calculate the NEWS and information of ICU admission or not had to be documented on the MET-chart. Exclusion criteria were patients with COPD, because their oxygen saturation should be judged individually depending on their habitual state. Of the included charts, the summation of the MEWS was miscalculated in 12 % of cases. A test of the interrater reliability between three raters was conducted using the Swedish NEWS version and a randomized allocation of 50 MET-charts. For MET evaluation in relation to ICU admission, all the included MET-charts were used.

Study II

Data of patients with deviating vital signs were obtained from a previous prospective clinical interventional study by Bunkenborg et al. (2014), comprised of physiological, demographical and mortality data (13, 71). The study was performed at a 750-bed university hospital in Copenhagen, Denmark, for two 4-month periods from 1 September–31 December 2010

and 1 March–30 June 2011, and the aim was to evaluate the Modified Early Warning Score, MEWS. The 90-bed study setting comprised one medical, two surgical and one emergency admission ward for acute and planned treatment of adult patients (13, 71). In 2011, there were 460.000 inhabitants living in the catchment area of the university hospital (13).

A total of 1,225 patients, ≥ 18 years of age, with deviating vital signs were treated for at least 8 hours at the four wards during the two study periods (13, 71). These patients' vital signs such as blood pressure, heart rate, respiratory rate, oxygen saturation, body temperature, supplemental oxygen and level of consciousness were obtained.

Of the 1,225 patients, 118 were excluded due to missing data in other variables than the level of consciousness and supplemental oxygen. For missing data concerning supplemental oxygen or in the level of consciousness, the value from the most recent recording of the corresponding parameter was used. If there were no recordings of supplemental oxygen, the missing values were replaced with “no supplemental oxygen,” and if there were no recordings of level of consciousness, the missing values were replaced with “no alteration of the level of consciousness.”

A total of 1,107 patients with deviating vital signs, that is, with NEWS ≥ 1 , were thus included in the study (Figure 9).

The NEWS and its risk classification were retrospectively calculated on all patients meeting the inclusion criteria. The first recording of a deviating vital sign, that is, NEWS ≥ 1 , was chosen for the statistical analysis.

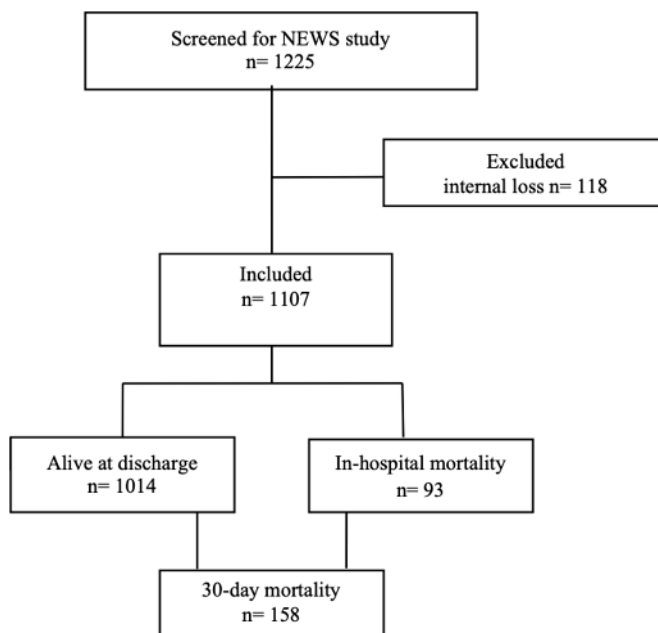


Figure 9. Flow diagram of patients included.

Study III

This was a retrospective multicentre medical record review study, using a 1:2 matched case-control design. Three emergency hospitals in Sweden, comprising one university hospital with 997 adult beds and two regional hospitals with 304 and 246 adult beds respectively participated (catchment area population of 1.3 million citizens).

All patients, ≥ 18 years of age, admitted for at least 24 hours, suffering an IHCA on a general somatic hospital ward from January 1st, 2016 to December 31st 2017 were reviewed for eligibility. Patients suffering an IHCA in the ICU, cardiac high dependency unit, cardiac catheterization laboratory, operating theatre, postoperative recovery unit or in the emergency department were not considered for inclusion. Further, patients with chronic obstructive pulmonary disease (COPD) were excluded because their oxygen saturation should be judged individually depending on their habitual state (16). Patients without any NEWS measurements during the studied period were also excluded. The included patients with IHCA (cases) were matched with controls without IHCA in a 1:2 ratio by the same admission year, hospital, ward, sex, age ± 5 years, primary admission diagnosis or admission diagnosis chapter according to the International Classification of Diseases 10th revision (ICD-10) (72).

Cases were identified in the hospitals' documentation systems and cardiac arrest records. The following data were collected: hospital, ward, date of admission, date of IHCA, age, sex, primary diagnosis according to the ICD-10, comorbidity, vital signs, NEWS-parameters and hospital mortality. After inclusion, the hospitals' electronic medical records were searched for matching controls. When the data of both cases and controls were collected the electronic database was searched both automated and manually for illogical values by one of the authors.

For calculation of the NEWS at least 4 of the 7 parameters needed to be registered at the same time and the missing parameters had to be documented in another NEWS measurement during the 24 hours, otherwise the NEWS was categorised as missing. The last measurement was carried forward manually to replace the missing value.

Study IV

This was a web-based questionnaire study performed in the southern part of Sweden. The healthcare region consists of 8 hospitals, comprising one university hospital and 7 community hospitals serving a population of 1.3 million citizens. The NEWS was introduced throughout the healthcare region in 2015 in the form of a coordinated implementation package with a mandatory web-based learning programme, regional guidelines and a documentation template in the digital medical record system.

The web-based questionnaire was distributed to all the 3165 RN working at general somatic hospital wards, ED and the CHDU in 2017. RN working primarily in the operating theatre, ICU or with outpatient care were excluded as they did not use the NEWS routinely. The ED in the region used the Rapid Emergency Triage and Treatment System (RETTTS) as a primary triage system (73). According to the regional guidelines the NEWS is to be assessed on all patients in the ED before they are admitted to a hospital ward.

The questionnaire was based on the original validated self-report questionnaire by Green and Allison (2006) (74). This questionnaire was further developed for use in a more recent study by Fox and Elliot (2015) with the inclusion of demographic questions, Likert-scale questions about participants' experiences of using the NEWS and open comment sections (74, 75). The survey items were translated into Swedish and then back translated into English by a British-Swedish translator to assure a correct translation and then tested on 99 RN, in a master thesis by Holm and Nordström in 2016 (76). The Swedish questionnaire was supplemented with six items for the present study. The Likert scale questions in the survey

contained six different levels of agreement. The Swedish questionnaire contained a total of 23 items and was tested in a small cohort of RN after which minor linguistic revisions were made. The items in the final questionnaire consisted of one section with demographic questions and were followed by questions concerning experiences of and barriers for using the NEWS (Appendix 1). The healthcare region's survey programme, a secure online system, was used to administer the questionnaires. A maximum of seven reminders were e-mailed to non-responders.

Statistics

Categorical and nonparametric data are presented with median scores (25–75 percentiles). The Kolmogorov–Smirnov test and histograms were used for testing normality, the chi-square test was used for categorical variable hypothesis testing, and the Mann–Whitney U test was used for hypothesis testing of nonparametric data. Weighted kappa (quadratic weights) was used to test the inter-rater reliability. Logistic regression analysis was used to test for associations. The outcome of the regression analysis is presented as *Odds ratio, OR*, with (95 % *Confidence interval, CI*). Discrimination was assessed by Area Under the Curve (AUC). Statistical significance was set at $p < 0.05$. All analyses were performed with the IBM Statistical Package for Social Services, SPSS, versions 22-25.

In study I, the two parameters, level of consciousness and supplemental oxygen, were transformed into dichotomous variables. For prediction of ICU admission multiple logistic regression analysis was used, including only those NEWS parameters that achieved $p < 0.2$ in the hypothesis testing. Goodness of fit was tested with the Hosmer and Lemeshow test and collinearity was tested with Spearman's *rho*. An additional regression analysis including patients with missing values (by use of mean values) was performed showing similar results.

In study II, data from the two study periods were compiled. Binary logistic regression analysis was used with high, medium and low risk as categorical independent variables for the prediction of mortality. Age was tested both as a metric variable and sorted visually into four categories (18–57, 58–70, 70–79 and 80–101 years) to mitigate the effect of outliers in the model fitting and ensure a balanced number of observations in each group. The metric variable age was the strongest significant covariate of the two. Gender was also tested as an independent variable but was not found to be significant.

In study III, the Mann-Whitney U-test and Chi-square test were used to test for differences between cases and excluded. We chose to divide the data into four different 6-hour timespans (24-18 h, 18-12 h, 12-6 h & 6-0 h) preceding the IHCA with inspiration from a report of the National Confidential Enquiry into Patient Outcome and Death (37). In case of multiple NEWS measurements within each timespan, the highest NEWS value was chosen. For control patients, the highest NEWS value during the 24 studied hours was chosen as their study period was chosen arbitrarily i.e. without a fixed time of event. The Friedman test was used to test for differences between cases and controls. The Wilcoxon signed rank test was used to test for differences between cases in different timespans. Conditional logistic regression analysis was used with high-, medium- and low-risk as independent variables for prediction of IHCA. The Charlson Comorbidity Index (CCI), Age adjusted CCI (ACCI), categorized ACCI, sex, medical affiliation and the metric variable age were tested as covariates.

In study IV, categorical and nonparametric data are presented with median scores (IQR=Interquartile range). The metric variable nursing experience was divided into 0-2, 3-5, 6-10 and >10 years as previously performed in the study by Green and Allison (2006) (74). The questionnaire was analysed based on the respondents' nursing experience and the medical affiliation of their workplace and the Likert scale questions in the questionnaire were collapsed into dichotomous variables, where strongly agree, agree and fairly agree were considered a positive response and unsure, disagree and strongly disagree were considered a negative response.

Ethical considerations

In study I-III there were several ethical aspects to consider. The methodology did not contain any parts that could affect the patient's present or future care. However, as a large number of medical records were accessed sensitive personal information on the patients were exposed threatening their integrity. Special attention was devoted to reducing the risk of breaching the integrity of the patients. For example, the number of researchers handling the data was kept to a minimum, research data was anonymized after the data collection and stored at the regional government healthcare provider with rigorous security and restricted logged access.

Another important ethical consideration was made on the informed consent in study I-III. Since the studies could not affect the patients' present or future care and were purely non-interventional, we had to decide if informed

consent was beneficial or maleficent. Patients suffering an IHCA or unplanned ICU-admission are fragile. A large proportion of them die and survivors are often deeply traumatized and affected both physically and mentally. Obtaining informed consent was therefore considered to be problematic not only to the patients but also to their relatives. It might cause stress and anxiety when reminded of their traumatic experiences. In some cases, informed consent would not be obtained due to the fact that a lot of patients are dead, have moved to another country, are missing an address or were homeless. The nature of the data that we chose to extract for our research purposes was not considered as highly sensitive information and we decided that informed consent would be more maleficent than beneficial. This ethical consideration was taken into account by the Ethical Review board in Lund, Sweden.

Ethical approval for study I was provided by the Ethical Review board at Lund University (VEN 103-14). Informed consent was considered to do more harm than good and was waived.

Ethical approval for study II, which was a secondary analysis of previously collected data, was provided for the original study by the regional Human Research Ethical Review Board in Denmark (Dnr. H-C-2008-120), the Danish National Board of Health (Dnr. 7-604-04-2/65) and the Danish Data Protection Agency (Dnr. 2009-41-3227). According to Danish law, no ethical approval is required for noninterventional studies not including biological material as is the case in this secondary analysis of data. Furthermore, the present study was approved by the Danish Patient Safety Authority (Dnr. 7-604-04-2/65), and therefore, patient consent was not required.

Ethical approval for study III was provided by the regional Research Ethical Review Board (EPN) of Lund, Sweden (Dnr. 2016/940). Informed consent was considered to do more harm than good and was therefore waived. Further, study III was registered on Clinical Trials (NCT03143062).

Ethical approval for study IV was waived as this was a questionnaire study on healthcare staff. The study was approved by the regional Chief Medical Officer and the regional NEWS project manager. Informed consent was obtained by the participants.

Results

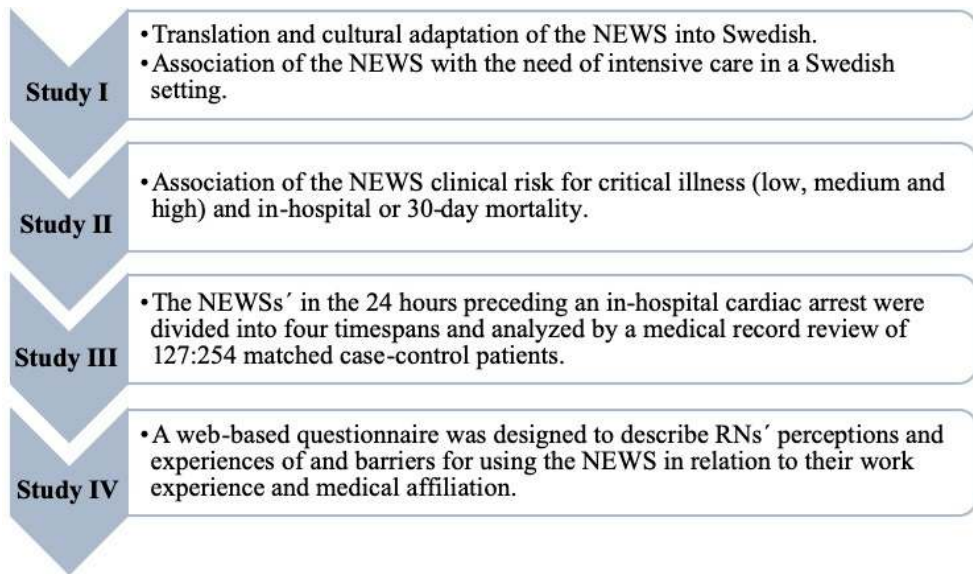


Figure 8. Flowchart of the studies.

Study I

After the translation process was performed, only minor adjustments were made in the Swedish NEWS version and a final version was accepted. A total of 868 MET-charts were reviewed. Of these, 333 were excluded (49 with COPD and 284 with one or more parameter values missing). Accordingly, 535 MET-charts were included in this study (Fig. 10).

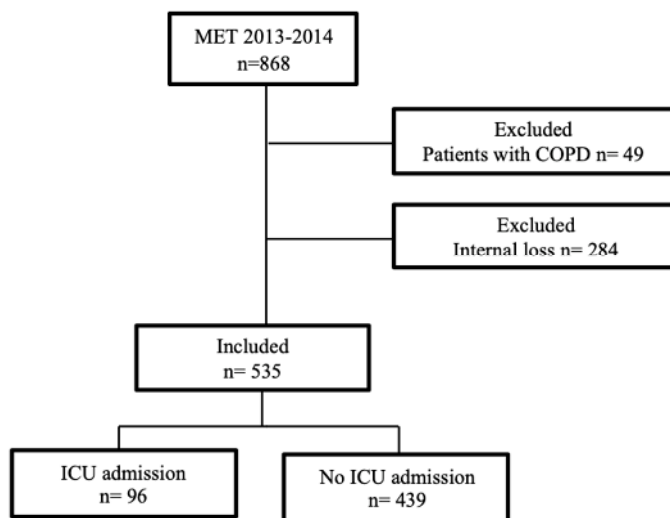


Figure 10. Flow diagram of included patients.

The only difference in baseline characteristics between the included and excluded MET-charts was the median age, 67 (54-76) vs. 70 (60-78), $p=0.009$ (Table 2).

Table 2.
Reviewed MET-charts 2013-2014 of Swedish in-hospital patients (n=868)

	Included (n=535)	Excluded (n=333)	P-value
Age (median)	67 (54-76)	70 (60-78)	0.009
Male	304 (57 %)	191 (57 %)	0.382
Clinical affiliation:			0.817
Medicine	307 (57 %)	189 (57 %)	
Surgery	160 (30 %)	91 (27 %)	
Emergency	65 (12 %)	47 (14 %)	
Total NEWS (median)	8 (6-11)	9 (7-12)	0.167
ICU admission	96 (18 %)	55 (17 %)	0.859

The inter-rater reliability test showed a perfect agreement between the three raters without a single faulty score, ($\kappa=1.0$).

The median NEWS-values for those admitted to the ICU vs. those not admitted was 10 (8-12) and 8 (6-10) $p<0.001$. Amongst those admitted to the ICU, the largest group that scored the highest NEWS-parameter value (3 p) was due to deviating respiratory rate (49 %) and the smallest group was found in body temperature (4 %) (Table 3).

Table 3.

The percentage with the highest score and the median in the NEWS-parameters upon admission to the ICU (n=96)		
	% with the highest score in the NEWS parameter	Median score in the NEWS-parameters (25-75 percentiles)
Supplemental oxygen	83	2 (2-2)
Respiratory rate	49	2 (0-3)
Oxygen saturation	43	2 (0-3)
Level of consciousness	32	0 (0-3)
Systolic blood pressure	16	0 (0-2)
Heart rate	15	1 (1-2)
Body temperature	4	0 (0-1)

AUC for the NEWS in discriminating those admitted to the ICU was 0.68 (95 % CI: 0.622-0.739, $p < 0.001$). The NEWS parameters respiratory rate, heart rate, oxygen saturation, level of consciousness and supplemental oxygen were included in the multiple logistic regression analysis showing that lower oxygen saturation and lower levels of consciousness were significantly associated with ICU admission. An increase in risk of ICU admission by 27 % was shown for each point of step-up in the NEWS parameter oxygen saturation (95 % CI: 1.06-1.52, $p = 0.01$) and by 77 % for level of consciousness (95 % CI: 1.12-2.82, $p = 0.02$) (Table 4).

Table 4.

Multivariable analyses (logistic regression) of the NEWS-parameters association with ICU admission (n=96)			
	OR	(95 % CI)	P value
Respiratory rate (NEWS)	1.22	(0.99-1.49)	0.06
Oxygen saturation (NEWS)	1.27	(1.06-1.52)	0.01
Supplemental oxygen (dichotomous)	1.33	(0.66-2.68)	0.43
Heart rate (NEWS)	1.13	(0.89-1.42)	0.31
Level of consciousness (dichotomous)	1.77	(1.12-2.82)	0.02

Study II

The median age was 66 (50–78) years, and 537 (49 %) were males (n: 1,107). The admissions comprised of 25 % (n: 276) medical and 71 % (n: 790) surgical patients. The median NEWS was 4 (2–5). According to the NEWS, 62 % (n: 685) of the patients were classified as low risk, 27 % (n: 295) as medium risk and 11 % (n: 127) as high risk. Of those at medium risk, 29 had a total NEWS < 5 but with a score of 3 in one parameter and were thus uplifted to the medium-risk group. The mortality rate was 8 % (n: 93) before hospital discharge and 14 % (n: 158) within 30 days of discharge. The excluded patients had significantly shorter length of stay in comparison (Table 5).

Table 5.

Characteristics of the included and excluded patients			
	Included (n=1107)	Excluded (n=118)	p-value
Age	66 (50-78)	68 (53-75)	0.16
Male	537 (49 %)	58 (49 %)	0.53
Clinical affiliation:			0.35
Medicine	276 (25 %)	32 (27 %)	
Surgery	790 (71 %)	75 (64 %)	
Missing	41 (4 %)	11 (9 %)	
Hospital length of stay, median days	7 (4-12)	4 (2-8)	<0.001
Total NEWS, median	4 (2-5)		
NEWS risk classification:			
Low	685 (62 %)		
Medium	295 (27 %)		
High	127 (11 %)		
In-hospital mortality	93 (8 %)	6 (5 %)	0.48
30-day mortality	158 (14 %)	9 (8 %)	0.15

The NEWS risk classification was significantly higher amongst those who died before hospital discharge and within 30 days of discharge compared to those who did not. In-hospital death occurred in 5 % (n: 33) of the admissions that were classified as low risk, in 12 % (n: 35) of the medium-risk group and in 20 % (n: 25) of the high-risk group ($p<0.001$). Occurrence of 30-day mortality for those classified as low, medium and high risk was 9 % (n: 61), 20 % (n: 58) and 31 % (n: 39), respectively ($p<0.001$).

The unadjusted regression model showed that medium risk and high risk were significantly associated with a 2.66 (95 % CI: 1.62–4.37, $p<0.001$) respectively 4.84 (95 % CI: 2.77–8.48, $p<0.001$) increase in odds of in-hospital mortality compared to low risk.

Area under the curve for the NEWS risk classification in discriminating in-hospital mortality was 0.66 (95 % CI: 0.60–0.72, $p<0.001$).

The age-adjusted regression model for in-hospital mortality showed that medium risk and high risk were significantly associated with a 2.11 (95 % CI: 1.27–3.51, $p=0.004$) respectively 3.40 (95 % CI: 1.90–6.01, $p<0.001$) increase in odds of death compared to low risk (Table 6).

Table 6.

Binary age-adjusted logistic regression analysis for mortality on the NEWS risk categorisation		
NEWS risk category compared to low-risk	In-hospital mortality OR (95 % CI)	30-day mortality OR (95 % CI)
Medium	2,11 (1,27-3,51)	1,98 (1,32-2,97)
High	3,40 (1,90-6,01)	3,19 (1,97-5,18)

The discriminative ability of the age-adjusted regression model was assessed by the AUC to 0.75 (95 % CI: 0.70–0.79, $p < 0.001$).

The unadjusted regression model showed that medium risk and high risk were significantly associated with a 2.50 (95 % CI: 1.70–3.70, $p < 0.001$) respectively 4.53 (95 % CI: 2.86–7.18, $p < 0.001$) increase in odds of 30-day mortality compared to low risk. Area under the curve for the NEWS risk classification in discriminating 30-day mortality was 0.65 (95 % CI: 0.60–0.70, $p < 0.001$). The age-adjusted regression model for 30-day mortality showed that medium risk and high risk were significantly associated with a 1.98 (95 % CI: 1.32–2.97, $p = 0.001$) respectively 3.19 (95 % CI: 1.97–5.18, $p < 0.001$) increase in odds of death compared to low risk (Table 6).

The discriminative ability of the age-adjusted regression model was assessed by the AUC to 0.76 (95 % CI: 0.72–0.79, $p < 0.001$).

Study III

A total of 127 patients suffering an IHCA (cases) was included (*Figure 11*). Median age of the cases was 73 (62-80) years, 76 (60 %) were male and 80 (63 %) were medical patients (*Table 7*).

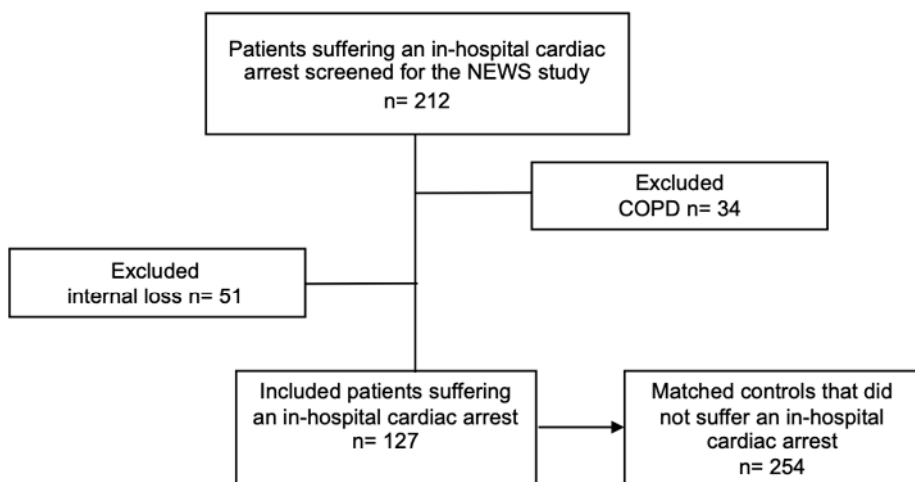


Figure 11. Flow diagram of included patients and their matched controls.

When including the 254 control patients there was a total of 970 NEWS measurements and missing data occurred in 203 (21 %) of these. The most common missing NEWS parameter was temperature with 178 (18 %), followed by supplemental oxygen 10 (1 %). Twenty-six of the 970 NEWS measurements were upgraded to medium-risk due to a score of 3 in a single parameter. Of the NEWS measurements, 226 was excluded due to multiple NEWS measurements within its timespan, leaving 744 for further analysis.

Table 7.

Variable	Included with IHCA (cases) (n=127)	Included without IHCA (controls) (n=254)	Excluded with IHCA (n=85)	p-value Included IHCA vs excluded IHCA
Age	73 (62–80)	73 (64–80)	74 (66–82)	0.27
Male	76 (60 %)	152 (60 %)	52 (61 %)	0.85
Clinical affiliation:				0.54
Medicine	80 (63 %)	160 (63 %)	50 (59 %)	
Surgery	47 (37 %)	94 (37 %)	35 (41 %)	
Main reasons for admission according to the ICD10 codes retrieved at admission (%).				
				0.06
Neoplastic disease	11 (9 %)	22 (9 %)	7 (8 %)	
Circulatory system	15 (12 %)	30 (12 %)	11 (13 %)	
Respiratory system	11 (9 %)	22 (9 %)	19 (22 %)	
Injury/trauma	11 (9 %)	22 (9 %)	6 (7 %)	
Gastrointestinal system	10 (8 %)	20 (8 %)	5 (6 %)	
Musculoskeletal system	7 (6 %)	14 (6 %)	0	
Infectious diseases	10 (8 %)	20 (8 %)	4 (5 %)	
Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified	37 (29 %)	74 (29 %)	19 (22 %)	
Hospital length of stay when IHCA occurred, median days	3 (2–8)	n/a	5 (2–9)	0.77
In-hospital mortality	97 (76 %)	6 (2 %)	65 (77 %)	0.87
Age adjusted Charlson comorbidity index	3 (5–7)	3 (4–6)	4 (5–6)	0.74
Categorized burden of age adjusted Charlson comorbidity index				
Minimal 0-2 p	21 (16 %)	55 (22 %)	n/a	n/a
Low 3-5 p	58 (46 %)	108 (42 %)		
Moderate 6-7 p	28 (22 %)	60 (24 %)		
Severe ≥8 p	20 (16 %)	31 (12 %)		

Distribution of the NEWS risk classifications in the timespans 24-18, 18-12, 12-6 & 6-0 hours before IHCA are displayed in table 8.

When testing the distribution of the NEWS risk categories among cases in different timespans, a difference was found between 0-6 hours and 6-12 hours before IHCA ($p=0.04$) (Table 8).

Table 8.

The NEWS risk classification in the different timespans.			
Timespans	Patients with IHCA (cases)	Patients without IHCA (controls)	p-value cases vs controls
NEWS risk classification 24-18 h before IHCA:	(n=56)	(n=112)	
-Low	34 (61 %)	101 (90 %)	<i><0.001</i>
-Medium	9 (16 %)	8 (7 %)	
-High	13 (23 %)	3 (3 %)	
NEWS risk classification 18-12 h before IHCA:	(n=63)	(n=126)	
-Low	33 (52 %)	107 (85 %)	<i><0.001</i>
-Medium	19 (30 %)	15 (12 %)	
-High	11 (18 %)	4 (3 %)	
p-value between timespan 24-18 vs 18-12 h	<i>0.819</i>	<i>n/a</i>	
NEWS risk classification 12-6 h before IHCA:	(n=67)	(n=134)	
-Low	36 (54 %)	109 (81 %)	<i><0.001</i>
-Medium	15 (22 %)	21 (16 %)	
-High	16 (24 %)	4 (3 %)	
p-value between timespan 18-12 vs 12-6 h	<i>0.658</i>	<i>n/a</i>	
NEWS risk classification 6-0 h before IHCA:	(n=62)	(n=124)	
-Low	24 (39 %)	100 (81 %)	<i><0.001</i>
-Medium	10 (16 %)	16 (13 %)	
-High	28 (45 %)	8 (6 %)	
p-value between timespan 12-6 vs 6-0 h	<i>0.048</i>	<i>n/a</i>	

The NEWS risk classifications medium or high-risk association with IHCA was tested by a conditional regression analysis. The results are displayed in table 9. The CCI, ACCI, categorized ACCI, sex, medical affiliation and the metric variable age were tested as covariates in the different timespans but not found to be significant.

Table 9.

Conditional logistic regression analysis for IHCA on the NEWS risk classification.				
All values are presented as crude odds ratio (OR).				
NEWS risk classification compared to low-risk	24-18 h before IHCA OR (95 % CI)	18-12 h before IHCA OR (95 % CI)	12-6 h before IHCA OR (95 % CI)	6-0 h before IHCA OR (95 % CI)
Medium	2,47 (1,18-5,17) <i>p=0.016</i>	2,33 (1,32-4,11) <i>p=0.003</i>	1,59 (0,87-2,92) <i>p=0.131</i>	1,63 (0,78-3,42) <i>p=0.195</i>
High	3,17 (1,66-6,04) <i>p<0.001</i>	3,57 (1,79-7,10) <i>p<0.001</i>	3,69 (2,04-6,67) <i>p<0.001</i>	4,43 (2,56-7,67) <i>p<0.001</i>
AUC (95 % CI)	0,58 (0,49-0,67) <i>p=0.087</i>	0,61 (0,52-0,69) <i>p=0.018</i>	0,59 (0,51-0,67) <i>p=0.041</i>	0,64 (0,56-0,72) <i>p=0.002</i>

Study IV

A total of 1263, of the 3165 distributed questionnaires, were completed (response rate: 40 %). Of these, 45 had stopped working as RN, 20 had not used the NEWS and 154 worked solely with administrative work or in outpatient care, leaving 1044 for further analysis (*Figure 12*).

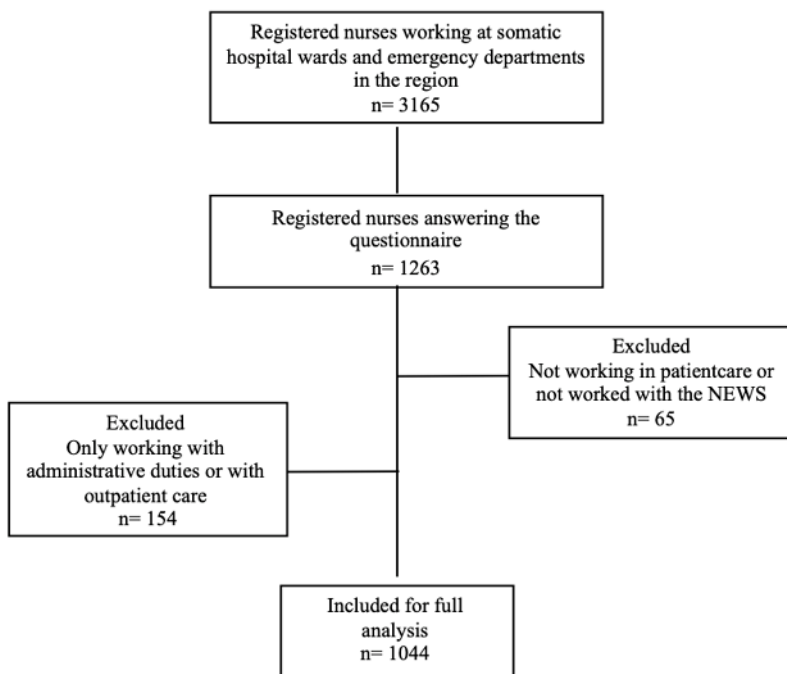


Figure 12. Flow diagram of included registered nurses.

The RN had 7 years (md) of nursing experience (IQR = 13 years) and 55 % worked at the university hospital. Forty-four percent worked on a medical hospital ward, 27 % on a surgical ward, 9 % on an orthopaedic ward, 14 % on an ED and 6 % on a CHDU.

Adherence to the recommended frequency of monitoring of the NEWS guidelines was 71 % and to the clinical response scale 74 % (*Table 10*).

The reasons stated for not adhering to the NEWS guidelines were: lack of response from the doctor (50 %), lack of added value to the situation (35 %), lack of time (29 %) and too much time to document (5 %).

The NEWS was reported to provide 89 % of the RNs with clear instructions about what to do should a patient trigger on the scale and 81 % thought the

NEWS aided them in decisions whether or not to call the doctor to review the patient (*Table 10*). Furthermore, 71 % of the RNs reported better ability to prioritize their care and 77 % that NEWS supported their gut feelings about an unstable patient (*Table 10*).

Table 10.

NEWS survey questions 9, 10, 12-21.						
Number (percentage) of registered nurses. n=1044.						
Question	Strongly agree	Agree	Fairly agree	Unsure	Disagree	Strongly disagree
Q9: Adherence to frequency of monitoring	143 (14)	233 (22)	363 (35)	123 (12)	131 (12)	51 (5)
Q10: Adherence to clinical response	140 (13)	256 (25)	373 (36)	130 (12)	107 (10)	38 (4)
Q12: Clear instructions on what to do	323 (31)	358 (34)	245 (24)	77 (7)	37 (4)	4 (0)
Q13: Make decisions to call the doctor	234 (22)	331 (32)	278 (27)	117 (11)	64 (6)	20 (2)
Q14: NEWS only makes extra work	37 (4)	65 (6)	86 (8)	228 (22)	358 (34)	270 (26)
Q15: Allows me to better prioritise	121 (12)	303 (29)	312 (30)	167 (16)	106 (10)	35 (3)
Q16: Takes away clinical judgment skills	22 (2)	58 (6)	64 (6)	202 (19)	378 (36)	320 (31)
Q17: Get a better response from the doctors	60 (6)	202 (19)	289 (28)	284 (27)	145 (14)	64 (6)
Q18: The doctors review the patient within the time frame	40 (4)	124 (12)	300 (29)	310 (30)	210 (20)	60 (5)
Q19: Increasing number of times to call the doctor	61 (6)	130 (12)	149 (14)	435 (42)	178 (17)	91 (9)
Q20: Supports gut feeling about an unstable patient	112 (11)	318 (31)	363 (35)	172 (16)	54 (5)	25 (2)
Q21: Need of more information or education	10 (1)	40 (4)	65 (6)	212 (20)	311 (30)	406 (39)

There were 259 RN with 0-2 years nursing experience, 210 with 3-5 years, 186 with 6-10 years and 389 with >10 years of nursing experience.

The shorter the period of working experience, the greater the proportion of RN answering positively to NEWS and allowing them to better prioritise their care (60 % with >10 years of nursing experience, 70 % with 6-10 years, 76 % with 3-5 years respectively 83 % with 0-2 years, $p<0.001$).

Similarly, the shorter the period of working experience, the greater the proportion of RN answering positively to getting a better response from the doctor when using the NEWS (45 % with >10 years of nursing experience, 49 % with 6-10 years, 54 % with 3-5 years and 66 % with 0-2 years, $p<0.001$).

The longer the period of working experience, the greater the proportion of RN answering confirmatively for the item “Using the NEWS only makes

extra work for me” (24 % with 0-2 years of nursing experience answered positively, 28 % with 3-5 years, 36 % with 6-10 years and 37 % with more than 10 years of nursing experience, $p=0.002$).

For the item “NEWS supports my gut feeling about an unstable patient”, 84 % of those with 0-2 years of nursing experience answered positively, 74 % with 3-5 years, 75 % with 6-10 years and 72 % with more than 10 years of nursing experience ($p=0.003$). There were no significant differences in the main cause or causes for not following the NEWS guidelines based on years of nursing experience.

When categorising the RNs according to their workplace medical affiliation, reported adherence to the recommended frequency of monitoring in the NEWS guidelines was highest in the surgery and orthopaedic fields, 66 %, and lowest in the CHDU, 52 % ($p=0.04$) (*Table 11*). Corresponding reported proportions for adherence to the clinical response scale was highest in orthopaedics, 82 %, and lowest in the CHDU 48 % ($p<0.001$) (*Table 11*).

Table 11.

NEWS survey questions 7, 9, 10, 12-21 categorised on medical affiliation.						
Number (percentage) of registered nurses answering in positive favour of the question.						
Question	Surgery	Medicine	Orthopaedic	Emergency department	Cardiac HDU	<i>p-value</i>
Q7: Workplace medical affiliation	283	463	96	144	58	<i>n/a</i>
Q9: Adherence to frequency of monitoring	188 (66)	262 (57)	63 (66)	86 (60)	30 (52)	<i>0.04</i>
Q10: Adherence to clinical response	218 (77)	336 (73)	79 (82)	108 (75)	28 (48)	<i><0.001</i>
Q12: Clear instructions on what to do	257 (91)	412 (89)	86 (90)	126 (88)	45 (78)	<i>0.07</i>
Q13: Make decisions to call the doctor	227 (80)	381 (82)	81 (84)	121 (84)	33 (57)	<i><0.001</i>
Q14: NEWS only makes extra work	82 (29)	143 (31)	27 (28)	58 (40)	20 (35)	<i>0.15</i>
Q15: Allows me to better prioritise	205 (72)	329 (71)	72 (75)	103 (72)	27 (47)	<i>0.001</i>
Q16: Takes away clinical judgment skills	54 (19)	61 (13)	9 (9)	10 (7)	10 (17)	<i>0.01</i>
Q17: Get a better response from the doctors	153 (54)	266 (58)	48 (50)	68 (47)	16 (28)	<i><0.001</i>
Q18: The doctors review the patient within the time frame	125 (44)	224 (48)	38 (40)	65 (45)	12 (21)	<i>0.02</i>
Q19: Increasing number of times to call the doctor	94 (33)	167 (36)	37 (39)	31 (22)	11 (19)	<i>0.02</i>
Q20: Supports gut feeling about an unstable patient	208 (74)	361 (78)	76 (79)	111 (77)	37 (64)	<i>0.12</i>
Q21: Need of more information or education	33 (12)	53 (11)	12 (13)	16 (11)	1 (2)	<i>0.24</i>
NEWS survey questions 11 and 22. Number (percentage) of registered nurses within the medical affiliation.						
Q11: Main cause to not follow the NEWS (multiple choice)?						
- Lack of time	71 (25)	107 (23)	30 (31)	82 (57)	10 (17)	<i><0.001</i>
- Lack of response	156 (55)	234 (51)	67 (70)	43 (30)	18 (31)	<i><0.001</i>
- Not think a valuable tool	100 (35)	185 (40)	24 (25)	27 (19)	32 (55)	<i><0.001</i>
- Too much time to document	10 (4)	20 (4)	2 (2)	16 (11)	4 (7)	<i>0.004</i>
Q22: Deviation from the NEWS guidelines.						
Individual deviation	184 (65)	322 (70)	73 (76)	83 (58)	26 (45)	<i><0.001</i>
General deviations	59 (21)	108 (23)	5 (5)	30 (21)	23 (40)	
Deviations is not applied	40 (14)	33 (7)	18 (19)	31 (21)	9 (15)	

Discussions

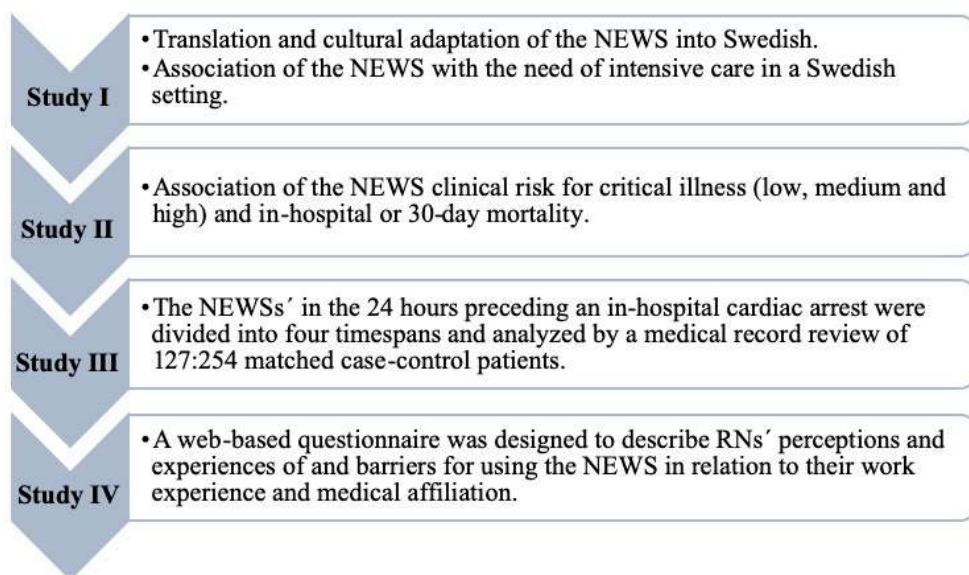


Figure 8. Flowchart of the studies.

Methodological aspects

The NEWS is an instrument which required specific methodological aspects to be considered. Firstly, the instrument type had to be considered in order to decide which methodological aspects should be used.

Two distinctly different measurement types are psychometric and clinimetric instruments.

A psychometric instrument measures reflections of a latent variable (77). If the latent variable is manipulated the reflections should be affected, but if you manipulate the reflections the latent variable is not affected (77). For example, if you are depressed (latent variable) a reflection might be that you are tired all the time. If the depression is cured by therapy you might feel less tired all the time but if you only treat your tiredness you will still be depressed.

A clinimetric instrument sums a range of items that have a direct causal impact on a composite outcome (77). If one item is affected the composite outcome is also affected (77). For example, if you have an instrument like the NEWS to identify critical illness and measure a low blood pressure, you might affect the critical illness by administering intravenous fluids to normalize the blood pressure.

Another difference between these measurement types is that in contrast to a clinimetric scale the internal consistency, i.e. how reliably test items designed to measure the same latent variable actually do so, is important to a psychometric scale (77).

The NEWS is according to the statements above classified as a clinimetric instrument and can therefore not be evaluated by psychometric analysis.

Validity of the NEWS instrument

The NEWS is an instrument developed through a balance of assessment of the available evidence, experienced clinical and professional judgment, patient and user opinion, evaluation, validation, and pragmatism (16). The face validity and content validity were performed by an expert panel of experienced doctors and nurses in the UK. This step was not repeated in our Swedish setting because we estimated that the physiological components affected in deterioration should not differ significantly between British and Swedish patients.

The construct validity of the NEWS could be translated into the relation between SAEs and the NEWS with its physiological parameters. From the results in study I-III we can conclude that the construct validity of the NEWS in a Swedish setting is good i.e. that higher NEWS-values are associated with higher odds of SAEs compared to lower NEWS-values.

There is no national Swedish golden standard amongst the “track and trigger” scales which makes it difficult to assess the criterion validity. However, the predictive capabilities of the NEWS as shown in study I-III indicate that the NEWS has good predictive capabilities and fair discriminative abilities in a Swedish setting.

Reliability of the instrument can be referred to as the ability for different raters to obtain the same results. The Swedish translation of the NEWS was tested with the inter-rater reliability test in study I, showing a perfect agreement between the three raters indicating that it is reliable and ready to use in Swedish clinical settings.

Different aspects of study validity

Internal validity refers to what conclusions the researchers can draw from the study and to what extent those conclusions are correct and not related to anything else i.e. that the design, conduct and analysis have been performed in a way that minimizes the risk of bias.

External validity refers to the generalizability of the results to other settings.

Construct validity refers to the conceptual basis for the effect i.e. is there an explanation to the findings or the measure.

Statistical conclusion validity refers to the relevance and quality of the chosen statistical methods. The statistical power is a part of the statistical conclusion validity and can be described as the likelihood that a study can detect an effect if there is an effect to be detected. If the study is adequately powered the probability of making a Type II error is reduced i.e. concluding that there is no effect when there actually is an effect.

Aspects of study validity, study I

Internal validity: We chose to conduct the study with two different methods to answer our aims. The first phase of this study was to translate and culturally adapt the NEWS. This was performed by a step-by-step approach with a well-known method in order to maintain the validity of the original instrument. We feel confident that this approach has reduced the apparent threats to the internal validity such as a faulty translation or meaning and individual interpretations. The translation process was carried out smoothly without difficulty. This could partly be explained by the fact that the translators were all healthcare staff with intensive care knowledge, which can be considered as either a strength or a potential limitation. The intensive care personnel have to be regarded as specialists in monitoring of vital signs and thus have a greater understanding of the parameters in the NEWS than RNs on the hospital wards. Another plausible explanation could be that the NEWS concept itself was non-complicated and that the amount of text in the NEWS was very limited.

The Swedish translation of the NEWS was tested between raters to ensure that it was reliable. The authors, who carried out the translation also conducted the inter-rater reliability test and this presumably contributed to a better knowledge of the scale. In this study, the inter-rater reliability test resulted in perfect agreement between the raters. In real hospital settings personnel often act under pressure of time. The fact that the raters did not act under any form of time pressure might therefore be regarded as a limitation of the study.

In the last phase we used an observational design and retrospectively calculated the NEWS on patients seen by the MET by reviewing their medical records. This was done manually which on one hand might have increased the internal validity by reducing the number of implausible values. On the other hand, the NEWS was calculated manually which might introduce a threat to the internal validity in case of calculation errors. To reduce this threat the NEWS was calculated by two researchers and the results compared in order to detect miscalculations and errors.

The observational design does not allow for causal interpretations to be made. There might be some unmeasured confounding factor affecting the results.

A threat to the internal validity is missing data, especially if it is systematic i.e. those with a specific condition or trait. The rather small sample and the relatively large number of excluded MET-charts was a weakness of this study. To assess the risk of bias we analyzed the excluded and the included MET-charts for any systematic differences. However, only a somewhat higher age was seen in baseline characteristics amongst those excluded compared to those included, which suggests that the internal loss was presumably random. To assess the impact of the missing data on the predictive capabilities of the NEWS an additional regression analysis including patients with missing values (by use of mean values) was performed and showed similar results. In conclusion, we are aware of this limitation to the study but our interpretation is that the missing data would probably not significantly impact the results.

External validity: This was a single-center study at a large university hospital and some of the patients with high NEWS were moved to a high dependency unit (HDU). However, in a smaller non university hospital these patients would probably have been moved to the ICU, due to lack of HDUs. Thus, generality across smaller hospital settings may be limited.

Construct validity: The construct in this study is that sicker patients have more deviating vital signs and consequently higher NEWS which should correspond to admission to the ICU. Admission to the ICU is a fixed and reliable measure. However, threats to this construct in our study could be that the ICU was fully occupied and therefore the patient remained on the hospital ward. We estimate that this occurred on rare occasions and should not have a significant impact on this study.

Statistical conclusion validity: When testing the reliability of the Swedish translation of the NEWS, the interrater reliability test was chosen. This test measures the level of agreement between raters and was well suited for

testing if the Swedish translation could be used by different raters and still lead to the same results.

The ability of the NEWS to discriminate those admitted to the ICU or not was evaluated by use of the Area Under the Curve (AUC). The AUC tells us how good the NEWS is at distinguishing between patients admitted to the ICU compared to those who were not and gives a single measure, independently of the prevalence, that sums the discriminative ability of the NEWS across the entire range of cutoffs. This method is commonly used in “track and trigger” research when evaluating the discriminative ability of the instruments.

The study was highly powered to analyse the median NEWS-values for those admitted to the ICU vs. those not admitted. The sample size was in line with the 10 events per variable “rule of thumb” mentioned by Perduzzi for testing by a logistic regression analysis (78).

Aspects of study validity, study II

Internal validity: This study was designed as a retrospective analysis of a vital signs database. The observational design did not allow for causal interpretations to be made due to the fact that there might have been some unmeasured confounding factor affecting the results. However, we tried to account for two possible confounders, gender and age, in our analysis to clarify our results.

Missing recordings of vital signs is a well-known problem in healthcare settings (7, 9, 37, 79). Our study was no exception to this, and there were missing variables in the supplemental oxygen and level of consciousness. We used a well-known method of imputing missing values by using the last known value. However, there were some missing values that we could not replace because they did not have any value in that parameter during the studied time period. Therefore, we used the following rationale for replacing those values:

- If a recording of a parameter was missing, the value from the most recent recording of a corresponding parameter was used, which is an acknowledged imputation technique.

In cases where no recent recording of a corresponding parameter existed, the following strategy was used:

- In the parameter level of consciousness, the vast majority of cases had no alteration in the level of consciousness. If a “mean” was to be imputed it would be “no alteration”.
- We had a clinical reasoning within the author team about how we ourselves tend to document vital signs. We tend to document vital signs that deviate to a higher extent than vital signs that do not deviate. Altered level of consciousness is easily detected when you assess the other vital signs and should therefore have been noted in the medical record.
- In our setting supplemental oxygen is most often noted in the same parameter field as oxygen saturation and if the patient does not receive any oxygen the rater unfortunately usually does not write 0 liters/min. We are unable to guarantee that patients without a recording of 0 liters/min did not receive supplemental oxygen. Thus, these values were treated as missing, despite the higher likelihood that these patients were not receiving supplemental oxygen.
- Two additional regression analyses were performed where the supplemental oxygen was set to yes for all missing data and one that was set to no and this did not affect our results significantly. Therefore, we drew the conclusion that our imputation did not generate a significant risk of biasing the results.

External validity: The vast majority of included patients were surgical, which might affect the generalizability of the results to a sample of medical patients. This was a single-center study in a Scandinavian university hospital setting, and we believe that the results are generalizable to other similar hospital settings in Scandinavia. Generalizability to non-university hospital settings should preferably be evaluated in a larger multicenter trial.

Construct validity: The construct in this study consisted of the expected association between mortality and preceding deviating vital signs, resulting in higher NEWSs. Mortality is a robust, well-documented outcome measure. However, threats to this construct within our study could be that the patients who did not die had more deviating vital signs at occasions when their vital signs were not measured, or after their hospital stay. We estimate that this has occurred only on rare occasions and should not have a significant impact on this study.

Statistical conclusion validity: For prediction of mortality a logistic regression analysis was used, which is the appropriate regression analysis to conduct when the outcome variable (dependent variable) is binary (80). It is used to predict or explain a relationship between one dependent binary variable and one or more independent variables which can be of nominal, ordinal, interval or ratio scale. The advantage of the regression analysis over the Chi-square test or the Mann-Whitney U-test is that you get a direction and a magnitude of the difference between the dependent and the independent variable. Logistic regression analysis takes the complex interrelationships among variables into consideration and can demonstrate independent relationships after adjustment for possible confounding. This procedure takes you one step closer to causality even though the observational design per se does not allow for causal relationships to be drawn (80). In study I, we used the Hosmer and Lemeshow test when testing the goodness of fit in the logistic regression analysis. This test groups cases together by their predicted values from the logistic regression and calculates a Chi-square test between the observed and expected numbers of events and non-events. If the test is non-significant it rules out a gross lack of fit. However, this test is tricky to evaluate, has serious limitations and is generally not used in EWS research (15, 16, 45, 47, 50, 51, 67, 80). The drawbacks of the test are that it can be insensitive and lack power when a model is misspecified. Further, the number of groups which can be freely manipulated in the statistical software and the distribution of values within these groups can affect the results (80). The Chi-square test requires a sample size that allows the predicted values in the table to all exceed a minimum number of five. Finally, large sample sizes ($n > 1000$) which are most often used in EWS research can cause significant results in small discrepancies. Instead, we chose to use the AUC as an overall measure of fit of the regression model by use of the predicted probabilities from the logistic regression. The rationale to this, besides its common use in EWS research, was that the AUC would provide the probability that a randomly selected pair of patients, one patient that died and one that survived, will be correctly classified by the test. This means that the patient that died would have a higher predicted probability of the event compared to the patient that did not (80).

Sample size calculation could not be performed because the analyses were made on previously collected data. However, the sample size was well above the 10 events per variable “rule of thumb” mentioned by Peduzzi in 1996 (78).

Aspects of study validity, study III

Internal validity: When designing this study, we had to account for IHCA being a rare event and we also wanted to compare similar patients suffering an IHCA with those who did not. A prospective study was therefore ruled out and a retrospective case-control study was designed. The advantage of this study design was that we could include patients from three entire hospitals admitted during two years with our limited resources. The observational design does not allow for causal interpretations to be made due to the fact that there might be some unmeasured confounding factor affecting the results. However, we tried to account for possible confounders in comorbidity, sex, medical affiliation and age in our analysis to clarify our results.

The data collection was done systematically, and cases were identified in the hospitals' documentation systems and cardiac arrest records. Since all the IHCAs are reported to a national cardiac arrest registry for quality control and each hospital has an IHCA-response team which keeps records of all their IHCA alarms we feel confident that we have a representative IHCA cohort from the hospital wards and thus reduced the risk of selection bias.

A limitation was the exclusion of patients; those with COPD, which were excluded because their oxygen saturation should be judged individually depending on their habitual state and those suffering an IHCA without having a documented NEWS in the preceding 24 hours. No major differences were found comparing patient characteristics between excluded and included patients, but a tendency towards a difference in main reasons for admission as categorized by the ICD-10 was found, which was probably due to us deciding to exclude all patients with COPD.

We found indications of inconsistencies to the NEWS guidelines, both in the time between measurements and in missing values. The time between measurements were generally longer than recommended by the NEWS-guidelines. We could not account for this in any reasonable way which may pose a threat to the internal validity.

When the NEWS was assessed there were missing variables in one fifth of the NEWS. Missing data occurred, mostly concerning temperature and in some cases supplemental oxygen. We tried mitigating the effects of missing variables by imputing the last recorded value in the parameter and we do not suspect this has introduced any significant bias. Further, temperature has previously been shown not to be a predictor of IHCA and there were just one percent missing in supplemental oxygen values, which is deemed non-significant to the results (81). In order to reduce the risk of bias in our imputation we decided to only calculate the NEWS if at least 4 of the 7

parameters in the NEWS were registered at the same time and the missing parameters had to be documented in another NEWS measurement during the 24 hours, otherwise the NEWS was categorised as missing.

In order to increase the data quality, it was meticulously searched both automatically and manually for illogical values by one of the authors

We chose to use the highest NEWS from the different timespans. This might pose as a potential limitation if it was not the closest NEWS to the IHCA. Since the timespan 6-0 hours before IHCA was the most important for detecting deterioration in our study we considered performing a subgroup analysis. However, there were 20 patients with multiple measurements 0-6 hours preceding IHCA. Of these, 18 patients had the highest NEWS closest to the IHCA and since only two patients did not, we did not perform a subgroup analysis.

The selection of the controls in the case-control design is prone to selection bias. In order to evaluate the NEWS in patients suffering an IHCA we chose to match them with control patients that were as equal as possible in respect to all potential confounders. This should hypothetically bring us as close to the isolated manifestations of the IHCA as possible. However, when matching this meticulously there was also a risk of introducing an unmeasured bias. For example, some diagnoses are associated with socioeconomic status, which therefore might pose as a confounder, however if the socioeconomic status is not measured it might pose as an unmeasured bias. We were aware of this risk of bias but the advantages far outweighed the disadvantages and we did not claim causality.

External validity: A strength in our study was the multicentre approach where both a large university hospital and smaller community hospitals were included, as this increased the generalizability of our results. We therefore suggest that the results of this study can be generalized to somatic hospital wards in European settings with the exception of patients suffering from COPD since they were excluded from the analysis.

Construct validity: The construct in this study was that patients suffering an IHCA showed more deviating vital signs and consequently had higher NEWS than those who did not suffer an IHCA. IHCA is a robust, well-documented outcome measure. However, threats to this construct within our study could be that the patients who did not suffer an IHCA have more deviating vital signs at an occasion when their vital signs are not measured. We estimate that this has occurred only rarely and should not have a significant impact on this study.

Statistical conclusion validity: From a statistical perspective this was the most challenging and advanced analysis in this thesis. The assumption of independent measurements were violated and therefore we could not use tests based on this assumption. To further complicate matters we had chosen two controls for each case because this would increase our power in the study and there was an appealing clinical reasoning that this could mitigate the effects of choosing an unrepresentative control patient. This was a bit tricky and required a different set of statistical tests than we had used before. In previous studies we had used the logistic regression analysis to predict or explain a relationship between one dependent binary variable and one or more independent variables. This approach could not be used in this study because we needed to account for the matching of cases to their corresponding controls. Since none of us had used this analytical approach before we chose to consult a statistician familiar with this kind of research. The best statistical analysis for this method was deemed to be a conditional logistic regression analysis. Simplified, you could say that this method, based on logistic regression, creates a stratum for each case and its corresponding two controls. These strata are then analyzed individually and summed up to a total effect measure. This analysis can be impacted by confounders and we therefore chose to investigate a range of potential confounders. We again chose to use the AUC as an overall measure of fit of the regression model by use of the predicted probabilities from the conditional logistic regression. The rationale for this was that the AUC would provide the probability that a randomly selected pair of patients, one patient that died and one that survived, will be correctly classified by the test. This means that the patient that died would have a higher predicted probability of the event compared to the patient that did not.

There were some difficulties with calculating power in this study because of the complicated statistical considerations. We assessed that the study was highly powered to perform the dependent samples analysis of the NEWS risk classification in the different timespans. The power in the conditional logistic regression was more difficult to assess. We performed an a priori sample size calculation by using Ken Rothmans EpiSheet which showed that 100 cases and 200 controls would generate a power of >80 % to detect an odds ratio of 2.0, which was considered clinically relevant, with an α -level of 0.05 (82). We estimated that including all IHCA's for two years would be sufficient to attain this power. Unfortunately, we did not reach this power due to insufficient number of NEWS measurements in the different timespans even though we included 127 cases, which was well beyond the a priori requirements. The implications of this are that the conditional logistic regression analysis considering the medium risk group should be interpreted with caution, especially in the timespans 12-6 and 6-0 hours before IHCA.

Aspects of study validity, study IV

Internal validity: In order to investigate perceptions, experiences and barriers to using the NEWS in our healthcare region we chose to design a survey study. The advantage of this study design was that you can reach a large sample size and at the same time reduce the personal influence of the researchers as in an interview study. In terms of data collection method we modified and used a previously used questionnaire. We do not regard this questionnaire as a psychometric instrument since it does not measure a phenomena. Furthermore, manipulation of the reflections of the latent variable would in fact affect the latent variable which contradicts psychometric properties (77).

A major source of bias in any survey is the non-response bias, and in our study the response rate was low, 40 % (83). Web-based surveys have been shown to be more prone to this problem than postal surveys or personal interviews. In turn, postal surveys have been shown to be more prone to invalid responses and personal interviews to sampling bias and interviewer bias. We followed the proposed “twelve principles of conducting a survey” by Jones et al (2006) to attain a maximal response rate (83) (Table 12).

Table 12.

Twelve principles of conducting a survey	Followed
Clearly define the purpose and objectives of the survey	Yes
Give the survey an appropriate, accurate title	Yes
Make the survey as brief and simple as possible	Yes
Keep each question short, simple, unambiguous and unidimensional. The questions should be designed to specifically answer the study objectives	Yes
Avoid questions and data collection techniques that influence the answers	Yes
Decide how the data will be compiled and analysed before conducting the survey	Yes
Identify and target a representative and appropriately sized sample of the overall target population. Quantify the response rate to the survey and assess the characteristics of respondents and non-respondents	Yes
Pilot (pretest) the questionnaire, ideally with a representative sample of the focus population that is not going to be included in the sample to be used for the final survey	Yes
Revise the questionnaire following the results of the pilot. Re-pilot the revised questionnaire	Yes
Distribute questionnaire to the broader sample from the target population	Yes
Allow space for voluntary additional comments	Yes
Always thank the respondents	Yes

We sent a maximum of seven reminders to non-responders which might seem like a high number, however we can justify this approach by seeing a clear rise in the response rate every time we sent out a reminder.

In order to estimate the bias in our results we performed a non-response analysis, which did not reveal any significant differences between responders

and non-responders indicating that the potential risk of bias might be low. However, this non-response analysis should be interpreted with caution due to the small sample.

External validity: A strength in our study was the multicentre approach where both a large university hospital and smaller community hospitals were included which increased the generalizability. This suggests that the results of this study can be generalized to somatic hospital wards in European settings.

Construct validity: The construct in this study was that perceptions and experiences of using the NEWS affected adherence to the concept. Threats to this construct in our study could be that the adherence to the NEWS was affected by additional variables that we did not investigate in our survey.

Statistical conclusion validity: In this study we used descriptive data and uncomplicated statistical tests. The statistical conclusion validity is judged to be high. The power in the analyses was considered to be high.

Discussions of the results

Discussion of the results in study I

The Swedish translation of the NEWS was tested showing a perfect agreement between raters, indicating that it is reliable and ready to use in Swedish clinical settings.

The median NEWS for those patients who were admitted to the ICU was 10 (8-12) and the predictive accuracy (AUC) of the NEWS in discriminating these patients was 0.68 indicating the ability of the NEWS to detect clinical deterioration in Swedish settings.

The outline clinical response scale that comes with the NEWS concept, recommends contact with the MET at NEWS ≥ 7 (16). The result of the present study supports this threshold value as an activation criterion for the MET in Swedish settings. A recent study by Tirkkonen et al. (2014) also supports a cutoff point at NEWS of ≥ 7 as a good discriminator of SAEs and MET activation (68). Thus, this seems like a reasonable cut off point because the MET should be involved before severe patient deterioration and the potential need of intensive care arises. An early contact with the MET might help to prevent the deterioration. The MET can also assist in decisions of level of care limitations in order to prevent unnecessary suffering in the ICU.

A confounder in the MET-charts was the miscalculation of the EWS, which was seen in 12 % of cases. Correct summation of the NEWS is of key importance since the score is linked to different clinical responses at different thresholds. The use of a personal digital assistant has been shown to reduce miscalculation significantly compared to traditional documentation with pen and paper (79).

The findings of this study suggest that the parameters level of consciousness or oxygen saturation can be used to predict admittance to the ICU. An altered level of consciousness increases the risk of admittance to the ICU by 77 %. Each point of increase in the parameter oxygen saturation increases the risk of admission to the ICU by 27 %. This knowledge can be useful to clinicians in the assessment of the critically ill patient on hospital wards. Aggressive measures could be taken at an early stage if any of these two parameters are affected and might prevent the deterioration leading to the need for intensive care. With this knowledge clinicians could also at an early stage begin to discuss and plan for the level of care that should be given if the patient deteriorates.

In this study a tendency towards, but no significant association ($p=0.06$), was found regarding the NEWS parameter respiratory rate and admittance to the ICU. The relationship between respiratory rate and ICU admission has previously been established regarding the MEWS (14). In order to test if a greater statistical power could affect the result, we chose to include another 30 patients admitted to the ICU that had previously been excluded, showing no major difference in results. In fact, it made the tendency much weaker because the p -value went from 0.06 to 0.11. The MEWS scores 3 points at a respiration rate of ≥ 30 /minute and the NEWS scores 3 points at a respiration rate of ≥ 25 /minute (16, 47). This could indicate that the threshold for receiving 3 points in the NEWS on the parameter respiration at a rate of ≥ 25 /minute is more unspecific in predicting the need of intensive care than having a threshold of ≥ 30 /minute, which might explain the non-significant association. This relationship needs to be further investigated in a larger multicenter study before any conclusions can be drawn.

Discussion of the results in study II

This study demonstrates that the NEWS risk classification has good predictive capabilities on in-hospital and 30-day mortality in a mixed population of patients with deviating vital signs, admitted to a hospital ward. Patients classified by NEWS as medium or high risk experienced a more than twofold and threefold increase in odds of in-hospital mortality, respectively, compared to low risk. Spagnolli et al. (2017) have recently shown that medically affiliated patients had a more than threefold increase in odds of in-

hospital mortality, if classified as NEWS medium risk upon hospital ward admission, and a nine-fold increase, if classified as NEWS high risk (84). The results of the present study and those of Spagnolli et al. indicate that the NEWS risk classification can be used to predict in-hospital mortality in a mixed patient population. The difference in odds ratio between our study and that of Spagnolli et al. might be due to the fact that our patient population consisted solely of patients with deviating vital signs. Further, Spagnolli et al. had fewer medium-risk patients (11 %) than high-risk patients (17 %) compared to medium-risk (27 %) and high-risk (11 %) patients in our study, which may generate a larger discrepancy in the NEWS between those who die and those who do not comparing the two studies.

Our study quantifies the increasing odds of mortality amongst patients with deviating vital signs. Quantifying the odds of mortality could help in motivating healthcare staff to use the NEWS by “putting a number” on the potential risk of death for these patients, thus making it more visual and less abstract. The high increase in odds of both in-hospital and 30-day mortality seen in the NEWS high-risk group might also aid healthcare staff in understanding the importance of systematic assessment of the patients’ vital signs. Another and equally important task for the healthcare staff is to act appropriately when patients’ vital signs deviate. For this purpose, the NEWS includes an outline clinical response scale that serves as a clinical decision support for the healthcare staff. This might be one of the most promising parts of the NEWS in actually reducing mortality as previous studies have shown that nurses need a clear structure and decision support when assessing vital signs and deteriorating patients (23, 85). The decision to call a physician or the RRT can sometimes be hard to take, especially when the deviations in vital signs are subtle (86). The NEWS can guide and aid the nurses in the decision to call a physician or the RRT.

In line with the results by Silcock et al., (2015), we confirmed that the NEWS risk classification could be used as a predictor of 30-day mortality, for high-risk patients, a threefold increase in odds of death (87). Unlike Silcock et al., we also showed that patients classified by NEWS as medium risk experienced a twofold increase within 30 days. Both these studies thus further indicate the usefulness of the NEWS risk categorization for predicting 30-day mortality.

A strength in our study is the predictive ability of the NEWS for both in-hospital and 30-day mortality in hospital ward patients independently of referral status. Furthermore, the NEWS seems to have a fair discriminative ability as confirmed by the AUC when adjusting for age. This might add to the knowledge about the ability to predict outcome in all patients, not only for those in a prehospital setting.

Discussion of the results in study III

The results in our study suggest a process of clinical deterioration in patients suffering an IHCA, with the timespan 6-0 hours being the most favourable for NEWS to identify patients at risk. In all timespans 18-24 % of cases were classified as high-risk whereas in the timespans 6-0 hours the percentage almost doubled. The corresponding proportion amongst controls was 3-6 % during all timespans. Further, there was a more than threefold increase in odds of IHCA in the high-risk group compared to low-risk during all timespans, indicating that a large proportion of patients suffering an IHCA can be detected up to 24 hours prior to the incident.

Medium-risk seems to be the most challenging group to differentiate against since the difference in proportion of patients suffering an IHCA compared to others was not particularly large, and it might be difficult for a ward-based physician not skilled in the assessment of acutely ill patients to assess these patients. In the revised NEWS2 outline clinical response scale, a clinician or team with competence in the assessment and treatment of acutely ill patients is recommended at this level (88). It seems that this might be a crucial step to find patients truly at risk of IHCA in this risk category.

The overall discriminative ability of the NEWS as tested by the AUC was poor. The greatest discriminative ability was seen in the timespan 6-0 hours before IHCA but it was still considered low (0.64), indicating that many patients might be missed. Our study showed that a large proportion of patients suffering an IHCA show minor deviating vital signs in the preceding 24-6 hours, thus making it more difficult for the NEWS to discriminate in these timespans. Previous studies showed greater AUC values for unexpected death and ICU-admission than for IHCA and support these findings (15, 69, 89).

Approximately 39 % of patients suffering an IHCA were classified as low-risk in the timespan 6-0 hours. However, none of the patients suffering an IHCA had a NEWS of 0 points, which might warrant a new risk category “Low-Low” or “Minimal” for those with a NEWS of 0 points. This might be helpful in turning more attention to patients with a NEWS of 1-4 points that actually might develop an IHCA.

Our results raise the question whether intermittent evaluation of patient vital signs is appropriate for all patients in the prevention of IHCA or if patients with deviating vital signs could benefit from a continuous vital signs monitoring since there were patients in all risk categories suffering an IHCA.

Discussion of the results in study IV

Our study showed that more than 70 % of the RNs reported adherence to the recommended frequency of monitoring and clinical response in the NEWS guidelines. Moreover, NEWS was reported to give them clear instructions about what to do should a patient trigger and allowed them to better prioritize their care. Furthermore, almost 80 % of the RNs in this study answered positively to the NEWS supporting their gut feelings about an unstable patient. This is an important finding that adds credibility to the NEWS for detecting deteriorating patients.

The RNs reported a generally positive attitude towards the NEWS, which is in line with the findings of Petersen et al. (2017) (90). In a comparison between our results and those in the study by Fox and Elliot (2015), many similarities can be seen, such as a majority of RNs answering positively about the NEWS providing them with clear instructions about what to do should a patient trigger and helping them to decide whether or not to call a doctor (75). There was a larger proportion of RNs in our study responding positively about the NEWS helping them to better prioritize their care, receiving better responses from the doctor when using the escalation criteria and that NEWS supports their gut feeling about an unstable patient. This might be explained by there being a larger proportion of highly experienced RNs in the study by Fox and Elliot (2015) in comparison with those in our study, since the results above showed that the responses to these items were influenced by the length of nursing experience.

A lack of response from the doctor was reported as the main cause for not adhering to the NEWS guidelines in this study. It is important that the doctors receive proper education about the NEWS. A decision concerning whether to call the doctor or not can be intimidating for some RNs, who fear receiving criticism and humiliation or disturbing the doctor with unnecessary calls (90-92). NEWS offers a clinical decision support for such cases, and in line with the results by Hogan et al. (2019) we confirmed that some RNs responded that the NEWS empowered them to call a doctor if they were concerned about a patient by providing evidence that something was wrong (61). We found an increasing proportion of RNs with shorter nursing experience answering positively to receiving a better response from the doctor when using the NEWS, which might indicate that doctors have greater confidence in experienced RNs.

The NEWS also appeared to aid an increasing proportion of the RNs with shorter nursing experience in better prioritization of their care according to their responses. This finding indicates that the NEWS should be introduced

already in the nursing education programs since it appears to offer a great deal of support to novice RNs.

The RNs with the longest nursing experience were those who were most negative about the NEWS, with more than one third of them answering that the NEWS only generated extra work for them. Similarly, one fourth also answered that the NEWS did not support their gut feeling about an unstable patient. This poses a barrier not only to adherence to the guidelines but also to the credibility of the NEWS amongst nursing students and those with shorter nursing experience.

Adherence to the recommended frequency of monitoring and clinical response in the NEWS guidelines was reported significantly lower in the CHDU compared to other medical affiliations. This might be due to many of the patients being on telemetry and thus warranting contact with the doctor on other occasions, such as changes in the electrocardiogram. On the other hand, it might be that the RNs do not calculate a NEWS once a patient is on telemetry. This can jeopardize patient safety as subtle changes in vital signs might not be noticed and acted upon in a timely manner. It is now recommended in the revised NEWS2 guidelines that NEWS should be used for summarizing patients' vital signs even if they are on telemetry (88).

Conclusions

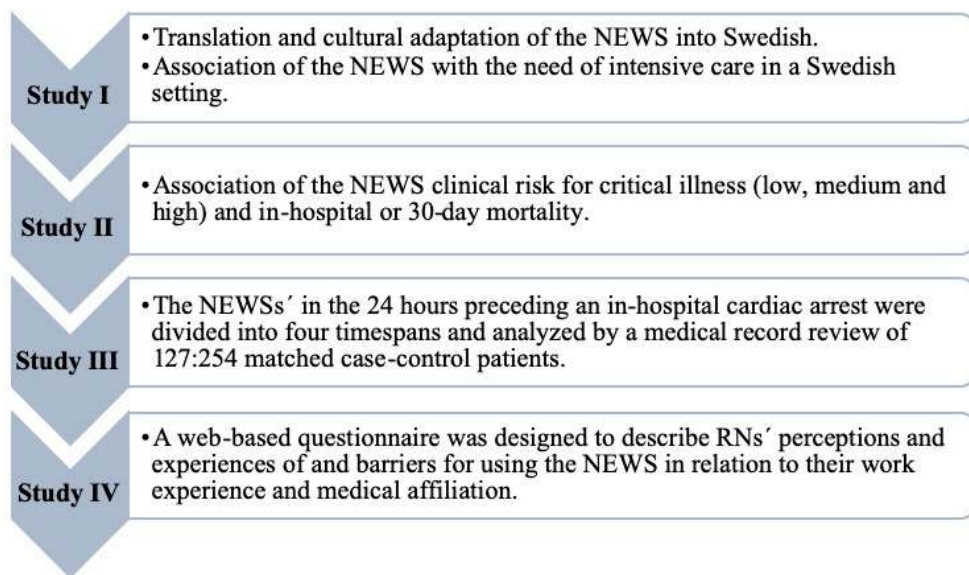


Figure 8. Flowchart of the studies.

Study I

The Swedish translation of the NEWS can be used without great risk of linguistic misinterpretation. As suggested in this study the NEWS can discriminate high-risk patients in need of intensive care in Swedish settings. High points in the NEWS parameters oxygen saturation and level of consciousness might predict the need for intensive care better than the others.

Study II

In line with previous studies, our study concurs that the NEWS can be used to identify deteriorating patients. Further, we have shown that the NEWS risk classification assessed in a mixed patient population with deviating vital signs on the hospital ward seems to be a reliable predictor of in-hospital and

30-day mortality and can be used by healthcare staff to discriminate deteriorating patients.

Study III

The proportion of patients classified as high-risk almost doubled between 12-6 and 6-0 hours before the in-hospital cardiac arrest, indicating a dynamic process of deterioration.

NEWS high-risk was associated with a more than threefold odds of IHCA compared to low-risk during the preceding 24 hours.

The NEWS, with its intuitive and, for healthcare staff, easily interpretable risk classification, is thus suitable for discriminating deteriorating patients with major deviating vital signs scoring high-risk on the NEWS. However, the NEWS had difficulties in discriminating patients suffering an IHCA showing only minor deviating vital signs in the preceding 24 hours.

Study IV

In general, the RNs perceived the NEWS as a useful tool, supporting their gut feeling about an unstable patient. Barriers to the NEWS were found in doctors and the most experienced RNs, indicating the need for resources to be focused on the adherence of these members of the healthcare team to the protocol.

Overall conclusion

The overall aim of this thesis was to test and evaluate the NEWS in a Swedish hospital setting. Based on the results in this thesis it can be concluded that the Swedish translated NEWS including the clinical risk scale is a sound “track and trigger” scale to identify high-risk patients at risk of SAEs in a Swedish hospital setting.

Further research and clinical implications

The incidence of mortality was highest amongst the NEWS high-risk patients, which gives an incentive to investigate whether these high-risk patients could benefit from continuous monitoring on a hospital ward. Furthermore, impact of aggressive and prompt medical treatment of these high-risk patients should also be evaluated in such a future trial.

Adherence to the NEWS is vital in detecting deteriorating patients. In this thesis we have identified doctors to be a potential barrier to the concept. The clinical response in the NEWS only instructs the doctors in the level of expertise needed and the urgency of examination. The NEWS concept does not, however, contain supportive information for the doctors, such as the urgency of medical treatment or algorithms for treatment as there is in several IHCA-guidelines. This might create uncertainty and a reluctance to adhere to the NEWS. It would be interesting for a future trial to evaluate whether adherence among the doctors could be improved by adding an algorithm for the doctors to the NEWS.

It seems there is a barrier to the NEWS in the RNs with long working experience. The hospitals could probably gain some adherence to the NEWS by creating a knowledge-based organization with structures to continuously educate and update all hospital staff. In my hospital region a majority of the focus is put on the newly employed.

Artificial intelligence or machine learning offer new ways to analyze and combine large amounts of data and might be able to recognize patterns of early signs of deterioration in a way that is impossible to man. Furthermore, a machine offers a relentless working capability that does not get tired, distracted or is colored by individual beliefs. This might add substantially to the detection of deteriorating patients.

Patients with medium or high-risk on the NEWS might be associated with high nursing workloads. One future implication of the NEWS could be to use it as a part measure of the nurses' workload and as a means of distributing the patients between hospital wards and nursing teams. It might be suboptimal for a nurse to have several high-risk NEWS patients due to the intensity of monitoring and often associated interventions. A hospital wide admission coordinator could divide patients between different hospital wards and nursing teams to optimize workload distribution.

In Sweden, the CCOT is most often led by an ICU-doctor assisted by an ICU-RN which is activated if the patient scores high-risk on the NEWS. It would be interesting to evaluate a concept where only the CCOT-nurse was activated when a patient scores medium-risk on the NEWS. The CCOT-nurse is often highly skilled in handling critical and deteriorating patients in the ICU. In my opinion the CCOT-nurse is an expert in detecting subtle changes that might indicate deterioration and by assessing patients already at medium-risk might shorten the time to identify critical illness and hence shorten the time to intervention.

A key component to the NEWS in detecting deteriorating patients is the adherence. Still, we found indications of insufficient adherence to the concept. In our hospital region we have different quality measures like the number of bed sores, adherence to fall risk and nutrition scores and so on. These quality measures are reported both locally, regionally and nationally in Sweden. During my medical record review, I found that almost all the patients had documentations of these quality measures as soon as they entered the hospital wards. Regardless of patient sickness and age these quality measures seemed to be prioritised. This raises the question whether the adherence to the NEWS could be increased by turning it into a quality measure that is reported both locally, regionally and nationally in Sweden.

In my hospital region, most surgical wards have an on-call surgeon from 5 PM to 7.30 AM. This on-call surgeon is most often responsible for the patients at the surgical hospital ward and the patients that need surgery during the shift. This means that the surgeon might be operating during large parts of the shift and still has to be responsible for all the patients at the surgical hospital ward. In these cases, there might be an improvement in the handling of patients with deviating vital signs on the surgical wards by introducing a workflow where the responsibility for the surgical ward patients with deviating vital signs is shifted to another doctor or team with competence in handling deteriorating patients. This could improve both the handling of deteriorating patients and might let the surgeons focus on their surgery, improving the outcome.

By creating a hospital wide dashboard where all the patients scoring medium- or high-risk on the NEWS are displayed, several advantages might be drawn. Firstly, a vital signs team which automatically assesses all patients with medium- or high-risk on the NEWS could be introduced in the hospital. Secondly, an enhancement hospital staffing team with nurses, originally designed to aid hospital wards in case of sudden short-term sick leaves, could be deployed as reinforcement to hospital wards when they have an increased proportion of patients scoring medium- or high risk on the NEWS. Thirdly, the proportion of patients in the NEWS risk categories low-, medium- and high could be analysed yearly and contribute to the assessment of staffing requirements on the different hospital wards.

The patients scoring medium-risk on the NEWS seem to be a complicated group to assess and many of them will actually develop into SAEs. There is a growing number of wireless continuous trend monitoring systems for vital signs. It would be interesting to evaluate if patients scoring medium-risk on the NEWS suffered less SAEs if they were wired to such a system already in the ED and during the entire hospital stay. Furthermore, it would be

interesting to evaluate if the proportion of medium-risk patients deteriorating to high-risk on the NEWS could be decreased and if the duration of time spent on medium-risk category could be shortened by introducing a wireless continuous trend monitoring system for vital signs since it might create an awareness of the hospital staff and shorten time to intervention.

Mortality seems to be one of the most common outcome measures when evaluating the impact of introducing new workflows, surgical procedures, medications or treatments. Mortality is a robust outcome measure but to me it is a bit blunt. Even if a patient does not die, conditions during hospitalization might have differed substantially between patients. ICU-admittance is often used as a proxy for measuring severity of critical illness or deterioration. However, this is a suboptimal outcome measure in my opinion since ICU-admittance might be impacted by different external factors. Admittance to the ICU might be affected by the level of bed availability in the different hospitals as well as seasonal variation, lack of staffing and bed occupancy at the hospital as well as the individual assessment by the ICU-doctors of which patients are to be treated at the ICU. Furthermore, the number of ICU-beds differs substantially between countries meaning that a patient classified as in need of intensive care in one country might not be classified as in need of intensive care in another country. To further cloud the interpretation of ICU-admittance, some hospitals have HDUs where intermediate patients are treated but in hospitals without HDUs these patients might have been classified as ICU-patients and treated in the ICU.

In addition to the mortality and ICU-admittance a more objective outcome measure could be to add both the NEWS' different physiological parameters and total score when evaluating the impact of introduction of new workflows, surgical procedures, medications or treatments. This could be very informative of the physiological impact and might signal improvement or harmful changes before the mortality or ICU-measures. Furthermore, it might give an insight into which physiological parameters that are affected by the procedure and initiate quality improvement undertakings.

Populärvetenskaplig sammanfattning

Avvikande vitala parametrar såsom pulsfrekvens, blodtryck, andningsfrekvens och medvetandegrad har påvisats föregå hjärtstopp på sjukhus, oplanerad inläggning på intensivvårdsavdelning (IVA) samt oväntade dödsfall. De första studierna som påvisade detta publicerades redan på 1990-talet. Trots att dessa faktorer varit kända en lång tid är fortfarande identifieringen av riskpatienter ej optimal. Det har utvecklats en mängd olika system sedan slutet av 1990-talet för att identifiera dessa riskpatienter via de avvikande vitala parametrarna. Problemen med många utav dessa tidiga system har varit att de är framtagna i små grupper av patienter, otillräckligt validerade samt i många fall har en ostrukturerad uppföljning.

För oss inom intensivvården är det en självklar rutin att övervaka och bedöma vitala parametrar kontinuerligt. På vårdavdelningar är det däremot inte lika självklart. I en artikel från Läkartidningen år 2013 beskrivs flertalet Lex Maria anmälningar som beror på bristande övervakning, bedömning samt dokumentation av vitala parametrar.

Genom ett samarbete mellan flertalet av de forskare och kliniker som tagit fram de tidigare bedömningsskalorna utarbetades National Early Warning Score, NEWS, som introducerades nationellt i Storbritannien 2012. De vitala parametrarna som bedöms i NEWS är andningsfrekvens, syremättnad, temperatur, systoliskt blodtryck, pulsfrekvens och medvetandegrad. Eventuell syrgasbehandling bedöms också. Samtliga parametrar är väl underbyggda i studier och rapporter där det påvisats att en försämring i dessa föregår kritisk sjukdom. Parametrarna poängbedöms utifrån svårighetsgraden i avvikelserna från skalans normalvärde. Den summerade poängen (NEWS-värde) indikerar sedan vilken risk för kritisk sjukdom patienten har. En tillhörande åtgärdsskala rekommenderar vidare åtgärder såsom tid till nästa bedömning, behov av läkarkontakt samt eventuell bedömning av en mobil intensivvårdsgrupp (MIG).

Syftet med denna avhandling var att översätta och kulturellt adaptera NEWS från engelska till svenska samt testa konceptet under svenska förhållanden för att säkerställa att den kan användas inom svensk sjukvård.

Avhandlingen består av följande fyra delstudier:

Studie I: I denna studie användes ett standardiserat koncept för översättning och kulturell adaptation för att anpassa NEWS utifrån svenska förhållanden. Momenten bestod i oberoende översättningar av forskarna från svenska till engelska, återöversättning av den svenska versionen till engelska av en oberoende svensk-brittisk sjuksköterska samt reliabilitetstestning av den svenska versionen. Resultaten visade att den svenska versionen av NEWS kan användas utan risk för språklig missuppfattning och stämmer väl överens med det brittiska konceptet.

Sedan inhämtades data om vitala parametrar samt inläggning på IVA via journaler från 868 MIG-uppdrag på ett universitetssjukhus och NEWS bedömdes retrospektivt. I detta material var NEWS-värdet högre för de patienter som lades in på IVA än de som ej lades in på IVA. Medianen för NEWS-värdet på de som bedömdes av MIG motsvarade ungefär den gräns som satts i det brittiska materialet för kontakt med MIG. Således kan vi troligen använda samma gränser för kontakt med MIG i Sverige som i Storbritannien med viss osäkerhet för mindre sjukhus.

Studie II: En databas bestående av vitala parametrar och demografiska variabler från ett danskt universitetssjukhus analyserades retrospektivt med syftet att utvärdera om NEWS riskkategorier kan användas för att identifiera patienter som riskerar att avlida på sjukhus eller inom 30 dagar efter utskrivning.

Resultaten visade att patienter i riskgrupp medium eller hög hade två till tre gånger högre sannolikhet att avlida jämfört med lågriskgruppen. Därav kan NEWS riskgrupper användas för att identifiera patienter som riskerar att avlida på sjukhus eller inom 30 dagar från utskrivning.

Studie III: Denna studie syftade till att undersöka NEWS i fyra olika tidsspann under de 24 föregående timmarna innan patienter på vårdavdelning drabbas av hjärtstopp. Dessa patienter jämfördes sedan med en kontrollgrupp av liknande patienter som ej drabbades av ett hjärtstopp. Samtliga patienter inkluderades från tre sjukhus i södra Sverige. Resultatet påvisade att de som drabbades av hjärtstopp hade högre NEWS än de som ej drabbades av hjärtstopp. NEWS riskgrupp hög var associerad med tre till fyra gånger så hög sannolikhet att drabbas av hjärtstopp som lågriskgruppen under de fyra tidsspannen. Således kan NEWS identifiera högriskpatienter som riskerar att drabbas av hjärtstopp på vårdavdelning.

Studie IV: En webb-baserad enkät användes för att identifiera sjuksköterskors uppfattningar och upplevda barriärer i användningen av NEWS relaterat till yrkeserfarenhet och kliniktilhörighet. Undersökningen utfördes på sjuksköterskor anställda på vårdavdelningar, akutmottagningar och hjärtintensivvårdsavdelningar i Skåne.

Generellt var sjuksköterskorna positivt inställda till NEWS och svarade att NEWS var ett värdefullt instrument som stödjer deras magkänsla om en kritiskt sjuk patient. Barriärer mot NEWS som framkom var läkarna. Resultatet visade att de mest erfarna sjuksköterskorna var mer negativt inställda till NEWS.

Sammantaget kan den svenska översättningen av NEWS användas i svensk sjukvård för att identifiera patienter som riskerar att drabbas av hjärtstopp på sjukhus, oplanerad inläggning på IVA samt oväntade dödsfall.

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Appendix

1: Vilket sjukhus arbetar du huvudsakligen på?

Helsingborg Hässleholm Kristianstad Landskrona
Lund Malmö Trelleborg Ystad Ängelholm

2: Är din nuvarande yrkesroll sjuksköterska?

JA NEJ

-om NEJ, tack för din medverkan, vänligen lämna in din enkät!

3: Antal år som yrkesverksam sjuksköterska?

4: Är NEWS infört på din avdelning?

JA NEJ

5: Har du använt NEWS?

JA NEJ

-om NEJ, tack för din medverkan, vänligen lämna in din enkät!

6: Arbetar du enbart administrativt eller på annan mottagning än akuten?

JA NEJ

-om JA, tack för din medverkan, vänligen lämna in din enkät!

7: Huvudsaklig inriktning på verksamheten?

Kirurgi Medicin Ortopedi Akutmottagning

8: Jag bedömer NEWS på följande patientgrupper (flera kan väljas):

Barn ≤ 16 år Vuxna ≥ 18 år Gravida kvinnor Vård i livets slutskede
Utskrivningsklara

9: Jag följer tidsanvisningarna för NEWS-bedömningarna som rekommenderas i NEWS riktlinjer.

Stämmer helt

Stämmer

Stämmer ganska bra

Varken stämmer eller stämmer inte

Stämmer inte särskilt bra

Stämmer inte alls

10: Jag följer åtgärderna som rekommenderas i NEWS riktlinjer.

Stämmer helt

Stämmer

Stämmer ganska bra

Varken stämmer eller stämmer inte

Stämmer inte särskilt bra

Stämmer inte alls

11. Vid de tillfällen du inte följer riktlinjer för NEWS – ange orsak nedan (flera kan väljas):

Tidsbrist Får ej gehör för NEWS-poängen av läkare Anser inte att NEWS är tillräckligt värdefullt För omständigt att dokumentera i patientjournalen

Annat:

12: NEWS ger mig tydliga instruktioner för vad jag ska göra om en patient får en eller fler poäng.

Stämmer helt

Stämmer

Stämmer ganska bra

Varken stämmer eller stämmer inte

Stämmer inte särskilt bra

Stämmer inte alls

13: NEWS hjälper mig ta beslut om jag ska eller inte ska kontakta läkaren för att be om bedömning av patienten.

Stämmer helt

Stämmer

Stämmer ganska bra

Varken stämmer eller stämmer inte

Stämmer inte särskilt bra

Stämmer inte alls

14: Att använda NEWS ger mig som sjuksköterska bara merarbete.

Stämmer helt

Stämmer

Stämmer ganska bra

Varken stämmer eller stämmer inte

Stämmer inte särskilt bra

Stämmer inte alls

15: NEWS hjälper mig prioritera min vård bättre.

Stämmer helt

Stämmer

Stämmer ganska bra

Varken stämmer eller stämmer inte

Stämmer inte särskilt bra

Stämmer inte alls

16: NEWS tar bort mina kliniska bedömningsfärdigheter.

Stämmer helt

Stämmer

Stämmer ganska bra

Varken stämmer eller stämmer inte

Stämmer inte särskilt bra

Stämmer inte alls

17: Genom att använda NEWS får jag ett bättre gensvar från läkaren.

Stämmer helt

Stämmer

Stämmer ganska bra

Varken stämmer eller stämmer inte

Stämmer inte särskilt bra

Stämmer inte alls

18: När jag informerar läkaren med hjälp av NEWS bedömer läkaren patienten inom tidsramen.

Stämmer helt

Stämmer

Stämmer ganska bra

Varken stämmer eller stämmer inte

Stämmer inte särskilt bra

Stämmer inte alls

19: Sedan införandet av NEWS har antalet gånger jag måste kontakta läkaren ökat.

Stämmer helt

Stämmer

Stämmer ganska bra

Varken stämmer eller stämmer inte

Stämmer inte särskilt bra

Stämmer inte alls

20: NEWS stödjer min magkänsla angående en instabil patient.

Stämmer helt

Stämmer

Stämmer ganska bra

Varken stämmer eller stämmer inte

Stämmer inte särskilt bra

Stämmer inte alls

21: Information och utbildning innan införandet av NEWS har varit tillräcklig.

Stämmer helt

Stämmer

Stämmer ganska bra

Varken stämmer eller stämmer inte

Stämmer inte särskilt bra

Stämmer inte alls

22: Tillämpas avsteg från NEWS efter individuell bedömning av läkare eller har ni generella avsteg för hela patientgrupper på din avdelning?

Individuell bedömning av läkare

Generella avsteg för hela patientgrupper

Avsteg tillämpas ej på min avdelning

23: Skriv dina synpunkter på NEWS, exempelvis utbildning, användbarhet, följsamhet, framtida utformning m.m.

TACK, för din medverkan!