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In-hospital patient safety - prevention of deterioration and unexpected death by systematic and interprofessional use of early warning scoring

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In-hospital patient safety

Prevention of deterioration and unexpected death by systematic and interprofessional early warning scoring

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Abstract: In-hospital patient safety is at times hampered, leaving general ward patients at considerable risk of gradual, even life-threatening, deterioration. In many European clinical settings, inappropriate nursing practice of bedside monitoring has recently been addressed as impending to in-hospital patient safety. Vital parameters have for two decades been known to deviate in individual patients hours ahead of serious adverse events, but this knowledge has not yet been rooted among nursing and medical in-hospital staff, contributing to misinterpretation of individual vital signs and inadequate bedside action being taken. Accordingly, this knowledge of the predictable value of deviations in bedside vital parameters has not until recently been reflected in general ward patient monitoring practice.

A clinical multi-component intervention comprising mandatory nursing bedside monitoring, based on structured in-hospital use of modified early warning scores in general ward patients, was implemented by interprofessional teaching, training and promotion in a large medical and surgical study setting at an urban Scandinavian university hospital. This thesis has been based on four non-randomized pre- and postinterventional studies on bedside practice in this context (I-IV). Outcome measures of particular interest were associations between early deviation in vital parameters and later severe deterioration (IV), and potential effects of the study intervention on unexpected death (III). Before implementation of the study intervention, nursing monitoring practice was found to be influenced by individual levels of professionalism, characterized by knowledge, reflection, and interprofessional collaboration (I). After this implementation, the three most common bedside vital parameters were found to be recorded more frequently (II), and the unexpected in-hospital patient mortality in the study setting to be significantly lower (III), than before. The medical emergency team was called in three times more often (III). Three quarters of the patients were rescored within eight- or four hour time limits hours stated in the algorithm of bedside management (II). Sudden tachycardia or tachypnea in slightly deteriorated, particularly older, in-hospital patients was found to be significantly associated with later severe clinical deterioration (IV).

Key words Patients safety, deterioration, early warning score, nursing monitoring practice

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LUNDS UNIVERSITET

Contents

Original papers

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

I   Bunkenborg G, Samuelson K, Åkeson J, Poulsen I. Professionalism in Nursing: Its impact on nursing practice when monitoring vital parameters and securing in-patient safety.

Journal of Advanced Nursing, 2012, 69 (7), 1466-77

II   Bunkenborg G, Poulsen I, Samuelson K, Ladelund S, Åkeson J. Interprofessional implementation of a systematic in-hospital bedside monitoring practice: A mixed methods study.

Submitted for publication

III   Bunkenborg G, Samuelson K, Poulsen I, Ladelund S, Åkeson J. Lower incidence of unexpected in-hospital death after interprofessional implementation of a bedside track-and-trigger system.

Resuscitation, 2014, 85 (3) 424-30

IV   Bunkenborg G, Poulsen I, Samuelson K, Ladelund S, Åkeson J. Bedside vital parameters associated with clinical deterioration in general ward in-hospital patients.

Submitted for publication

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Abstract

In-hospital patient safety is at times hampered, leaving general ward patients at considerable risk of gradual, even life-threatening, deterioration. In many European clinical settings, inappropriate nursing practice of bedside monitoring and management has recently been addressed as impending to in-hospital patient safety. Vital parameters have for two decades been known to deviate in individual patients hours ahead of serious adverse events, but this knowledge has not yet been generally rooted among nursing and medical in-hospital staff, contributing to misinterpretation of individual vital signs and inadequate bedside action being taken. Accordingly, this knowledge of the predictable value of deviations in bedside vital parameters has not until recently been reflected in general ward patient monitoring practice.

A clinical multi-component intervention comprising mandatory nursing bedside monitoring, based on structured regular in-hospital use and recording of modified early warning scores in in-hospital patients, was implemented by structured interprofessional teaching, training and promotion in a large medical and surgical study setting at an urban Scandinavian university hospital. This thesis has been based on four non-randomized pre- and postinterventional studies on bedside practice in this context (**I-IV**). Outcome measures of particular interest were associations between early deviation in various vital parameters and later severe deterioration (**IV**), and potential effects of the study intervention on unexpected death (**III**).

Before implementation of the study intervention, nursing monitoring practice was found to be influenced mainly by individual levels of professionalism, characterized by knowledge, reflection, and interprofessional collaboration (**I**).

After this implementation, the three most common bedside vital parameters were found to be recorded more frequently (**II**), and the unexpected in-hospital patient mortality in the study setting to be significantly lower (**III**), than before. Moreover, the medical emergency team was called in three times more often (**III**). Three quarters of the patients were rescored within the time limits of eight and four hours stated in the algorithm of bedside management (**II**). Sudden tachycardia or tachypnea in slightly deteriorated, particularly older, in-hospital patients was found to be significantly associated with later severe clinical deterioration (**IV**).

Summary in Danish

Patientsikkerhed på hospital – forebyggelse af uventede dødsfald via systematisk anvendelse af et Early Warning Score system

På hospitaler i den vestlige del af verden sker det, på trods af store indsatser for at øge patientsikkerheden, at indlagte patienters tilstand forværres alvorligt, og at nogle af disse patienter i værste tilfælde dør, som konsekvens af utilstrækkelig overvågning og uoptimal håndtering af situationen fra hospitalspersonalets side. I de sidste tyve år har man haft kendskab til, at patienter, der dør uventet på hospital, frembyder afvigende vitale parametre (puls, vejrtrækningsfrekvens, blodtryk og temperatur) i op til 48 timer inden det uventede dødsfald.

Studier fra andre europæiske lande har dog vist, at noget af problemet med uventede dødsfald på hospital skyldes, at en stor del af det kliniske personale ikke er fortrolig med viden om betydningen af afvigende vitale parametre, og at de er usikre på, hvordan de skal tolke og agere overfor afvigende vitale parametre. Derudover har der, indtil for nylig, fra hospitalsorganisationers side, ikke været fokuseret på at introducere en øget observationspraksis inklusiv øget kendskab til håndtering af ustabile patienter.

Formålet med dette studie var at undersøge patientsikkerheden på almen medicinsk og kirurgisk afdeling på et dansk hospital, set i relation til sygeplejerskers observationspraksis af vitale parametre og det tværfaglige samarbejde vedrørende ustabile patienter. Undersøgelsen blev påbegyndt i 2009, hvor fire måneder i foråret udgjorde før-interventions perioden, og fire måneder i efteråret 2010 og i foråret 2011 udgjorde de to efter-interventionsperioder.

Indledningsvist undersøgte vi via observationer og interview den aktuelle observationspraksis. Det videre studie blev designet som et interventionsstudie med henblik på at undersøge, om en obligatorisk, systematisk og tværfaglig anvendelse af et observations- og vurderingsredskab, et såkaldt Early Warning Score system, kan opspore patienter i risiko for at blive akut kritisk syge, og om dette i kombination med et nyt dokumentationsredskab og en handlingsalgoritme kan bidrage til hurtigere iværksættelse af korrekt pleje og behandling.

Det overordnede formål var at undersøge interventionens effekt på antallet af uventede dødsfald, hjertestop eller uventet indlæggelse på intensiv afdeling hos patienter indlagte på almen kirurgisk og medicinsk afdeling. Desuden var formålet at undersøge i hvor høj grad interventionen var blevet fulgt, og hvordan implementeringsprocessen blev oplevet af personalet tæt på klinisk praksis.

Sluttelig ønskede vi at bestemme forbindelsen mellem tidligt opståede, lettere afvigende vitale parametre, og senere alvorlig forværring.

Resultaterne af den indledende observations- og interview undersøgelse viste, at der hos sygeplejersker fandtes et meget varierende niveau af professionalisme; et begreb, der indeholder karakteristika som: viden, evnen til at reflektere, autonomi men også arbejdsmiljøet og det tværfaglige samarbejde er indeholdt i begrebet professionalisme. Den enkelte sygeplejerskes grad ad professionalisme har indflydelse på hendes observationspraksis, og dette kan få betydning for patientsikkerheden.

Vejledt af litteraturen og resultaterne fra observations- og interviewstudiet blev der foretaget en række forskellige implementeringstiltag. Klinikere fra projekt afdelingen evaluerede, at det meningsgivende i interventionen og det store faglige fokus i projektet havde været meget motiverende for deres deltagelse og havde styrket en vellykket implementering af den kliniske intervention. Både ledelse og medarbejdere var aktivt inddraget i implementeringsfasen.

I de afdelinger der deltog i studiet, ændrede den daglige observationspraksis sig således, at tiden mellem individuelle målinger af puls, blodtryk og temperatur blev mindsket betydeligt. Derudover opnåede 75% af alle patienter af få repeteret måling af deres vitale parametre inden for den tidsramme på 8 og 4 timer som handlingsalgoritmen foreskrev. Alt i alt blev der målt tre gange så mange sæt vitale parametre i hver af de to efter-perioder som i før perioden. Hospitalets Mobile Akut team blev tilkaldt 3 gange oftere i perioden efter i forhold til i perioden før interventionen.

Forekomsten af uventede dødsfald faldt markant, hvis man sammenligner før-perioden med den sidste efter-periode. Men allerede i den første efter-periode var der et tydeligt, men ikke statistisk signifikant fald.

I den sidste undersøgelse fandt vi, at små ændringer i puls og vejrtrækningsfrekvens er forbundet med senere alvorlig forværring, Stigende alder er ligeledes forbundet med senere alvorlig forværring. Desuden forværredes 25%, af de, der havde fået målt tidlige og små afvigelser, senere alvorligt, med øget risiko for død til følge. Ca. halvdelen forværredes allerede inden for de første 48 timer.

Konklusionen på projektet er, at det er muligt at bidrage til nedbringelse af antallet af uventede dødsfald på hospital via en daglig, tværfaglig og struktureret anvendelse af et early warning score system og et understøttende handlings og dokumentationsredskab.

Abbreviations

CI	Confidence Interval
CCORT	Critical Care Outreach Team
EWS	Early Warning Score
DNR	Do-Not- Resuscitate
HR	Hazard ratio
ICU	Intensive Care Unit
*MET	Medical Emergency Team
MEWS	Modified Early Warning Score
MRC	Medical Research Council
OR	Odds ratio
RCT	Randomized Controlled Trial
RN	Registered Nurses
RRS	Rapid Response System
RRT	Rapid Response Team
SBAR	Situation, Background, Assessment, Recommendation
SD	Standard deviation

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

Introduction

Whenever patients are being hospitalized they put for the present the responsibility of their wellbeing into the hands of professional nursing and medical staff. Most patients do so, and should do so with great confidence, as it is without doubt a priority of all hospital staff members to ensure patient safety. Besides being of concern to clinicians and their patients, patient safety is also of considerable interest to hospital managers and patient organizations amongst others.

Initiatives to optimize in-hospital patient safety have been found to be associated with considerable problems. A major challenge is the complex in-hospital context where several interacting groups of professionals work individually, autonomously, but also in collaboration to deliver high standard care and treatment. The complex system involves individuals with different educations and responsibilities, with differing experience, practice and knowledge, and with different attitudes and expectations, all of which may influence how to perform, communicate, and collaborate professionally.

The medical or surgical in-hospital patient is known to be at risk of deteriorating i.e. moving to a worse clinical state, without staff interpreting the decline correctly and therefore not acting appropriately (1-4). This is likely to happen daily in many general wards and represents a well-known and serious but yet preventable threat to patient safety. Unnoticed or inappropriately interpreted in-hospital deterioration may lead to serious medical complications, prolonged hospital stay, and sometimes even unexpected death (5;6).

Thorough analysis of why patient safety is sometimes seriously hampered leading to patients "falling through" the safety net of otherwise well managed organizations has become of interest to individual researchers and organizations at different levels and a target to actions both world-wide, nationally, regionally and within local hospitals (www.jointcommision org., NICE org.uk).

An important result of the patient safety work is that hospital staff members carry out daily tasks in accordance with updated clinical guidelines and instructions in order to improve patient safety as presented by the Joint Commission or the National Institute for Clinical Excellence (7). Nevertheless, some fundamental aspects of nursing and interprofessional patient management are still, or have until recently, been guided by individual clinical judgement only. One such aspect is

carefully observing the patient using ones senses, measuring and assessing vital parameters, and professionally interpreting all observation obtained. This has for decades, or even centuries, been a central task of nursing, and the results of bedside observations and assessments have often been the basis of interprofessional collaboration with physicians. Nevertheless, in spite of a historically strong tradition of observing patients, within both nursing and medical practice, patients still deteriorate and die unexpectedly without medical- and nursing staff neither noticing the initial decline nor reacting to prevent further deterioration (1;5;8-10).

For more than a decade, hospital managers and safety organizations have focused on specialised clinical staff members with different clinical and professional competences to respond to patients who are at risk of deteriorating and dying unexpectedly (11;12).

More recently the scope of this focus has turned towards daily clinical bedside practice of monitoring patients in general wards (9;13;14). However, little is still known about what influences daily practice and how it influences patient safety issues like unexpected death. In particular we need to know more about nursing practice of monitoring – and the interprofessional collaboration and communication in relation to this practice, and about useful clinical measures to optimize patient safety.

Background

Patient safety

In-hospital patient safety is frequently hampered, and general ward patients are found to suffer fatal adverse events like unexpected death or cardiac arrest or to need unplanned admission to the intensive care unit (ICU) (2;4;15).

The incidence of fatal events like unexpected death and cardiac arrest has however been reported using different outcome measures making comparison between studies and study settings, as well as picturing the size of the problem, most difficult. In a prospective Australian study from 2010 (16) the incidence of unexpected deaths was reported to be 1% (11/1157 admissions) before and 0.2% (2/985) after a study intervention, entailing a new chart and a track and trigger system (reported in more detail page 26), but the authors did not define unexpected death. Another Australian randomized controlled trial from 2005 (17) designed to prevent adverse events, reported the incidence of cardiac arrest to be 1.4 and that of unexpected death to be 1.2 per 1000 admissions before an intervention, where Medical Emergency Teams (MET, reported in more detail page 27) were introduced in a large number of hospitals. A Swedish prospective before-and-after trial, from 2009 (18), reported the number of cardiac arrests per 1000 admissions to be 1.12 before and 0.83 after an intervention also comprising a MET and a Rapid Response System (RRS; reported in more detail on page 26). Although not large in numbers locally or even nationally, each individual unexpected death represents a serious and traumatic event.

In Denmark almost half (48%) of all deaths take place inside hospitals (19). Death is often the ultimate outcome of aging, frequently preceded by weeks, months or even years of the presence of one or several chronic and severe diseases (www. who.int. and www.dst.dk), and thus most deaths are expected by the patient, his or her relatives and the hospital staff. However, in-hospital death is not always expected in a short-term perspective despite known serious disease, resulting in general ward patients dying alone and unexpectedly. Patients who die unexpectedly are either found dead with no resuscitation attempt being made, or have been subjected to unsuccessful cardiopulmonary resuscitation. Both situations have important clinical and ethical implications to patient safety.

Patient safety is strongly associated with the quality of health care. Accordingly, measuring the quality of care is a fundamental task for any modern health care organization and may be dealt with in several ways. Patient mortality rates are still often used as a parameter for measuring the quality of delivered care (20-24) and have been so for years, although other measures are considered to better reflect the entire picture of the quality of delivered health care (20-23). One argument against relying heavily on mortality rates in this respect is that the complexity mix in patient populations, also influencing mortality rates, cannot always be taken into account and adjusted for (23;25).

It is well known that during the last decades there has been a change towards an older, more complex multi morbid patient population in most countries worldwide (26). Simultaneously one-day-surgery facilities, fast track surgery and other types of day care/treatment facilities with shorter in-hospital stay have evolved (27;28), particularly in western parts of the world.

Patients admitted to general wards are likely to require more closely bedside monitoring than few decades ago for several reasons. Today patients under 24 hours care have more complex and serious diseases (26), calling for closer observation. Previous general ward patients are now being managed in day care-facilities, whereas some previous intensive care patients are now being cared for in general wards. In 2013 intensive care patients are highly dependent on advanced lifesaving equipment. Since the turn of the previous century the number of available intensive care bed has remained at 5-6 beds per 100 000 inhabitants in the Scandinavian countries (www.Sundhedsstyrelsen.dk) (29). This means that as soon as a patient can do without the special facilities of the ICU, he or she is transferred to a general ward.

Actions throughout an organization, targeting various potentially harmful components of a hospital stay, should all be fundamental parts of the strategy to improve in-hospital patient safety. Initiatives proposed to prevent serious in-hospital adverse events, (e. g. unexpected death) are optimization of cardiac team performance (30-32), optimization of safe communication in all, but especially in clinically critical situations, and better access to call for immediate help in critical situations (33). Such initiatives have been an issue of global interest among clinicians and researchers as well as hospital managers since the early nineties.

From a chronological perspective research into the area of patient safety, focusing on preventing unexpected death, has gradually moved from identifying antecedents to cardiac arrests (2;3), the evaluation of early warning signs of clinical deterioration, and the development of early warning score (EWS) systems (34;35), to the development and evaluation of MET (17;36) and instruments for bedside scoring in large validation studies (37;38). However, nurses' daily

monitoring practice, its relation to the areas mentioned above, and its influence on patient safety, remain to be studied in more detail.

Deterioration and adverse events

The term deterioration is often used to describe patients, who obviously worsen in their clinical condition, but the term may also be used in patients who more gradually move to a worse clinical state. Serious clinical deterioration in the general ward patient often involves dramatic bedside problems involving the patient's airway, breathing, and/or circulation (39;40). Such situations are potentially dangerous to the individual patient and a stressful experience to staff members, who have to leave other patients out of focus and at risk of sub-optimal care. Although serious deterioration does not always lead to death, clinical instability often means considerable physical as well as emotional suffering, .and is often accompanied with anxiety and fear.

Despite having been used extensively in clinical research reports, the term deterioration was not defined until 2012 in a literature review (41). In the nineties and early zeroes focus was on the end result of the deterioration; the cardiac arrest, unexpected death, and even unplanned admission for intensive care. Since then focus has changed and a mutual definition of deterioration is suggested, based on individual change to a worse clinical state (42).

In-hospital patients may deteriorate in response to further progression of their disease or injury in spite of appropriate care and treatment. However, patients may also deteriorate, not because of the disease or injury that brought them to hospital in the first place, but due to professionals' sub-optimal clinical management of the situation, including the bedside monitoring practice (43). Such potentially harmful or even fatal incidences called adverse events. Clinical research provides reasons to believe that adverse events are to some extent preventable (2;44-46).

One reason for focusing on cardiac arrest and unexpected death (no limitations to patient treatment) when talking about patient safety and deterioration in general ward patients could be that in the early nineties Schein et al. (3) described in a study of patients' physiologic abnormalities preceding 64 in-hospital cardiac arrests, that patients tended to deteriorate before suffering cardiac arrest. Hence, cardiac arrests and unexpected deaths were not always as unexpected as had been assumed. These findings were later supported by an Australian study (2) of 778 deaths reporting that in approximately 50% of in-hospital unexpected deaths (no limitations to patient treatment) physiological deviations (e. g. in respiratory rate, heart rate or blood pressure) occurred six to eight hours, or even up to 48 hours in advance. Antecedents to cardiac arrests were described and it was argued that attempts could and should be made to prevent cardiac arrests, unexpected death

and other related and fatal adverse events. A strong argument for focusing on preventing in-hospital cardiac arrests is that despite sincere attempts to optimize hospital care and cardiac arrest team performance, the survival rate after in-hospital cardiac arrest has remained at 20-25% for the last 25-30 years (47).

Deviations in bedside measurable vital parameters

Deviations in bedside measurable vital parameters (respiratory rate, heart rate, blood pressure, cerebral awareness and body temperature) have been found to predict in-hospital mortality in numerous retrospective studies since the early nineties (2;6;11;16). Previous interpretation of at what point such deviations should be considered as warning signs of deterioration and potential clinical adverse events was questioned in an Australian study from 2005 (35) based on a cross-sectional survey of 3 046 adult admissions in five hospitals, and proposed to be adjusted to also include minor deviations. Minor deviations, in vital parameters, in specific combinations have also been found to predict in-hospital death, based on other results obtained in the same 3 046 admissions (34).

Particularly deviations in the respiratory rate have been found to be an early sign of deterioration leading to adverse events (34;48). However, for reasons still not fully understood, measuring and assessing the respiratory rate fell out of clinical practice in most general wards years ago (48-50), and nurses have been reported to be quite unsure of how to interpret values of respiratory rate (50-52) and seldom to record them (48-50). This fundamental change in bedside policy is believed to put patient safety at risk and accordingly, the respiratory rate is often considered the neglected vital parameter. In many hospital settings specific and extensive efforts have been required in recent years to replace bedside measurement and assessment of the respiratory rate into daily nursing practice (50;52).

However, knowledge is still lacking concerning potential associations between early deviations in individual vital parameters and further severe deterioration. Such knowledge would be useful to guide clinicians in their daily practice and help them in rapidly identifying patients in most need of timely and appropriate bedside actions by an interprofessional team.

Nursing monitoring practice

For several decades nurses have combined clinical observation with measurements of vital parameters, particularly the heart rate, blood pressure and body temperature to assess the clinical state of their patients. Back in 1856 Florence Nightingale described her use of simple measurements and clinical observations

combined with reflections on what had been observed as useful and reliable means of getting to know her patients (53), and Virginia Henderson believed in and strongly argued in favour of the importance of nurses having a deep physiological knowledge of their patients to deliver high standard nursing care (54).

During the last twenty years and until very recently nurses' daily, routine measurements of vital parameters had turned into a rare and unstructured nursing practice in many in-hospital settings (4;50-52;55). In a Danish context, measurements of basic vital parameters outside the ICU had been extensively reduced, as found in a Danish study from 2009 (1). It was reported that 18% of medical in-hospital patients had serious deviations in their vital parameters and in 43% of these cases nursing staff was unaware of the potential risk of severe deterioration.

Measuring or assessing vital parameters and observing patients are fundamental and specific nursing tasks (54). Nevertheless, these tasks have also been described by nurses as routine task, often being delegated to nursing assistants and only necessary to carry out, in order to provide knowledge to physicians at morning rounds (4;56-58).

In the late nineties a British (4) study reported that general ward patients were exposed to sub-optimal care prior to an adverse event, and the role of nurses and their involvement in detecting deteriorating patients, was further explored (57-60). From qualitative research it appeared that nurses view the benefits of routinely measuring individual vital parameters as less valuable than their clinical gaze when it comes to detecting deteriorating patients. Nurses also reported their use of measuring and assessing vital parameters as a means of confirming clinical observations of deterioration rather than detecting deterioration (4;56-61).

Inability of some nurses to realize the clinical importance of deviations in vital parameters has been claimed to reflect lack of knowledge of what to look for, how to interpret clinical findings, and how to act to prevent further deterioration and death (62;63). A recent literature review (57) of research on nursing practice in this context based on publications from 1990 to 2007, has shown that nurses considered either measurements of vital parameters or their clinical gaze to be most important for detection of patient deterioration (57;58). This conflict has been taken into account in many hospital settings encouraging nurses to call for medical assistance by the MET based on abnormal bedside measurable vital parameters as well as on professional concerns without deviating vital parameters (64).

Research on nurses' recognition of, and response to, signs of deterioration, and their part in delivering suboptimal care, points at several factors being involved in current practice (10;58). The complexity of patients, actual workload, teamwork

and interprofessional communication all play important roles, - in addition to nurses' skills and competences – for rapid detection and appropriate management of deteriorating patients (10;58;61). Although some knowledge is available on nursing monitoring practice, other important aspects on this topic remain to be evaluated. These aspects comprise what influences nursing bedside monitoring practice and its importance to patient safety.

Interprofessional communication and collaboration

Since the mid zeroes qualitative research into nurses' experiences of communicating their bedside observations of patients and their clinical concerns to physicians have consistently found that nurses often experience their concerns about patients neither to be listened to nor accepted (61).

Bedside monitoring practice, including rapid and appropriate management of the deteriorating patients, should therefore be viewed in the light of interprofessional communication and collaboration. In the context of modern health care, the term interprofessional primarily refers to communication and collaboration between nursing and medical staff. A recent Cochrane review (65) argue that problems with interprofessional collaboration may negatively affect health care and patient safety. Collaborative practice between nurses and physicians requires certain knowledge, skills, and attitudes, not implicitly present, to be fruitful and to promote patient safety (66). Besides improving patient safety there are reasons to believe that optimizing interprofessional collaboration may potentially benefit the working environment and improve job satisfaction (67). Accordingly, designing clinical interventions and using implementation strategies that include fundamental aspects of interprofessional collaboration and communication is most important.

Preventing patient deterioration and ultimately serious or even fatal adverse events requires active and continuous involvement by various professions, but particularly nurses and physicians, co-working in teams (66;68). From the air transportation industry it is known that interprofessional collaboration and communication issues need to be taken seriously and managed by training of team processes (69), including team communication based on the situation, background, assessment and recommendation (SBAR) principles.

Verbal communication of clinical observations and concerns from nurses to physicians may be hampered by nurses' reluctance or disability to use medical terminology (61;70). Being able to report individual bedside observations and clinical concerns according to medically recognized principles is considered worthwhile for interprofessional in-hospital communication and collaboration (61).

There are still unrecognized, or even non-attended, problems associated with interprofessional, in-hospital communication and collaboration, especially between nurses and physicians (71). This might, at least in part, explain some of today's difficulties in improving patient outcome despite initiatives in providing appropriate skills, knowledge and clinical structures for earlier detection and appropriate management of deteriorating in-hospital patients.

Track and trigger systems

Rapid response systems

Based on analysis of unexpected in-hospital mortality, hospital organizations for patient safety have called for further actions to prevent fatal adverse events in in-hospital patients (7). Patients who die unexpectedly in hospital wards are often monitored at long time intervals or not at all, and rapid and appropriate bedside actions are not always taken (10). As a consequence, patients still die unexpectedly or suffer fatal adverse events, including heart arrest with cardiopulmonary resuscitation or non-intended admission for intensive care, in modern hospitals all over the world. This is the case although health care managers, clinicians, and researchers, have globally adopted a worthwhile intension to avert, potential preventable, serious, or fatal adverse events by motivating medical and nursing staff to monitor their patients more closely and to act earlier and more appropriately to improve clinical outcome.

Following the first international consensus report on Medical Emergency Teams (MET), American Rapid Response Teams (RRT) and British Critical Care Outreach Teams (CCORT) (15), the idea developed of regarding the entire process; identifying the deteriorating patient, calling the MET, managing the deteriorating patient, and administer structures to handle the system, as parts of one complete and inseparable system.

A RRS should support nursing- and medical staff in preventing adverse events (15;72-74), and to provide hospital staff and organizations with information on patient outcomes, to optimize individual and organizational performance and patient safety. The system constitutes of a defined pathway to track deteriorating patients based on Early Warning Score (EWS) or single parameter calling criteria. The trigger is a pre-defined EWS or single parameter threshold value, urging staff to respond by calling the MET (15;72-74).

International studies have reported that despite potential benefits and more than ten years' experience of RRS, there are still severe barriers to cross for these

systems to work smoothly and appropriately. High evidence of their possible life-saving effect is still lacking. A Cochrane review from 2009 has concluded that the current evidence of MET and EWS systems is inconclusive due to poor study design (75).

Medical Emergency Teams and single parameter calling criteria

During the past twenty years both clinical and research initiatives have addressed the problem of patients dying unexpectedly in our hospitals. The introduction of MET, based on the vision of breaking down the walls of the ICU has considerably contributed in this context (15;76;77). Skills and knowledge from well-educated and experienced ICU staff were to be summoned promptly to the bedside of the deteriorating general ward patient. Team constellation with respect to professional background, knowledge and skills was in the early days of METs of great interest to pioneers and researchers (15;76;77). Based on expert views and single center studies on vital parameters Australian researchers decided to create single parameter calling criteria when the first METs were taking into clinical use in the early nineties (78). These calling criteria included individual, bedside measurements of respiratory rate, heart rate, systolic blood pressure, oxygen saturation, body temperature and cerebral awareness. Threshold for calling the MET was set individually for each single parameter (15;78). The MET could also be called if nursing- or medical staff were worried about the clinical condition of a patient. The worried criterion has later been found to be the one used the most (64).

A large randomized controlled trial evaluating the effect of having a MET in place, reported no significant difference in effect on the incidence of unexpected death, cardiac arrests and unplanned admission for Intensive care between hospitals with or without MET systems (17). This has led to various reflections on the study design used and question whether a randomized controlled study design is optimal or even suitable for evaluation of interventions including a complex MET system (79). It also seems plausible that the study failed to address in enough detail the complexity of clinical and organizational issues, associated with changes in individual patient conditions, interprofessional collaboration and monitoring practice, and implementation of the intervention, in those hospitals where MET systems were used.

Despite the lack of strong evidence of positive impact of METs on in-patient mortality, the Australian idea of quickly transferring highly competent staff members to the bedside of severely compromised patients in general wards instead of awaiting traditional request for inspection by a more skilled senior staff member, made sense in the USA and the United Kingdom in the early zeroes,

where dedicated pioneers developed Rapid Response Teams (USA) (80;81) or Critical Care Outreach Teams (UK). In 2005 experiences from across Australia, USA and the UK and from the Netherlands and the Scandinavian countries had reached a level that called for an international conference on the topic followed by a consensus report (15), resulting in the previously mentioned definition of the RRS. Besides, much effort was put into proposing and evaluating various team constellations.

Early Warning Score systems

From the very first thoughts of developing EWS systems, their aim has been to detect deterioration in due time to prevent patient disability or death by rapid and appropriate bedside action (82). The EWS systems are clinical bedside tools designed to assist clinical health care providers (medical- and nursing staff) in evaluating vital organ function in individual patients based on bedside measurements and assessment of respiratory rate, heart rate, systolic blood pressure, cerebral awareness, body temperature and often also oxygen saturation (83-85). Each parameter is assigned a score between 0 and 3 (0 and 2 for body temperature) referring to defined intervals of numeric value obtainable. The scores are aggregated identifying a total EWS score, ranging between 0 and a maximum of 14 (Table 1). Patients scoring 0 have no abnormal deviation in any vital parameter and are clinically stable. Maximum scores recorded in the general ward patient seldom exceed 9.

There are numerous global EWS systems built on principles of the first one (82). Since then clinical use of repeatedly assessing combined individual vital parameters and interpreting changes in scores over time - instead of assessing results of a single measurement - has been widely recognized in clinical nursing and medical practice. The individual limits for each parameter value, with respect to obtaining scores of 0, 1, 2 and 3, have been further studied and discussed and various modifications based on clinical research have been proposed to optimize specificity and sensitivity of a scoring system (86-88).

A modified EWS system (MEWS) (88) was developed around the millennium, based on the original EWS system (82), but entailing modifications of thresholds for scoring points (Table 1). It was however validated in only 673 medical emergency admissions, entailing one set of measurements and assessments of vital parameters (not including the oxygen saturation) in each patient admitted. Until in 2010 the MEWS system remained the only validated EWS-system and its use spread rapidly throughout the UK, the Netherlands, and Scandinavia.

Table 1. *The Modified Early Warning Score (MEWS) instrument (88)*

Score	3	2	1	0	1	2	3
Respiratory rate		<9		9-14	15-20	21-29	$\geq$30
Heart rate		<40	41-50	51-100	101-110	111-129	$\geq$130
Systolic blood pressure	<70	71-80	81-100	101-199		$\geq$200	
CNS				Alert	Reacts to Verbal stimula-tion	Reacts to Pain	Unconscious
Temperature		<35		35-38.4		$\geq$38.4	

Studies indicating that MEWS values obtained at hospital admission may predict in-hospital mortality, and that MEWS positively impacted mortality and cardiac arrest rates (85) encouraged further research into the predictive ability of revised and expanded scoring systems, also including oxygen saturation to predict cardiac arrest and in-hospital mortality.

Much of this research has been based on retrospective studies of vital parameters measured at the point of patient admission to hospital of mainly medical patients (75). One of these studies, the SOCCER study (34;35), reports a significantly increased risk of in-hospital patient death, after early and minor deviations in more than two vital parameters. These results are in line with the approach and rationales behind EWS systems.

Gao et al. (2008) reported in a review (89) of all published EWS systems the ability of each system to predict mortality, aiming at identifying an EWS system superior to others. However, out of 33 available systems, of which only the MEWS claimed to be validated, it was not possible to point out one system being superior to the others.

The most recent study evaluating EWS systems was published in 2010 (37;38) and compares the British national EWS system, based on 198 755 sets of measurements, to a number of other widely used EWS systems. This study concludes that the British national EWS system has higher sensitivity and specificity for predicting in-hospital death and underpins the clinical value of

deviations in vital parameters in predicting death. Cerebral awareness as part of the EWS system has been questioned and so has age (90), however with no further conclusions.

The British National Institute of Clinical Excellence (7) has recommended use of EWS systems, and the development of the British national EWS, based on almost 200 000 sets of measurements was thoroughly tested for accuracy and comparison with other EWS systems (38). Nevertheless, the ability of EWS systems compared to clinical judgments, to detect deteriorating patients has remained under continuous discussion and challenge, within both nursing and medical practice (Odell 2010) and more knowledge of which bedside vital parameters are associated with deterioration would provide a sound base for further discussions into an optimized use of EWS systems.

The issue of setting limits to medical treatment e.g. by individual do-not – resuscitate (DNR) orders has been raised in the debate on effects of MET and entire RRS (92;93) and METs have been found to play a major role in identifying patients who are too frail to benefit from mandatory ventilation therapy or chest compression and initiating discussions of setting DNR orders (94). Setting individual limits to medical treatment has been reported often to take place on the same day as the first call to the MET (92;94). If not receiving aggressive cardiopulmonary resuscitation is the most ethical correct way to care for a patient, this development in clinical practice does not harm the patient and is argued to optimize patient safety (92). However, no patient should risk dying alone no matter whether a DNR order has been recorded or not. Within research on nurses' monitoring practice the issue of patients dying unexpectedly, and therefore sometimes alone, has not been raised much. It appears, however, appropriate to include nurses' role in assuring all patients of an ethical acceptable death when studying how nurses monitor in-hospital patients and detect those with clinical deterioration.

Implementation of clinical interventions

In 2008 the British Medical Research Council published an update of the *2000 MRC Framework for the Development and Evaluation of RCTs for Complex Interventions to Improve Health* (95). The revised edition aims at guiding researchers on development, evaluation and implementation of so-called *complex interventions*, characterized by several interacting components, several difficult behaviours required by those delivering – or receiving the intervention, several groups or organization levels targeted by the intervention, several outcome measures and considerable flexibility with which the intervention may be tailored (95).

According to this framework *implementing* an intervention should follow a four-step process entailing *developing, piloting, evaluating,* and *reporting.* It is emphasised not to focus too intensively on single components of this process (95).

Implementation refers to planning and realization intended to make any kind of intervention become part of daily practice (96). It is often a complex process starting long before the new clinical practice is introduced to its users (96;97). Implementing clinical interventions represents challenges to any hospital setting working with quality improvement tasks and clinical research (97).

Implementation has been argued to involve behavioural changes (98), and behavioural changes have even been proposed to be required for successful implementation is (99). To make participants of a specific implementation process change their behaviour, some elements are considered most valuable. Based on a large body of knowledge on implementation Damschröder et al. have presented a consolidated framework for implementation of research (100). In agreement with other reviews on implementation this framework points out five domains believed to influence implementation processes and outcomes - the interventions itself, the inner and the outer setting, participants and the implementation process.

The intervention itself, including underlying evidence and to what extend participants believe in the intervention is believed to be most important for successful implementation (100). To evaluate the implementation of track-and-trigger systems, or parts of them, this component is faced with difficulties since actual clinical benefits of track and trigger and EWS systems remain to be shown despite strong common sense appeal (75).

However, barriers among participants to adapt to new interventions are most common in many implementation processes and have to be appropriately met by implementation agents and stakeholders (96;100). To reduce obstacles to an

intervention requiring behavioural change, implementation researchers emphasize the importance of tailoring the implementation activities, i. e. designing strategies for implementation in accordance with the inner context (96;100).

Daily work in many clinical settings is burdened with demands to implement new programmes for health care, screening tools, systems for documentation etc. Each individual clinical intervention may seem meaningful and based on strong evidence, but implementation efforts may vary considerably and influence the outcomes of the intervention and/or implementation. Implementation of interventions as part of a research within clinical practices face the same challenges as implementation included in daily improvement activities (96;100). Implementation efforts need to be transparent and fully accessible to those who are concerned by these activities, not to hamper their active involvement in the implementation process and eventually also interventional outcome (96;100).

There is no evidence that specific implementation activities would be better than others or that more or combined activities should be preferred (97;99;101). However, it seems that implementation activities should target the unique mixture of barriers among the participants, and that positive expectations are required for successful outcome of an intervention (102).

Little has been reported on implementation activities in research reports on effects of MET and EWS systems, particularly before 2009. Incompletely reported details on implementation processes inhibits transparency (100), and studies enlightening implementation barriers, challenges and recommended strategies to achieve intended clinical use of an interventions, including use of EWS, are lacking.

Future studies should hence embrace aspects on the specific inner and outer settings, the participants involved, and important aspects of the process of implementation. This is particularly important since actual lack of this kind of information might give an impression that little has been done to support the process of implementation. If questions regarding the process of implementation were only addressed scarcely, this may be part of the reason why nursing and medical staff often neglect to call for help (103).

Adherence to an intervention deals with the extent to which the intervention was delivered as intended by its developer (102), and implementation fidelity is said to be high if an intervention adheres completely to the content, the frequency, duration and coverage (102).

Interventional outcome cannot be appropriately assessed without also evaluating adherence to the intervention (96;102), i. e. to what extent the intervention has been carried out as intended (96;102). Many clinicians involved in implementation processes realize that long-term sustainability of their efforts are not to find (102;104).

To appropriately evaluate effects of clinical interventions, the concept of implementation fidelity including adherence to the intervention and sustainability should be addressed (96;102;104;105). Few studies on clinical effects of MET including EWS systems, have reported interventional adherence or implementation fidelity, hence making it difficult to appropriately interpret interventional outcomes reported. The sustainability of effects of MET (but not EWS) systems has been evaluated in different settings, based on episodes of cardiac arrest and calls for the MET. Serious adverse events like cardiac arrest are rare, and large long-term studies, also addressing interventional adherence, would probably be required to confirm positive effects of MET and EWS systems on those events.

Scientific aspects

Until in 2009 EWS systems had been reported to predict in-hospital mortality in numerous retrospective studies all implying that scoring systems are useful to nursing and medical care givers in detecting deteriorating patients in due time (34;87;90;106-108). However, effects on patient safety of systematically using EWS systems together with an established MET system within a defined hospital study setting had not been thoroughly evaluated. Furthermore, since EWS systems were regarded as integrated key components of the entire RRS, little was known about what clinical benefits could be expected by implementing optimized monitoring practice and systematic use of early warning scoring. Evaluating effects of scoring system and rescue teams as single interventions might present an incomplete picture of effects, challenges and benefits of either component.

Most research published from 2005 to 2009 reports by what means the MET was called (17;64;81;109;110). Like other interventional studies of MET systems, the only randomized controlled study within this field reported if patients had fulfilled the calling criteria before fatal events and if nursing staff had responded to measured deviations in bedside vital parameters (17), but no details were provided on daily monitoring practice including interprofessional aspects.

Between 2009 and 2013, during the work with this thesis, European researchers have further evaluated and confirmed the predictive value of EWS systems. The roles of nurses in detecting deteriorating patients have been subjected to qualitative analyses enlightening some of the complexity of cooperatively identifying and managing deteriorating patients.

In spite of much effort to optimize patient safety it is still argued that hospital staff neglects to recognize severe physiological abnormalities of their patients in due time (8;10;44). It therefore seems reasonable to conclude that a major obstacle in

preventing serious adverse events is that nursing and medical staff are still at times unaware of the severity of the clinical condition of some of their patients, and they tend to neglect early important bedside actions to be taken, including calling for help, to prevent further medical deterioration and clinical adverse events. This can be explained partly by lack of knowledge regarding the significance of deviating vital parameters and the value of measuring and assessing vital parameters (8;10;44), but also by infrequent measurements and assessments of vital parameters as part of daily clinical nursing practice (1;8;44) and by an insufficient interprofessional approach to daily patient monitoring.

This thesis seeks to take into account some of the components and challenges contributing to patient safety in relation to nursing – and interprofessional monitoring practice. Accordingly the four studies of this thesis were designed to explore what influences and constitutes daily in-hospital monitoring practice if not guided by a mandatory monitoring practice algorithm, and if serious threats to patient safety, in terms of unexpected death, might be influenced by systematic optimization of the bedside monitoring practice.

Introducing systematic and mandatory use of any EWS systems in in-hospital patients is time-consuming and a major challenge to hospital organizations. To optimize the use of EWS systems in a highly busy healthcare system, where staff reductions and high patient safety standards are a priority of most hospital boards, we need to be able to focus on patients at higher risk of deteriorating and to learn more about predictive values of slightly increased early warning scores. This thesis also hints at providing detailed knowledge of which early deviations in vital parameters are particularly associated with severe worsening in general ward patients.

Aims

The overall aim of this thesis was to study in-hospital patient safety in relation to nursing monitoring practice of vital parameters in a general medical and surgical ward setting at a large Danish university hospital.

Specific aims of the research project were to:

- explore nursing practice of monitoring in-hospital patients, including intra- and interprofessional communication and collaboration **(I)**.

- evaluate adherence to a clinical in-hospital intervention, comprising optimization of interprofessional bedside monitoring practice including bedside actions **(II)**.

- evaluate short- and long-term effects of a clinical multi-component intervention, comprising a bedside track-and-trigger system, on unexpected in-hospital mortality **(III)**.

- determine the association between initial, minor deviations in bedside measurable vital parameters and severe clinical deterioration in the general ward patient **(IV)**.

Methods

Design

This thesis was designed to investigate different aspects of in-hospital nursing and interprofessional monitoring practice. To address this topic from different perspectives four studies with four different designs were conducted (Table 2). To explore what influences nursing monitoring practice, before altering practice through the intervention of this thesis, a qualitative design using both participant observation and semi-structured interviews was carried out (**I**).

To evaluate nurses' and physicians' adherence to the intervention and the implementation process a mixed methods approach was used, involving both quantity measures and semi-structured qualitative interviews (**II**).

To evaluate how implementation of a multi-component intervention comprising a mandatory, systematic and interprofessional use of a scoring instrument impacts patient safety measured by the mortality rate of unexpected deaths, a prospective, non-randomized pre-post interventional study was conducted (**II**).

Finally the thesis addresses determination of the association between early deviations in bedside vital parameters and severe deterioration. For this purpose a prospective, explorative design was used, using quantitative data from the two data-collection periods in which the intervention constituted daily practice (**IV**).

Table 2 shows an overview of the four papers, and Figure 1 shows the association between the four papers and areas related to patient safety as described in the background section of this thesis.

Table 2. Overview presenting designs, samples, data-collection and methods of analysis of the four papers in the thesis

	Paper I	Paper II	Paper III	Paper IV
Design	Explorative qualitative design	Mixed-methods design: Prospective and explorative qualitative	Prospective quantitative design Pre-post intervention	Prospective quantitative design
Sample	n=13	n=1671 n=4	n=25	n=1315
Data collection	Participant observation Semi-structured interviews	Numeric and clinical data from medical records and nursing charts Semi-structured interviews	Numeric and clinical data from medical records and nursing charts	Numeric and clinical data from medical records and nursing charts
Analysis	Qualitative content analysis	Kaplan-Meier calculations and Qualitative content analysis	Mortality rate ratio of unexpected deaths	Likelihood ratio test Binary logistic regression analysis Cox regression analysis
Outcome measures	Nursing practice of bedside monitoring practice	Pre- and post interventional monitoring practice Adherence to intervention	Incidence of unexpected in-hospital death Unplanned admissions for intensive care	Clinical deterioration from early deviations in vital parameters Time to Deterioration from early deviation

Figure 1. Chronological presentation of areas related to patient safety in terms of prevention of fatal adverse events – and corresponding scopes of the four papers of this thesis
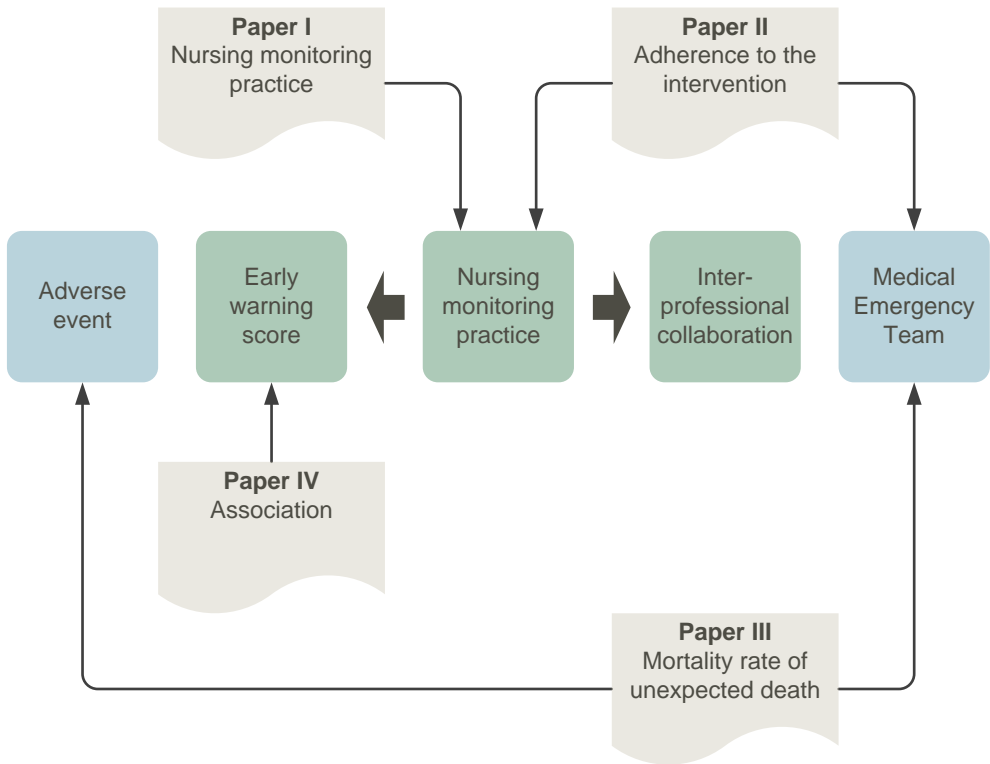
Setting and context

This thesis is based on four prospective, non-randomized interventional studies in a 68-90-bed four-ward department of both medical and surgical gastroenterology at Hvidovre Hospital, a Copenhagen University Hospital, in the capital region of Denmark.

In 2009, before the study intervention, almost 76% of all admissions to the study setting were emergency admissions and the number of beds at that time was 68. Due to enlargement of the hospital catchment area and a parallel organisational adjustment in patient uptake, the numbers of beds were 90 in the summer of 2011 and the proportion of emergency admissions was 85%.

The study setting comprised one emergency admittance ward, from which patients were transferred to either a medical ward, or to one of the two surgical wards. The other surgical ward was mainly for elective patients. In 2009 the department also comprised three semi-intensive beds and during the study period the number of semi-intensive beds doubled to six. Patients in either of the four study wards were transferred to and from the semi-intensive beds.

The four wards of the study setting shared an interprofessional team of department managers consisting of two members with a background within medicine and one within nursing.

All four wards had one nurse ward manager allocated and each formed a small team together with a senior consultant taking care of daily management within each ward. The number of nurses allocated to each ward rose during the study period corresponding to the local enlargement of patient beds, so that the organisational allocated number of nurses per patient bed stayed the same throughout the study period. At times there would be one to four patients in each ward beyond the number staffed to manage, and mostly one nurse would care for five to eight patients during a shift with assistance from nursing assistants, who besides helping patients with personal caring needs also served meals and drinks.

In the surgical ward, 45-minutes to one-hour patient rounds were led by a senior consultant, specialized in gastroenterological surgery in the morning, and by a less experienced consultant in the afternoon.

In the medical ward, a senior consultant specialized in gastroenterology led patients rounds lasting several hours in the morning, whereas less experienced physicians were in charge of patient rounds in the afternoon.

A local in-hospital MET system had been in place since 2007. Since nursing staff at the study setting had taken part in educational initiatives when this system was

implemented and had used the system frequently since then, they were in 2009 quite familiar with calling the MET.

Patients and participants

Most patients, admitted to the study setting, were hospitalized mainly for gastroenterological emergency disorders, and had been initially judged by their general practitioners or by emergency physicians at the large general emergency department of the hospital, to require further assessment by medical or surgical gastroenterologists. The study patients were then either discharged within two or three from the emergency admittance ward, or transferred to the medical or surgical wards of the study setting for prolonged in-hospital care.

In addition to having an acute or chronic gastroenterological disorder, also including gastroenterological malignancy, several study patients had chronic medical co-morbidities like chronic heart failure, chronic obstructive pulmonary disease and/or diabetes mellitus. Many of them had been admitted to the study setting before, or more than once during the time span of this study.

Participants in the first qualitative study (**I)** comprised 13 general ward, female registered nurses (RN). They were purposeful selected based on their age and length of experience within nursing (Table 3).

Participants in the second qualitative study (**II)** comprised all four nurse ward managers of the department, who were also opinion leaders during the implementation process. They were all women in their late thirties or early forties and had been in their job position for more than five years.

Table 3. Participants in the first qualitative observational and interview study of the thesis.

Participant	Age/years	Duration of clinical practice (years)
Nurse A	50	20
Nurse B	30	3
Nurse C	43	16
Nurse D	29	2.5
Nurse E	25	8 months
Nurse F	33	6.5
Nurse G	43	18
Nurse H	54	30
Nurse I	26	2
Nurse J	29	1 year and 9 months
Nurse K	28	4
Nurse L	30	5
Nurse M	27	9 months

A total of 3 907 patient admissions lasting eight hours or more to the three stationary wards of the study setting during all three study periods in 2009-2011 were eligible for inclusion in the quantitative part of the second study (**II**)**,** and 1671 of these admissions, where deviations in vital parameters corresponding to a total MEWS value of ≥ 2 had been recorded at least once, were included.

In total 6 183 patients were admitted to all four wards of the study setting for 24 hours or more during study periods in 2009- 2011. Of these patients 156 died during hospitalization, and were eligible for inclusion in the quantitative third study (**III**)**.** The final study sample comprised those 25 patients, who died unexpectedly during their admission without a DNR-order. They were either found dead (no cardiopulmonary resuscitation attempts made), or died after cardiac arrest (cardio-pulmonary resuscitation attempt made), or in the ICU within 24 hours of transfer from the study setting.

A total of 2 962 patient admissions lasting 8 hours or more to the study setting in the two postinterventional study periods 2010 - 2011 were eligible for inclusion in the last study **(IV).** The study sample consisted of those 1 315 admissions where a total MEWS value of at least 2 had been recorded once or more.

Intervention

The multi-component intervention aimed at optimizing patient safety by changing attitudes and behaviours of nursing and medical staff. The intervention comprised three major components (Figure 2), based on structured principles of bedside monitoring, recording and management of in-hospital patients. Thereby the intervention covered three main areas related to patient safety and previously described in the chronological presentation of patient safety issues.

Figure 2. Main components of the clinical intervention and their associations to areas related to patient safety as reported in the background section.
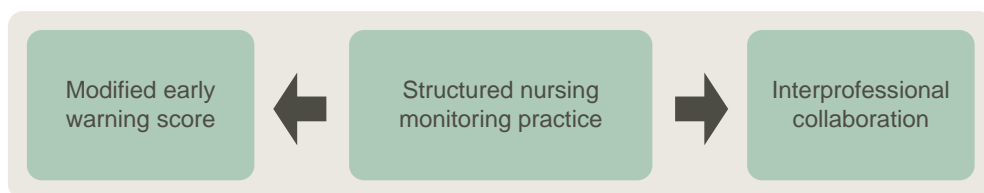
Monitoring practice

The main component of the study intervention was a mandatory, systematic, and interprofessional in-hospital monitoring practice.

According to this practice values of respiratory rate, heart rate, blood pressure, cerebral awareness, and body temperature were to be systematically measured or assessed in all patients, except for those under terminal care, throughout the period of admission.

MEWS values corresponding to each separate vital parameter measured or assessed were immediately calculated and recorded together with the total MEWS value. Bedside values were scheduled to be obtained approximately eight-hourly in patients scoring 0 or 1 – and more frequently in patients with higher total MEWS values and/or signs of clinical deterioration, according to an algorithm also including guidelines for appropriate bedside actions. Individual values of oxygen saturation and supply were also to be measured and recorded, however with no corresponding scoring (Figure 3).

The intervention also included daily interprofessional knowledge-sharing sessions based on individually obtained MEWS values, at the daily morning and afternoon ward rounds and when physicians were called during evening and night shifts.

Figure 3. Observation chart designed to be part of the clinical intervention in a pre- and post-interventional study at an urban Danish university hospital.

Modified Early Warning Score (MEWS) Subbe et al. Q J Med 2001; 94: 521-526   20__

Score	3	2	1	0	1	2	3
Resp. rate		< 9		9-14	15-20	21-29	≥ 30
Heart rate		< 40	41-50	51-100	101-110	111-129	≥ 130
Blood press.	< 70	71-80	81-100	101-199		≥ 200	
avpu				alert	responds to voice	responds to pain	unresponsive
Temperature		< 35		35-38.4		≥ 38.5	

Date		Score		Score		Score		Score		Score		Score		Score
Time														
Respiratory rate														
Heart rate														
Blood pressure														
avpu														
Temperature														
MEWS Total	Init.		Init.		Init.		Init.		Init.		Init.		Init.	
Saturation														

Saturation

Saturation ≤ 95: Optimize patient positioning and supply oxygen

Saturation ≤ 90 despite oxygen supply: Call MET and physician on-call

MEWS score = 0 • Continue observation and score every 8th hour

MEWS score = 1
• follow algorithm for bedside nursing action
• if score is due to major drop or rise in just one parameter contact physician on-call
• if score is due to minor drop or rise in just one parameter, continue observation and score every 8th hour

MEWS score = 2 - 4
• follow algorithm for bedside nursing action. If score is due to minor drop og rise in more than one parameter, continue observation and score every 4th hour
• if score is due to major drop or rise in just one parameter, contact physician on-call, re-observe and re-score
• if the RR ≥ 30 call MET and physician on-call, re-observe and re-score

MEWS score ≥ 5
• follow algorithm for bedside nursing action
• contact physician on-call, re-observe and re-score • Call MET

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Modified Early Warning Score (MEWS) Subbe et al. Q J Med 2001; 94: 521-526

20_ _

Score	3		2		1		0		1		2		3
Resp. rate			< 9				9-14		15-20		21-29		≥ 30
Heart rate			< 40		41-50		51-100		101-110		111-129		≥ 130
Blood press.	< 70		71-80		81-100		101-199				≥ 200		
avpu							alert		responds to voice		responds to pain		unresponsive
Temperature			< 35				35-38.4				≥ 38.5		

Date		Score		Score		Score		Score		Score		Score		Score
Time														
Respiratory rate														
Heart rate														
Blood pressure														
avpu														
Temperature														
MEWS Total	Init.		Init.		Init.		Init.		Init.		Init.		Init.	
Saturation														

Bedside nursing action

Airway A   Raise patient to an upright sitting position or/and support neck and shoulders to establish and secure patient airway

Breathing B   Supply oxygen by nasal cannula or face mask until saturation of oxygen is ≥ 95

Circulation C   Establish and secure intravenous line and supply fluid according to medical orders
Raise foot end of patient bed
In severe hypotension, lower head end of patient bed

Observation and scoring chart

All assessed vital parameters and corresponding MEWS values were recorded in a new observation and scoring chart. The chart was designed in close collaboration with nursing staff in the study setting to provide a comprehensive view of the clinical course in each patient. Ranges of values of each vital parameter recorded, indicating different scores of severity, were colour-coded in green, yellow, orange, or red on top of the observation chart (Figure 3).

Algorithm for bedside action

The intervention also included an algorithm with brief guidelines on when and whom to call, and on immediate bedside responses of nurses and physicians to deviating vital parameters according to basic ABC principles of emergency management, and on how frequently to re-score.

The bedside algorithm was also colour-coded in green, yellow, orange, and red in agreement with the MEWS coding. Green colour coding was used for MEWS values of 0 requiring no specific further action, whereas red coding was used for MEWS values of 5 and above calling for urgent and appropriate bedside action (Figure 3).

Implementation

Teaching and training

The programme of teaching and training was designed and realized by me in close collaboration with the hospital department of education and human resource development, and with ward managers and a senior anaesthesiologist. During the sessions of theoretical teaching and full-scale simulation training, it was emphasized that each staff member should seek to obtain an optimal impression and view of each patient by combining clinical observation and professional gaze with numerical bedside values of vital parameters and MEWS to detect patient deterioration throughout the process of implementation. Activities for implementation are presented in Table 4.

All nurses and nursing assistants employed at the study setting took part in a four-hour teaching session of theory, addressing issues of vital parameters/early warning signs, monitoring practice and basic principles of emergency

management. Nursing staff employed between February 2010 and June 2011 participated in two-hour teaching sessions. Physicians went through 45-minute specific teaching sessions of theory, or 30-minute sessions for new medical employees.

All nursing staff participated in a four-hour session of in situ full-scale simulation training between September 2009 and January 2010. The training entailed four different cases in which a patient gradually deteriorated. An actor simulated four different deteriorated patients typical of the study setting. The participators were given basic patient information similar to that obtained at shifts' turnover, and could ask for further information including values of bedside vital parameters. They could also call the MET and medical assistance if they wanted to. A moderator guided the process by providing information on changes in the clinical condition. Two members of the nursing staff took part in each training session, and the sessions lasted approximately 25 minutes. They were observed by 4-6 nursing colleagues, by a staff member from the hospital department of education and human resources, and by myself. Each training session was followed by individual reflective de-briefing under supervision by educational staff members.

For organizational and staffing reasons, only approximately one in ten physicians had formal simulation training.

Trained nurses in the study setting guided physicians individually in clinical use of observation charts and algorithms of bedside action.

Promotion

Nurse ward managers in the study setting were tasked to be opinion leaders, continuously promoting the intervention and motivating nurses and nursing assistants to pursue the intervention by reassuring them of clinical benefits of optimizing monitoring practice. The opinion leaders constantly aimed at bridging the gap between evidence-based knowledge and clinical application. They all had long experience (>5 years) being a nurse ward manager and had all been present during the entire implementation process, thus being familiar with the aim of the intervention and its individual components.

Collaboration and communication

Three one-hour knowledge-sharing sessions for senior nursing and medical staff, aiming at optimizing interprofessional collaboration and communication on deteriorating patients, were held during the process of implementation

Table 4. Activities used to implement clinical intervention of systematic in-hospital patient bedside monitoring and management practice at a four-ward medical and surgical study setting in an urban Danish university hospital.

Implementation activity	Extent and main purpose
Interprofessional programme of teaching and training for medical and nursing staff members in the study setting	Four-hour teaching session of theory, addressing early warning signs, sepsis, monitoring practice and ABCDE principles of emergency management, for optimization of basic professional knowledge
	Four-hour session of full-scale simulation training, addressing detection and interprofessional emergency management of deteriorated patients, for optimization of professional collaborative and clinical skills
Interprofessional programme of knowledge-sharing sessions for medical and senior nursing staff members	Three one-hour sessions for promotion of interprofessional communication and collaboration on deteriorated patients
Nurse ward managers and ward nurses as opinion leaders for staff members in each ward of the study setting	Continuous promotion of individual participation in the intervention for optimization of monitoring practice and patient safety, and for continuous bridging of gaps between research knowledge and clinical bedside application
Visits by main investigator in each ward of the study setting	Weekly one hour feedback sessions addressing educational, interprofessional, organizational and clinical issues aiming at optimizing staff's understanding of the intervention

Feed-back

I made regular feed-back visits to the individual four wards of the study setting on a weekly basis addressing issues of teaching, training and clinical practice including interprofessional communication and collaboration, as well as supervising the operational design for feed-back to nursing staff and ward managers.

Preconception

A main preconception of mine was that nursing staff in the study setting would focus mainly on nursing tasks closely associated with clinically relevant medical or surgical diagnostic and therapeutic procedures and that this might lead to sub-optimal routine patient observation and management of high-risk patients with multiple or serious medical problems.

As interviewer in the qualitative second study (**II**), and as the person who had invented and carried out the study intervention, I had been deeply involved in the implementation process. This provided me with a strong preconception of the process itself and substantial impressions of how nurse ward managers might have experienced it. The research group handled these preconceptions by using investigator and data triangulation in qualitative parts (**I-II**) of the thesis. However, the three co-investigators had not been employed in hospital wards similar to those of the study setting for many years and hence came to evaluate the information obtained with fresh eyes.

Data collection

The overall aim of this thesis called for analysis of both qualitative and quantitative data collected during different periods of time throughout the process of implementation. A chronological view of the timespan, periods of data collection, and interventional and implementation activities is shown in Figure 4.

Figure 4. Schematic presentation of study periods, data-collection, and process of implementation in a pre-post interventional study at an urban Danish university hospital
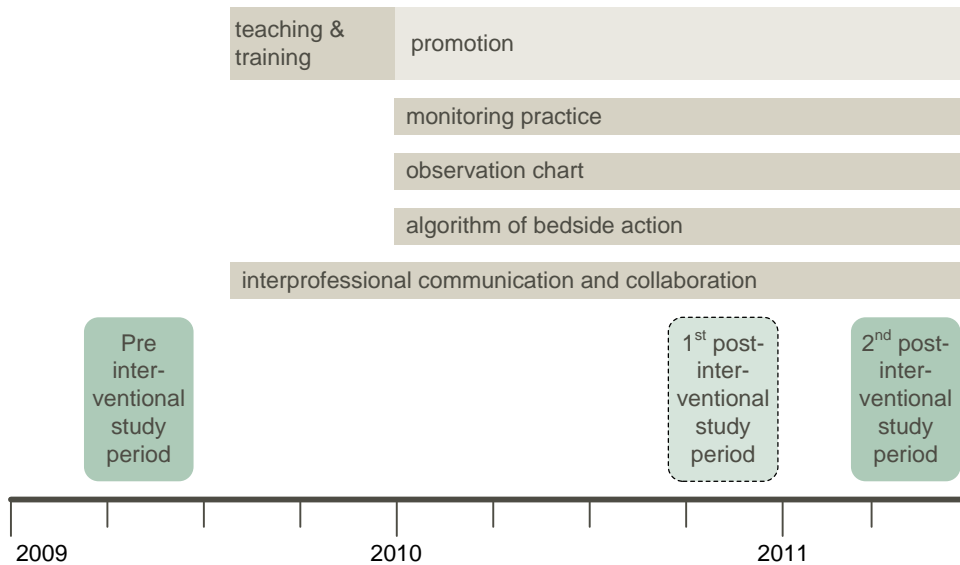
First, to explore nursing monitoring practice, a qualitative observational and interview study (**I**) was carried out in March-June 2009. These four months also constituted the pre-interventional study period for longitudinal quantitative data. (**II-IV**).

Following these four months, the process of implementation started by including teaching and training sessions and promoting interprofessional communication and collaboration (Table 4). In February 2010 the multi-component intervention was taken into use in the study setting, and the implementation process continued, promoting and supporting the intervention by opinion leaders and feed-back visits. The two four-month study periods September-December 2010 and March-June 2011 were the first and second post-interventional data-collection periods (**II-IV**).

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Promoting and supporting the intervention and process of implementation continued throughout the entire timespan.

Participant observations and interviews

Structured bedside observations (**I**) and semi-structured interviews (**I-II**) of participants were used to obtain the qualitative data analysed and reported.

The thirteen observations in this thesis (**I**) were carried out as structured observations in the natural settings of the participants, and placing the researcher on the side-line of the daily activities, only very briefly interacting with the participants. An overall predetermined perspective on what might be of interest and of influence to daily monitoring practice guided the approach.

An observation guide (Table 5) guided the observer who continuously during the observations took notes.

Table 5. Guidelines for bedside observation of participants included in the first study (I) carried out at a four-ward medical and surgical study setting in an urban Danish university hospital.

Clinical practice of observation, assessment, and management of patients

How and when did nurses obtain clinical information on vital parameters of their patients?

Which clinical parameters were measured on the day of observation, how often were they measured and which parameters had been measured the day before?

Were specific vital parameters measured as a result of any observed specific nursing activity or specific nurse/patient or nurse/physician interaction?

Practice of documentation and reporting of observations

Where and when did nurses record measurements of vital parameters?

To whom did nurses and nursing assistants report their findings?

Interprofessional collaboration and communication

What actions were taken as a result of values of measured vital parameters?

Intraprofessional (nurses) collaboration and communication

What actions were taken as a result of values of measured vital parameters?

Semi-structured half-hour (**I**) to one-hour (**II**) interviews were made with an inductive approach according to detailed guidelines (Tables 6-7), always starting

with an open question, in an undisturbed part of the ward immediately after each period of observation (**I**) or in an office close to the ward (**II**). All interviews were recorded and transcribed verbatim. Notes were also taken to promote follow-up (**I-II**).

Before the interview, each participant was briefed about study aims and design, emphasizing that her individual experiences of ward practice with respect to observation, assessment and recording of medical conditions and vital parameters, together with relevant interprofessional communication and collaboration, were key elements of the study (**I**). After each interview the participant was asked not to mention study issues to colleagues to prevent future participants from modifying their individual practice during bedside observation (**I**).

Table 6. Interview guide for pre.interventional semi-structured interviews of registered nurses at a four-ward medical and surgical study setting at a Danish urban university hospital

Clinical practice of observation and measurement	Clinical practice of documentation	Collaboration and communication
How would you describe normal procedures in regard to measuring vital parameters in your ward?	Please, describe the general practice of recording measurements of vital parameters?	Please describe your routines regarding the reporting of measurements of vital parameteers during ward rounds?
How do nursing staff know which patients need having measured their vital parameters?	Where, in your opinion, do nursing staff record vital parameters, measured during clinical deterioration?	How do you communicate with physicians about patients' vital parameters?
Who decides which parameters to measure in the individual patient?		How do you and your nursing collegueas share tasks of monitoring patients?

Table 7. Interview guide for individual semi-structured interviews of ward nurse managers and opinion leaders to evaluate adherence to clinical intervention of systematic in-hospital patient bedside monitoring and management practice at a four-ward medical and surgical study setting in an urban Danish university hospital.

Questions	Probes
Please, tell me about your experience of the implementation process in your ward during the last 18 months, aiming at implementing the current intervention.	Could you please tell me more about that?
	Why do you think it is so?
Please, describe the implementation strategy as you recall it or as you experienced it.	
	Have you got any further comments?
Please, point out elements in the implementation strategy, which you believe to have had particular positive or negative impact on both the implementation process and the intervention itself.	
Please, describe any specific circumstances, events or actions taken during the implementation process, which you believe to have had particular positive or negative impact on the implementation process.	
Please, tell me to what degree you consider the implementation to have been successful.	

Measurements

Information was obtained from hospital patient registers on total numbers of patient admissions to the study setting lasting 8 and 24 hours, respectively, on total numbers of patients who died, and on the individual security number for each patient admission, during the three four-month study periods. Based on this information, data for all quantitative analysis were manually collected by inspection of medical and nursing records of patient admissions.

Medical and nursing records of all patients, who died while being admitted to the study setting during study periods, were analysed in further detail. The exact time of admission and the exact time of death were checked to confirm that the patient had been admitted to the study setting for at least 24 hours before dying. The medical records were thoroughly evaluated to see if a DNR-order had been put down, and nursing records were analysed to find out if death had been expected, e.g. if it had been recorded that family members were present at the bedside, or that the patient had passed in peace. If neither of the two was found, and admission for at least 24 was confirmed, the patient admission was included in the study, and medical and nursing records were subjected to further data collection.

All medical records of admission for intensive care of patients from the study setting during the three study periods were also analysed to identify patients who died in the ICU less than 24 hours after arrival from the study setting. Those patients were categorized as having died unexpectedly and included in the study (**III**). Their medical and nursing records were subjected to further data collection. This process simultaneously identified patients in the subgroup *unplanned admission for intensive care* (**III**).

Calls to the study setting during study periods were identified from a local hospital database of all calls responded to by the cardiac arrest team. The exact time of admission and the exact time of cardiac arrest were checked to confirm that the patient had been admitted to the study setting for at least 24 hours before the cardiac arrest. Those patients were also checked against the group of patients who were recorded to have died in the study setting to identify any missing ones and survivors. During this procedure a small group of patients having survived an in-hospital cardiac arrest was identified. Both those who died and those who survived the cardiac arrest were subjected to further analysis (**III**), though keeping the survivors outside the mortality rate analysis.

Medical and nursing records of all patients, who had been admitted to the study setting for at least eight hours, were manually checked for date, time and place of admission to confirm their eligibility to be included (**IV**). We then identified those who at least once during hospitalization had a total MEWS value of 2 recorded in their observation charts and subjected their medical and nursing records to further data collection (**IV**). Those who remained at MEWS 0 or 1 throughout admission were subjected to less detailed data collection (**IV**). Patients were included more than once if they had been admitted to the study setting at least twice during the three study periods.

Quantitative data most important to the studies (**II-IV**) were numerical values of bedside measurable vital parameters (respiratory rate, heart rate, blood pressure, body temperature, cerebral awareness and oxygen saturation), and oxygen supply,

together with the time, date and locations of each measurement, and corresponding separate and total modified early warning scores obtained.

Vital parameter data from the 24-hour period of admission immediately preceding unexpected death (**III**) or the first measurement of a total MEWS value of 2 together with corresponding data from the remaining period of admission (**IV**) was also obtained.

Analysis

Qualitative content analysis

The text emerging from the transcribed interviews and observation notes (**I**) and interviews (**II**) were analysed as two individual text bodies, separated from each other in time and aim, by content analysis inspired by the descriptions by Graneheim and Lundman (111).

A deductive approach was applied to the observational notes (**I**), whereas inductive content analysis was applied to the interview texts.

Researcher triangulation was used (**I-II**) further improve knowledge and understanding by allowing second researchers to independently interpret the text.

Each set of observational (**I**) notes and interview text (**I-II**) represented a unit of the analysis. They were all read through several times by two researchers independently of each other and divided into meaning units representing several sentences relating to the same central meaning. Having divided all interview text (**I-II**) and all observation notes (**I**) into meaning units, each meaning unit was condensed whereby the text was shortened but the core meaning of the text remained. A first step of abstraction then followed whereby codes were created, labelling each condensed meaning unit. After coding, each of the two researchers moved on to the process of creating categories, which entail content-sharing commonality and are threads throughout the codes. Sub-categories were identified during the process of abstraction leading to the final categories. At this point the two researchers met to discuss their findings (**I-II**) and to merge text sections from observations and interviews (**I**). In collaboration with a third researcher the final categories were formed (**I-II**). A theme was created by all authors to express the latent content of the entire text material (**I-II**).

Statistical analysis

Descriptive statistics were used for basic analysis in all study periods (**II-IV**). Categorical data is reported as numbers with percentages in brackets, and continuous data as mean values with standard deviations (SD) and median values with 95% confidence intervals (CI) in parenthesis.

The rate of unexpected deaths per 100 patient admission years was compared between the three study periods using Poisson regression analysis with the logarithm to the risk-time as an offset (**III**) (112;113).

The mortality rate was calculated based on the total risk time defined as the total number of individual patient days spent in the study setting, adjusted for the initial 24 hours of admission and the time spent in hospital after a DNR order had been recorded (**III**). The mortality rate ratio between the mortality rates in 2011 and 2009, and in 2010 and 2009, respectively, and their statistical 95% confidence intervals (CI), were calculated (**III**).

Adherence to the intervention was evaluated using Kaplan-Meier estimates to calculate time intervals between measurements of vital parameters and to estimate the cumulative measurement incidence (**II**) (112;113). In this analysis, measurement of vital parameters was regarded as an event comparable to the event *death* when using Kaplan-Meier in survival analysis, and patients were censored when they were either discharged or died. The results are reported as survival curves and in percentages with 95% CI in parenthesis (**II**).

The Logrank test was used to compare calculations of time to the next measurement of the individual single-parameter (heart rate, blood pressure, body temperature) between the pre-interventional study period and each of the two postinterventional study periods (**II**).

Since patients in everyday clinical practice cannot be monitored simultaneously, we accepted in our analysis grace periods of 1.0 h in patients scoring total MEWS values of 0 or 1 and a grace period of 0.5 h in those scoring total MEWS values of 2, 3 or 4, beyond the time intervals between measurements stated in the bedside algorithm (Figure 3).

Associations between severe deterioration and early deviations in vital parameters were determined using binary logistic regression and Cox regression analyses (112;113) where the dependent variable was deterioration to MEWS ≥ 4 and independent variables were vital parameters of the MEWS instrument (except cerebral awareness which was assessed inappropriately) together with oxygen saturation, patient age and gender.

Association between demographics or deviation in vital parameters and clinical deterioration were analyzed in two ways. Logistic regression was used to determine whether deterioration occurred or not from the time of first total MEWS scoring of 2 or 3 until discharge from the study setting. Cox proportional hazard regression analysis was used to establish, from calculated cumulative incidences with death and discharge as competing events, whether demographics and vital parameters were associated with time to attain a total MEWS value of ≥ 4 from the time of the first total MEWS of 2 or 3 (**IV**).

We hypothesized (**IV**) that both higher and lower values of heart rate, respiratory rate, blood pressure and temperature might be associated with clinical deterioration, and to allow for this we adopted the following analytic strategy: First the parameters under consideration were entered as quadratic as well as linear values. Subsequently we removed quadratic terms with P values above 0.10. Results from the resulting logistic regression are presented as odds-ratios (OR) with corresponding 95% CI and P values. Likewise, results from the resulting Cox-regression are presented as hazard-ratios (HR) with corresponding 95% CI P values. The cumulative incidence is illustrated as graphical plots, and the difference between patients deteriorating from total MEWS values of 2 and 3 respectively, was tested with a log-rank type test (**IV**).

P-values below 0.05 were considered statistical significant (**II-IV**).

Ethical considerations

The study design and the research programme were approved by the Danish Ethical Committee, (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, formal ethical approvals are not required for studies not involving biomedical issues.

Issues of potential risks to patients as an effect of the intervention was discussed with the Danish National Board of Health and the Danish Ethical Committee and both organizations agreed that the intervention did not introduce new procedures to patients but instead intensified the use of well-known procedures, hence not putting patients at risk. The head of the department and hospital directors approved the study.

During observation sessions (**I**) patients and their relatives were informed by me that nursing staff and their clinical practice was being observed.

As a trained intensive care nurse and MET nurse I was aware that I needed to interfere in case of neglect of signs of severe deterioration, which might put

patients at risk, but this was never required (**I**). After the observations the participants were informed in more detail of the aim of the study, and they now gave written informed consents of their participation.

As only very few male RN were employed at the study setting we chose not to include male RN as it would be difficult to secure their anonymity.

The Helsinki Declaration (www.wma.net) was followed in all steps of the qualitative parts of this research process (**I-IV**). Participants were asked to participate in the observations after having been informed that the aim was to observe nursing practice with no further description of which parts of nursing practice were of special interest to the researcher (**I**). It was emphasized that the aim of the study was not to judge what was right or wrong but to achieve knowledge of what influences monitoring practice. Fourteen nurses were asked, one declined and the thirteen gave oral consent of being observed.

The participants were informed about the voluntary aspect of participating and guaranteed the freedom to terminate the observations of the interviews at any time (**I-II**). They were assured of their confidentiality throughout the entire research process. None of the participants should experience feelings of being exposed or feelings of incompetence. During the implementation activity of simulation training qualified de-briefers guided all participating staff members through reflecting on the scenario in which they had participated, to make every one gain learning results again without feelings of being negatively exposed.
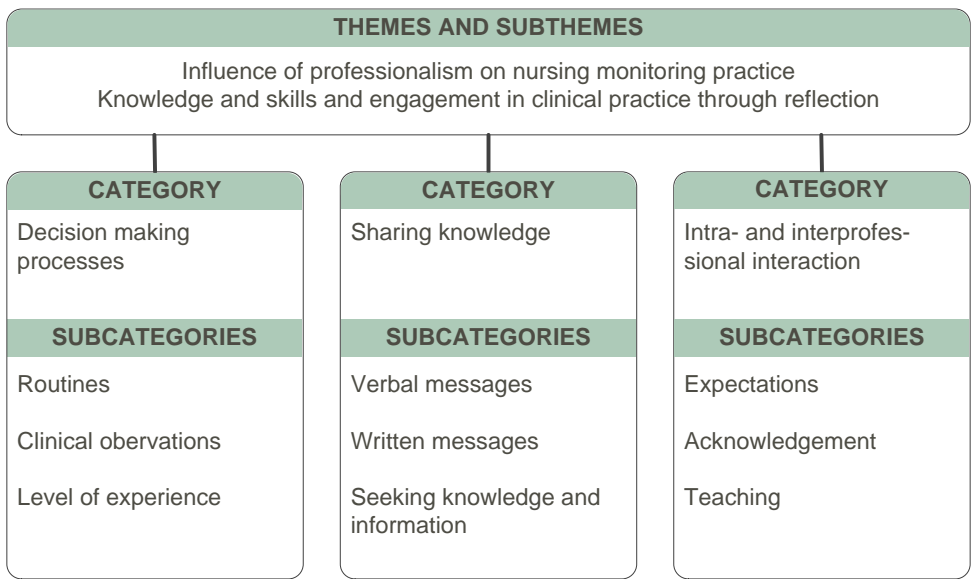
Results

Nursing monitoring practice

We aimed at exploring nursing practice of monitoring in-hospital patients (**I**) to gain deeper knowledge of what constitutes this monitoring practice and to learn about intra- and interprofessional communication and collaboration practices in relation to monitoring patients.

We identified one theme and two sub-themes, covering three categories. All categories were associated with the theme, the sub-themes and with each other as presented in Figure 5.

Figure 5. Findings from semi-structured interview of 13 RN at a four ward medical and surgical ward study setting in a Danish urban university Hospital.

THEMES AND SUBTHEMES		
Influence of professionalism on nursing monitoring practice Knowledge and skills and engagement in clinical practice through reflection		
CATEGORY	**CATEGORY**	**CATEGORY**
Decision making processes	Sharing knowledge	Intra- and interprofessional interaction
SUBCATEGORIES	**SUBCATEGORIES**	**SUBCATEGORIES**
Routines	Verbal messages	Expectations
Clinical obervations	Written messages	Acknowledgement
Level of experience	Seeking knowledge and information	Teaching

Professionalism

The concept of professionalism was found to cover essential core features influencing several aspects of monitoring patients, communicating, and collaborating about monitoring issues which would then determine the quality of nursing monitoring practice. The concept of professionalism, entailing characteristics like personal involvement in and reflection on clinical practice, knowledge, skills and clinical experience, appeared to be both the high standard of nursing practice, which some nurses aimed at every day, but also to be a challenge to others.

A professional attitude towards the task of monitoring was observed to guide individual nurses in their clinical decision-making. Professional awareness was observed and expressed to have decisive impact on nursing monitoring practice. Nurses who by performing their daily tasks in relation to monitoring patients revealed a deeper and broader understanding of patients and of the complexity of nursing were also observed to monitor their patients more thoroughly and to take time to involve in reflections on their clinical observations, the necessary actions and consequences, than those reflecting a less developed professional awareness.

Nurses' involvement in their clinical practice and the priority they gave to professional issues, were both found to considerably influence clinical monitoring practice. Individual perception and understanding of medical deterioration, combined with professional knowledge and skills, were observed to be associated with monitoring patients. The levels of knowledge and skills were found to influence both monitoring practice, decision-making, sharing of knowledge and inter-professional collaboration. Conclusions were reported to be drawn based on professional knowledge and individual reflections or on uncertainty of the importance and significance of values of vital parameters. Nurses' reflections and expressions on what might be gained by extending measurements and optimizing monitoring practice indicated personal engagement in clinical practice.

Decision-making

Individual clinical decision-making processes were observed and expressed to differ considerably in the wards despite similar local routines and guidelines. Vital parameters were routinely measured at 6 a. m. and at 4 to 5 p. m., and never more often as a routine. They included measurement of body temperature, heart rate and blood pressure in some, but not all, patients. The respiratory rate was never measured as a routine procedure, and physicians were reported seldom or never to ask for it.

Clinical practice and decision-making would either be organized according to written standard care plans or to decision-making by individual nurses regardless of their clinical experience. Decision-making was observed and verbalized to be influenced by clinical knowledge of individual patients including their previous vital signs, but also by the workload during the present or the following working shifts.

Nursing assistants often carried out planned tasks of measuring vital parameters and briefed the nurses when worried by their findings. Nurses believed that the individual level of nursing experience would impact how nurses observed patients, assessed their observations and paid attention to further observations and actions. Accordingly, nurses with intermediate or long experience (Table 3) were observed to carry out, record, assess and act on their bedside measurements in a more reflected and thorough manner, and to be more aware of the clinical value of combining bedside values of vital parameters with clinical observations to earlier detect patient deterioration. Others were observed to measure only vital parameters closely associated with specific clinical signs while neglecting others. Feelings of worry about a patient's clinical condition would make nurses measure vital parameters before calling the physician, knowing that the physician would ask for this piece of information. However, not all nurses were familiar with the value of knowing vital parameters in all their patients.

Sharing of knowledge

Nurses looked for recent information on vital parameters in patient charts at the start of each working shift, and argued that they used this routine to become familiar with the basic physical state of each patient and to be well prepared for the ward round. Other nurses described this working habit as a means of detecting values of vital parameters, in their patients, deviating from what would be expected taking into consideration surgical procedures or epidural lines.

Apart from body temperature, vital parameters were only occasionally reported by nurses or requested by physicians during ward rounds. Both professionals considered there to be neither need nor time for sharing values of normal, or presumably normal, vital parameters.

Overview charts showed which patients were to have their vital parameters measured. Nursing assistants often carried out tasks of measuring scheduled vital parameters and were observed to always record their individual routine measurements in the nursing observation charts during each working shift. In the interviews, all participants strongly emphasized the practice of recording all non-scheduled measurements made in deteriorating patients.

Specific text markings or verbal messages from colleagues alerted nurses to patients at particular risk of deterioration. Nurses reported use of special codes to indicate whether vital parameters were normal or not. Nevertheless, no nurses were able to recall discussions or instructions on how to decide which vital parameters were to be considered abnormal, or on how to deal with them. In that respect they relied on their professional experience and basic nursing training.

Intra- and interprofessional interaction

Collaboration between nurses and physicians was observed and reported to be characterized by professional involvement. Both professions gave priority to clinically relevant matters during ward rounds. There were different opinions on collaboration in deteriorating patients. Nurses felt that individual clinical deterioration had to be quite severe to make physicians respond rapidly. By contrast, others felt that, whenever they needed medical assistance, it would always be close at hand.

Some physicians were reported to require a complete clinical description of the patient, including values of their vital parameters, to attend, whereas others were reported to attend just by the nurse expressing being worried. Younger and less experienced nurses were less willing to give their personal opinions to the physicians, while more-experienced ones would provide more input, take more active part in medical decision-making and propose clinical measures to be taken. All participants were found to expect physicians to listen to them and take them seriously. Mutual acknowledgements of clinical skills and professional judgment were frequent characteristics of the interaction between nurses and physicians, but the opposite was also observed. Many physicians acknowledged the work of the nurses and appreciated their observations and individual reflections, however, opposite opinions were also observed and expressed.

Unexpected patient death

The analysis of unexpected in-hospital mortality rate (**II)** was conducted in patients who had been admitted to hospital for 24 hours or more, and the analysis was based on the total risk time spent in hospital by this group of patients. Table 8 shows descriptive results of the patients eligible for inclusion.

*Table 8. Descriptive statistics and mortality figures in patients eligible for inclusion in the third study (**III**)*

	2009 (n = 1870)	2010 (n = 2079)	2011 (n= 2234)
Female (%)	1 085 (58)	1 171 (56)	1 310 (59)
Age (years)	58 $\pm$19	57 $\pm$20	57 $\pm$20
Surgical (%)	1 469 (79)	1 643 (79)	1 758 (79)
Overall mortality (%)	74 (2.6)	115 (3.1)	93 (2.3)
Dead with a DNR order after 24 h in study setting	46	52	38
Dead unexpectedly after 24 h in study setting	12	4	3
Dead in ICU within 24h of transfer from study setting	1	3	2
Total number of unexpected deaths	13	7	5

The study sample consisted of 13 unexpected deaths occurring during the pre-interventional four- month study period, and of 7 and 5, respectively, during the two four-month post-interventional periods. The total unexpected in-hospital patient mortality rate (MR) was significantly lower during the second post-interventional study period than before the intervention – 17 versus 61 per 100 adjusted patient years resulting in a mortality rate ratio between 2009 and 2011 of 0.271 (0.097-0.762) (*P* = 0.013). The corresponding mortality rate during the first post-interventional period was 25 versus 61 per 100 adjusted patient years resulting in a mortality rate ratio of 0.404 (0.161-1.012) (*P* = 0.053) as shown in Table 9.

Table 9. Unexpected patient mortality and patient load in the study setting during three four-month study periods before (2009) and after (2010 and 2011) in-hospital implementation of a track-and-trigger system, a patient observation chart, and an algorithm for immediate bedside action, at an urban Danish university hospital.

	Study period before clinical intervention (2009)	First study period after clinical intervention (2010)	Second study period after clinical intervention (2011)
Total number of patients admitted for ≥24 hours	1 870	2 079	2 234
Adjusted in-hospital risk time (days)	7 758	10 348	10 991
Total number of patients with unexpected death	13	7	5
Adjusted annual unexpected patient mortality rate per 100 patient admission years	61	25	17
Adjusted ratio (95 % confidence interval) of adjusted unexpected patient mortality rates per 100 patient admission years after versus before the study intervention	1.000	0.404 (0.161-1.012) $P = 0.053$	0.271 (0.097-0.762) $P = 0.013$

Unpublished results describing the 25 cases of patients who died unexpectedly during all three study periods are presented in Table 10.

Being low in numbers the 25 cases (13-7-5 respectively during the three study periods), may not be suitable for analysis besides the mortality rate ratio. However, recordings of deviating vital parameters were found in all but one of the 25 patients.

Table 10. Casereports of the 25 patients who died unexpectedly during study periods

Patient no. (year)	Age year	Gender	Acute/ Planned	Surgical/ medical	Event Type	Parameters recorded within 48h prior to event
1 (2009)	90	Female	Acute	Surgical	C arrest	Heart rate = MEWS 2
						Saturation = 94%
2 (2009)	82	Female	Planned	Surgical	C arrest	Heart rate = MEWS 1
						Saturation 96%
3 (2009)	70	Female	Acute	Surgical	C arrest	No vital parameters recorded
4 (2009)	56	Male	Acute	Surgical	C arrest	Heart rate = MEWS 3
						RR = MEWS 3
5 (2009)	77	Female	Acute	Medical	C arrest	Heart rate = MEWS 2
						Saturation 94%
6 (2009)	91	Male	Acute	Surgical	Found	Heart rate = MEWS 1
7 (2009)	76	Male	Acute	Surgical	Found	Saturation 75%
8 (2009)	79	Male	Planned	Surgical	Found	Heart rate = MEWS 2
						Saturation 68%
9 (2009)	71	Male	Acute	Medical	Found	Heart rate = MEWS 2
						Blood pressure = MEWS 2
10 (2009)	72	Male	Acute	Medical	Found	Heart rate = MEWS 1
11 (2009)	56	Male	Acute	Medical	Found	No deviations above MEWS 0
12 (2009)	69	Male	Planned	Surgical	Found	Temperature = MEWS 2
13 (2009)	75	Male	Acute	Surgical	Dead ICU	Heart rate = MEWS 2
14 (2010)	66	Male	Acute	Surgical	C arrest	RR = MEWS 1
						Blood press = MEWS 1

15 (2010)	78	Female	Acute	Surgical	C arrest	RR = MEWS 1
						Saturation = 93%
16 (2010)	83	Female	Acute	Medical	C arrest	Heart rate = MEWS 2
						RR = MEWS 2
17 (2010)	82	Male	Acutey	Surgical	C arrest	Heart rate = MEWS 2
						RR = MEWS 3, Saturation 75%
18 (2010)	83	Female	Acute	Surgical	Dead ICU	Heart rate = MEWS 1
						RR = MEWS 3
19 (2010)	87	Male	Acute	Surgical	Dead ICU	Heart rate = MEWS 3
						RR = MEWS 3
20 (2010)	66	Male	?	Surgical	Dead ICU	RR = MEWS 2
						Blood press = MEWS 2
21 (2011)	75	Female	Acute	Medical	C arrest	Heart rate = MEWS 2
						RR = MEWS 2
22 (2011)	82	Female	Acute	Medical	C arrest	Heart rate = MEWS 2
						RR = MEWS 2
23 (2011)	95	Female	Acute	Surgical	Found	Heart rate = MEWS 2
						RR = MEWS 2
24 (2011)	47	Male	Acute	Medical	Dead ICU	Heart rate = MEWS 2
						RR = MEWS 2
25 (2011)	77	Female	Acute	Medical	Dead ICU	Heart rate = MEWS 3
						RR = MEWS 3

Descriptive results of patient samples

In the second quantitative study (**III**) patient sample consisted of all admissions to the three stationary wards (not including the emergency ward) lasting 8 hours or more during all three study periods. In the third quantitative study (**IV**) patient sample consisted only of admissions from 2010 and 2011. Table 11 presents descriptive characteristics of these patient samples.

Table 11. Descriptive statistics of patients eligible for inclusion in the studies reported in paper III and IV

	2009 n = 945	**2010 n = 1396**	**2011 n =1566**
Patients with deviating vital parameters (%)	356 (38)	673 (48)	642 (41)
Gender (female %)	183 (51)	383 (54)	309 (48)
Age	62 ±18	63 ±20	62 ±19
Surgical (%)	258 (73)	464 (69)	473 (74)
Admitted acutely (%)	276 (78)	577 (85)	547 (85)
Length of stay	10 ±12	10 ±13	13 ±13

Adherence and sustainability

Sustainability over time and adherence to the intervention, also named implementation outcome, were analysed in two different ways to gain a complete picture of the concept.

Firstly, in each separate study period we analysed time intervals between individual bedside measurements of heart rate, systolic blood pressure, and body temperature dividing measurements in to three groups depending on the result of the previous measurement, the numeric values of the individual parameter. The numeric values were transformed to the corresponding MEWS values form 0 to 3.

We found that in all tests, except for the test analysing systolic blood pressure values compatible with a single parameter MEWS value of 3, time between measurements was significantly shorter ($P < 0.001$) after the intervention

(2010 and 2011) compared to before the intervention (2009). Measurements of systolic blood pressure resulting in very low value, (70 mmHg = MEWS 3) were repeated just as quickly in 2009 as in 2010 and 2011 (Figure 6a-6c).

Figure 6a, 6b, and 6c. Kaplan-Meier curves of time to re-measure for the single parameters; heart rate, blood pressure and body temperature in the pre-intervention and the second post intervention periods

Figure 6a
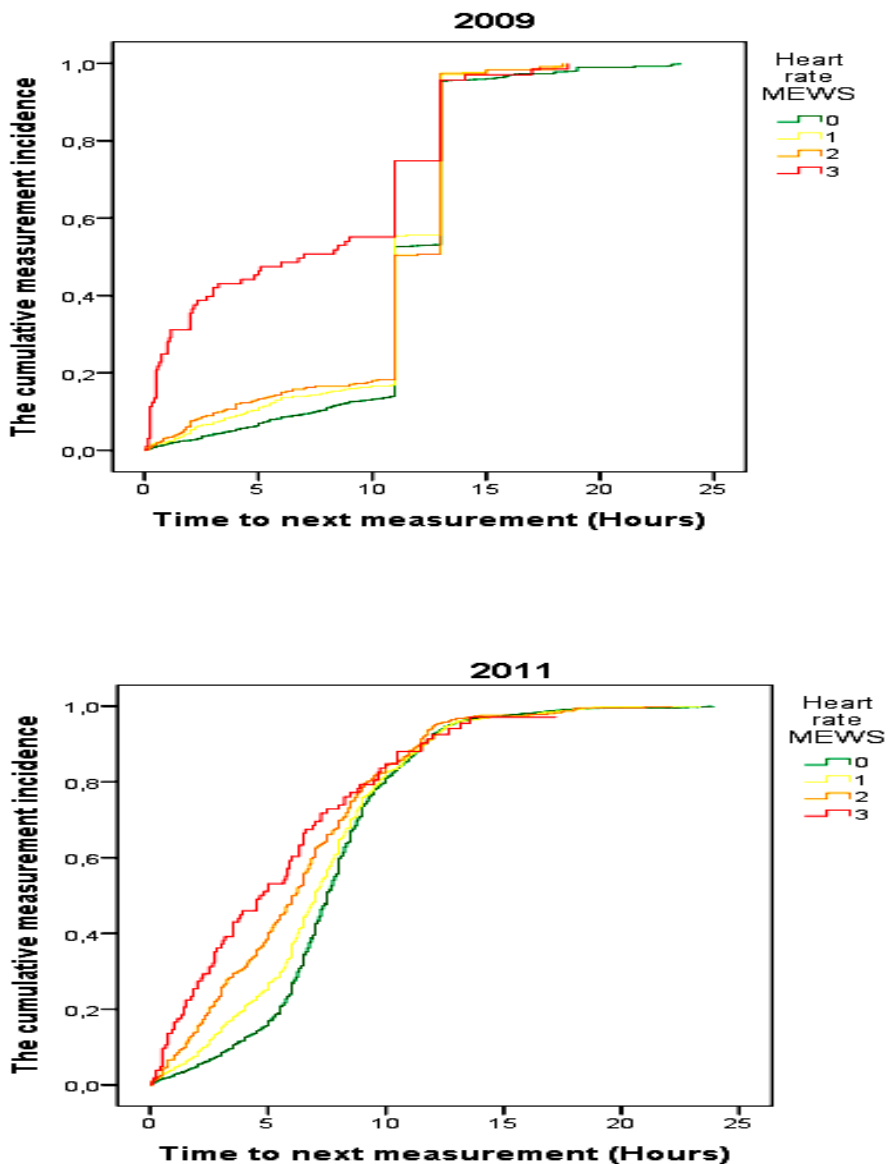
Figure 6b
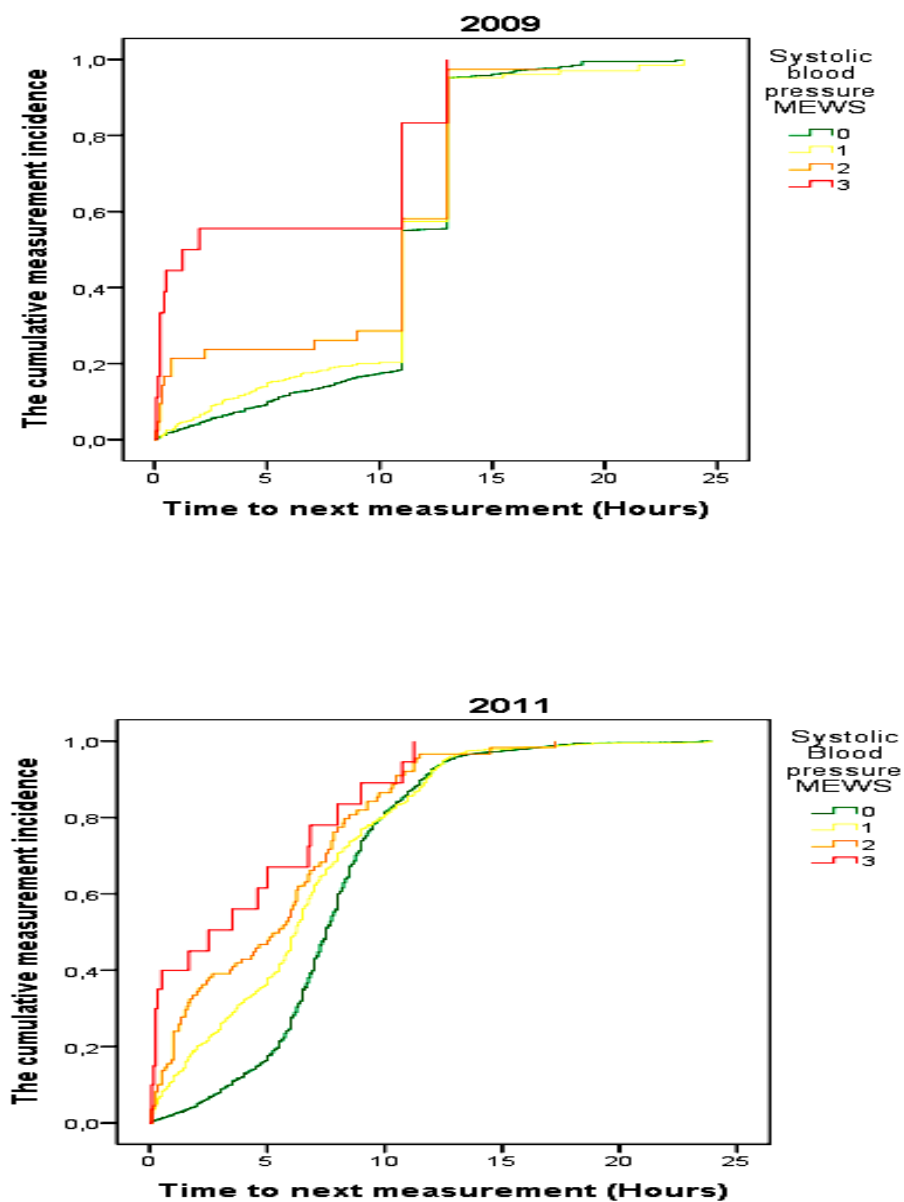
Figure 6c
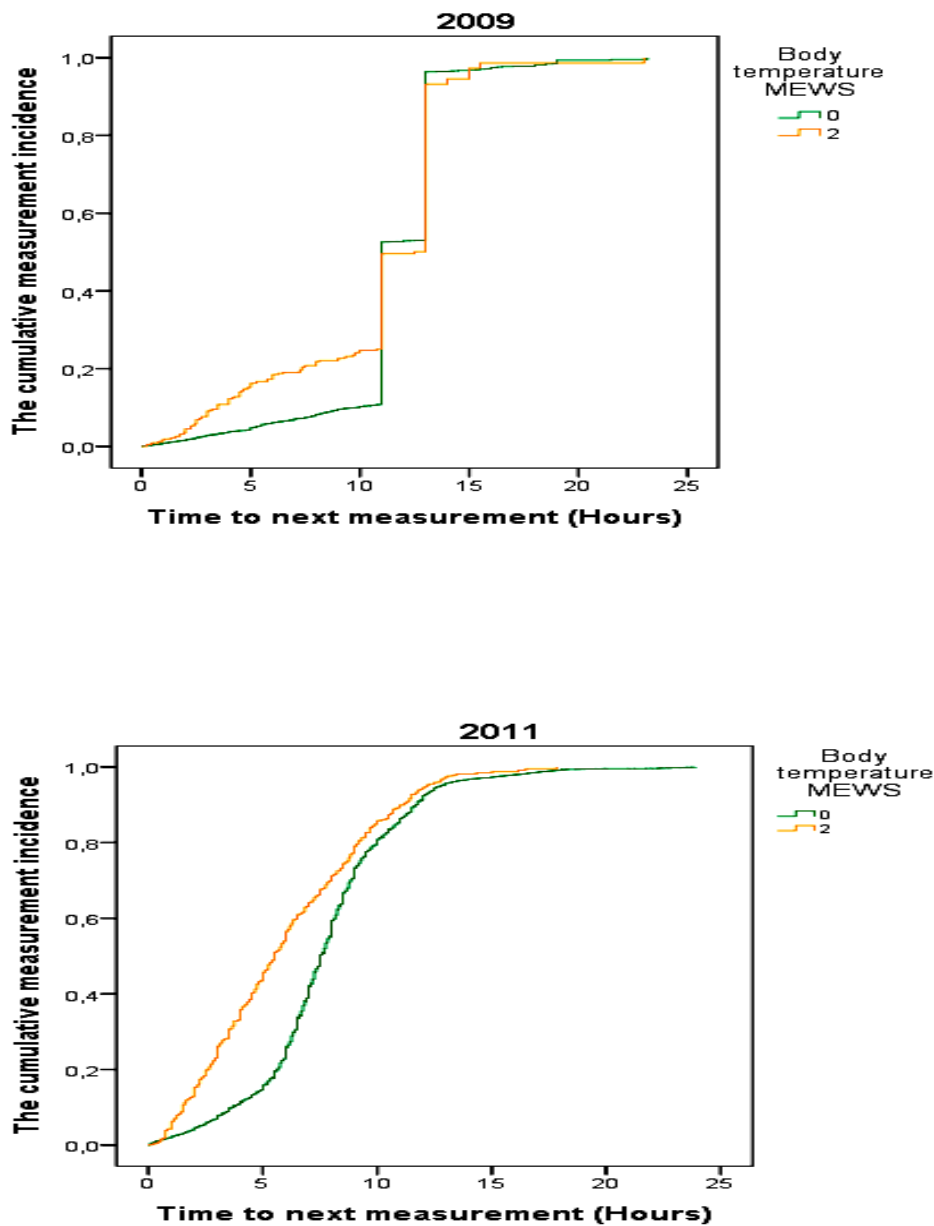
Secondly we looked at time to repeat a measurement in the two post interventional study periods as shown in Figure 5. The algorithm for action prescribed that measurements, resulting in total MEWS values of 0 and 1, were to be repeated within 8 hours, and that measurements, resulting in total MEWS values of 2, 3, and 4, were to be repeated within 4 hours.

We found, that in both 2010 and 2011, measurements were repeated within eight hours in 71% of patients with total MEWS values of 0. In 2010 and 2011, measurements were repeated within eight hours in 69% and 72%, respectively of patients with total MEWS values of 2, and in 71% and 77%, respectively, of patients with total MEWS values of 4. The Kaplan-Meier curves (Figure 7a and 7b) show time to re-measure in 2010 and 2011.

Figure 7a Kaplan-Meier curves presenting time to re-measuring and scoring of vital parameters following initial MEWS values of 0 or 1 (green), 2 (yellow), 3 or 4 (orange), 5-8 (red) in 2010.
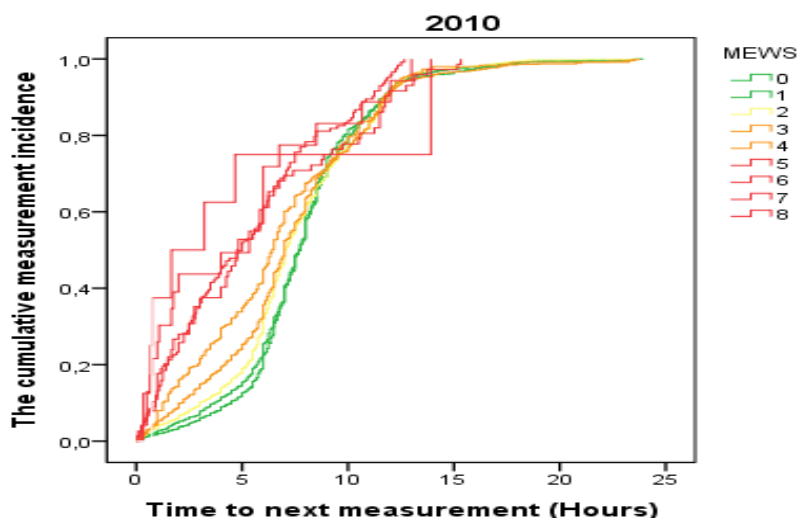
Figure 7b Kaplan-Meier curves presenting time to re-measure and score vital parameters following initial MEWS values of 0 or 1 (green), 2 (yellow), 3 or 4 (orange), 5-8(red) in 2011.
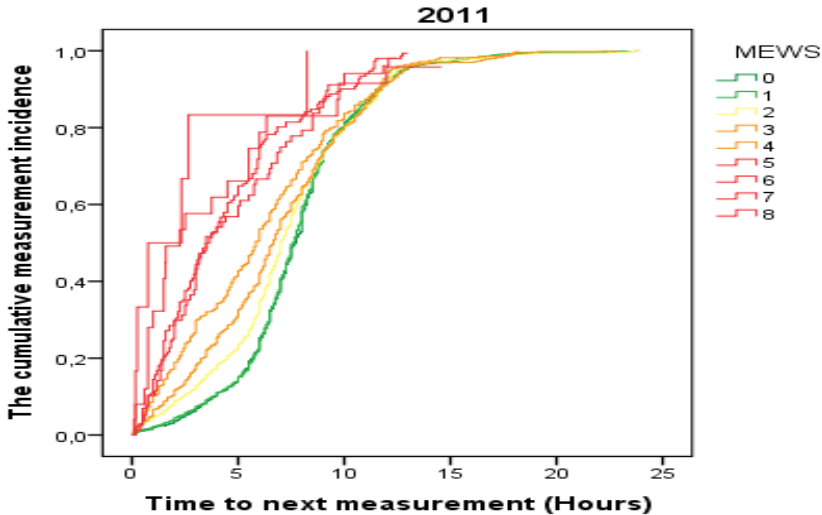
In patients with total MEWS values of 5 and more, the median time intervals between measurements were 4.7 (95% CI 3.6-5.9) hours in 2010, and 3.5 (2.8-4.2) hours in 2011 ($P = 0.082$). The algorithm for action prescribed that a measurement, resulting in a total MEWS value of 5 or more were to be responded to by calling the MET. There were 100 MET calls in 2010 and 128 MET calls in2011. During each study period, 297 measurements resulted in total MEWS values of 5 or more in 116 individual patients. Nurses called the MET after 50 (17%) of these measurements in 2010 and after 73 (25%) in 2011 ($P = 0.026$).

When looking at the total number of measurements performed in each individual study period we found that staff performed 4 500 measurements in the patient sample before the intervention and 14 211 and 13 293 respectively in the patient samples belonging to the two post interventional study periods.

The process of implementation

Results describing adherence were complemented by findings from four interviews aiming at evaluating how the implementation process was experienced. Figure 8 shows the findings presented in a theme and three categories.

Figure 8. Findings from qualitative content analysis of four nurse ward managers in an interventional study at an urban Danish university hospital

THEME		
Motivation by clinical relevance and meaningfulness		
CATEGORY	**CATEGORY**	**CATEGORY**
Development of implementation process	Nurse ward managers as role models	Impact of intra- and inter-professional collaboration
SUBCATEGORIES	**SUBCATEGORIES**	**SUBCATEGORIES**
Individual patient benefits from intervention	Commitment by perceived ownership	Promotion of awareness & personal involvement
Progress by professional attention	Expected interventional impact on patient safety	Intention to change professional behaviour
Support of development by dialogue	Strategic efforts to come across difficulties	

Motivation by clinical relevance and meaningfulness

The strong clinical relevance and meaningfulness of the intervention was identified to be the one constant driver on the process of implementation, impacting members of the nursing staff, including the ward managers. The clinical relevance and meaningfulness of the intervention embraced several other components of the implementation process and was highly motivating to nursing staff throughout the process of implementation. Interventional components and various activities of implementation were believed to have enhanced professional focus on patient safety issues. The nurse ward managers felt that they had struggled to make staff participate in interprofessional implementation activities, and also to develop an intention to change their individual bedside monitoring practice.

Nurse ward managers considered the process of implementation to have reached a degree, where patients benefited from the intervention. The never stopping progression of the implementation process was thought to be due to the strong clinical focus of the intervention. Nurse ward managers judged that nursing staff had benefited professionally from various components of the intervention as well as from activities of the implementation.

Teaching and training of clinically relevant knowledge and skills in a safe and positive environment was believed to have supported the development of the implementation process and so had the visible beneficial results of the intervention.

The individual nurse ward manager was, in her role as an opinion leader and by being positive and idealistic about the intervention, believed to carry much responsibility for the development of the implementation processand to have highly influenced it. The nurse ward managers felt, that the chance to deal with professionally meaningful issues had been a main reason why they became highly devoted to the implementation process.

The interprofessional components of the intervention and implementation process were judged by the nurse ward managers to have been the most difficult parts to deal with and efforts at making physicians participate more had been necessary during the first six months of the implementation process, bearing in mind the value of interprofessional teaching, training and communication. The nurse ward managers had often observed intentions to change behaviour and join the process of implementation among nursing staff, and evaluated nurses' collaborative participation in the teaching programme to have been crucial to the process of implementation. They had the impression that nursing staff considered the intervention as ways of promoting higher standards of nursing care and avoiding

serious adverse events and they had observed nursing staff members to have supported the implementation process by reassuring each other of its importance.

Association between early deviation in vital parameters and severe deterioration

In the analyses conducted to answer the aims of study IV, patients were divided into groups depending on how they deteriorated from having a total MEWS value of 0 and 1.

At first, logistic regression was performed in the group of patients moving from total MEWS values of 0 and 1 to a total MEWS value of 2 (803 admissions) and secondly in those moving from total MEWS of 0 and 1 directly to a total MEWS value of 3 (332 admissions).

The logistic regression involving the 803 patients, worsening from a total MEWS of 0 or 1 to a total MEWS value of 2, demonstrated respiratory rate ($P = 0.012$), heart rate ($P < 0.001$) and age ($P = 0.028$) but not gender ($P > 0.300$) to be significantly associated with severe deterioration to total MEWS values of 4 or above. Odds ratios were 1.032 (95% CI 1.021-1.044) for heart rate, 1.062 (95% CI 1.013-1.112) for respiratory rate, and 1.012 (95% CI 1.001-1.022) for patient age as shown in Table 12.

Table 12. *Logistic regression analysis of 803 hospital admissions, where patients initially deteriorated directly from MEWS 0 or 1 to MEWS 2. Deterioration to MEWS ≥4 was used as the dependent variable and respiratory rate, heart rate, saturation, age and gender as independent variables.*

Variable	Regression coefficient (standard error of mean)	Odds ratio (95% confidence interval)	P value
Respiratory rate	0.060 (0.024)	1,062 (1.013-1.112)	0.012
Heart rate	0.032 (0.006)	1.032 (1.021-1.044)	<0.001
Saturation of oxygen	– 0.015 (0.029)	0.985 (0.930-1.043)	>0.300
Age	0.012 (0.005)	1.012 (1.001-1.022)	0.028
Gender	0.016 (0.178)	1.016 (0.716-1.442)	>0.300

The logistic regression involving the 332 patients deteriorating directly from total MEWS of 0 and 1 to a total MEWS values of 3 showed that the heart rate was significantly associated with further deterioration to total MEWS values of 4 and above ($P = 0.009$) but neither was age nor gender.

When also considering the aspect of time between early deviations and later deterioration, the Cox Regression confirmed that the heart rate, the respiratory rate, and age was significantly associated with severe deterioration, the equivalent of a total MEWS value of 4 or above in the group counting 803 admissions. Only heart rate was significantly associated with deterioration to total MEWS of 4 in the group of 332 admissions. Table 13 presents the Hazard Ratio of the Cox regression model.

Table 13. Cox regression analysis of 803 hospital admissions, where the patients initially deteriorated directly from MEWS 0 or 1 to MEWS 2, with calculation of time intervals between the first total MEWS of 2 and the first total MEWS of ≥4. Deterioration to MEWS ≥4 was used as the dependent variable with the respiratory rate, heart rate, saturation of oxygen and age as independent variables.

	Regression coefficient (standard error of mean)	Hazard ratio (95% confidence interval)	P value
Respiratory rate	0.050 (0.020)	1.051 (1.010-1.093)	0.013
Heart rate	0.022 (0.005)	1.023 (1.013-1.033)	<0.001
Saturation of oxygen	-0.023 (0.025)	0.977 (0.930-1.027)	>0.300
Age	0.009 (0.005)	1.009 (1.000-1.018)	0.053

Figure 9 shows the 1315 patient admissions who at minimum once had a deviation in their vital parameters corresponding to a to a MEWS value of 2. The group had been divided into sub-groups depending on their further deterioration from MEWS 0 or 1.

Figure 9 Flowchart of clinical deterioration and 30-day mortality in adult patients, admitted for at least eight hours in a four-ward medical and surgical study setting at a large urban Danish university hospital (see next page).

Patients admitted for at least 8 hours

(2962)

1647 — No deterioration from MEWS 0 or 1

803 — Deterioration directly to MEWS 2
- 450 — No further deterioration
- 151 — Further deterioration to MEWS 3
- 202 — Further deterioration to MEWS ≥ 4

332 — Deterioration directly to MEWS 3
- 224 — No further deterioration
- 108 — Further deterioration to MEWS ≥ 4

108 — Deterioration directly to MEWS 4
- 84 — No further deterioration
- 24 — Further deterioration to MEWS ≥ 5

72 — Deterioration directly to MEWS ≥ 5

30-day patient mortality rates (95 % confidence intervals)

8.7 (6.3-12) % | 13 (8.5-20) % | 27 (21-34) % | 8.5 (5.3-13) % | 22 (15-31) % | 11 (6.3-20) % | 29 (13-51) % | 15 (8.2-26) %

77

Time between early deviation in vital parameters and severe deterioration

A total MEWS value of 2 or more measured at least once during hospitalization was found in 44% (CI 43-46) of all patients, admitted to the study setting for more than 8hours. Of those admittances, 25% (CI 25-28) deteriorated further to a total MEWS value of 4 or above. The 30-days post discharge mortality rates were found to be 27% (CI 21-34) in those patients scoring total MEWS values of 4 and above, whereas those staying at MEWS 2 had a mortality rate of 8.7% (CI 6.3-12) (Figure 8).

Using the Cox regression analysis, we found that 8.1% (CI 6.2-10) of patients scoring their first total MEWS value of 2 had deteriorated to a total MEWS value of 4 within the first 24 hours after the first measurement of MEWS 2. Of patients deteriorating directly from MEWS 0 or 1 to a total MEWS of 3, 17% (CI 13-21) deteriorated to a total MEWS value of 4 or above within 24 hours. Within 48 hours 13% (CI 11-15) and 22% (CI 18-27) respectively deteriorated to total MEWS values of 4 and above. Comparison between the two groups of the proportion of patients, deteriorating within 48 hours, showed a significant difference between groups (*P*<0.001), as illustrated in Figure 10.

Figure 10. Proportions of patients deteriorating from MEWS 2 or 3 to MEWS 4 within 48h in a prospective interventional study at a Danish urban university hospital
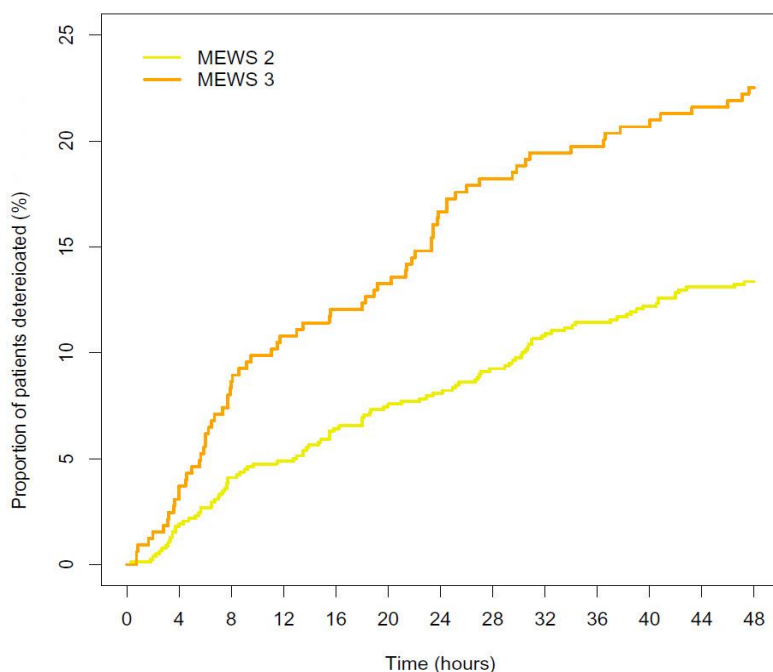
Discussion

Methodological considerations

A complex intervention

In this thesis the development and evaluation of the intervention behind this thesis was deeply inspired by the MRC Framework (95).

The intervention fulfilled to a wide extend, the definition by MRC, as it entailed three different and interacting components, several difficult behaviours and behaviour change were required by a wide range of staff members of different clinical background, and both clinical and organizational levels were targeted by the intervention. We measured several interventional outcomes and acknowledged that the intervention to a certain degree was tailored to the individual context.

Developing the multi-component intervention of this thesis faced the challenge of providing strong evidence of the effect on patient outcome of the different components in the intervention, though this aspect is emphasized by the MRC to be important. However, some evidence was available at that time as has been presented in the background section of this thesis. To our knowledge no similar study had been conducted at the time of planning for this study, and the intervention and implementation process was designed based on available evidence of EWS, MET and on evidence from other scientific areas besides patient safety and EWS. We planned the intervention, comprising a change in nurses' monitoring practice, based on the current evidence within nursing monitoring practice.

The MRC recommends that a piloting study is made before large scale implementation. The studies (**II-III**) are believed to represent feasibility studies before a large scale (regional) implementation of EWS.

The outcome measures (**II**) are considered to be rare events, which according to MRC provide an argument for not choosing the design of the randomized controlled trial.

Interventions demand implementation and according to the MRC implementation activities need to be described as have done (**III**) and in this thesis.

The context is important in implementation and the first qualitative study (**I**) provided us with knowledge of the specific context for us to take account of in the planning of implementation activities. As recommended by the MRC this interventional study comprises both quantitative and qualitative methods for long-term evaluation of both interventional effects and implementation fidelity and process evaluation. By the means of the four papers and by this thesis several components including interventional effects are reported as recommended by the MRC.

MEWS- instrument

In 2009, the MEWS instrument was the only EWS system which claimed to be validated (88). However, the validation was very incompletely described and only based on 596 hospital admissions. However, despite this, since no other well evaluated EWS instrument was available at that time, we chose to use the MEWS in our study.

In recent years the MEWS has been applied to a database of 198.755 sets of vital parameter observations, to test how MEWS and other EWS instruments performed in distinguishing between survivors and non-survivors at 24 hours after the measurement of vital parameters, and the MEWS was reported to be the second best scoring instrument out of 33 instruments (38).

Learning

The planning of implementation activities and the entire intervention was influenced by the following definition on learning:

Learning is both an individual, inner process and an interacting social process between the individual and its surroundings (114). Accordingly learning always entails three dimensions; one dimension relates to the content; the knowledge, skills and understanding that is to be learned and the second dimension relates to the inner power – the drive, including motivation, emotions and intentions. The third dimension relates to the social interactions with the surrounding context, including actions, collaboration and communication (114), and these three dimensions must be taken into account when analysing and understanding - and planning a process of learning.

A complementing aspect of learning is the development of competences, which entails a person having professional knowledge and being able to use this knowledge in an adequate and meaningful way in well-known but also new, unpredictable and unsecure situations (115). The capability of an individual person to integrate his or her professional knowledge in the assessment of new situations, making decisions, and acting are important elements of developing competences. Developing competences through learning requires that the three dimensions of learning are present (115).

Specific training sessions like simulation-based medical education aiming at improving collaborative and communicative competences, like "speaking up", as well as clinical skills is one way to improve interprofessional collaboration and communication (116-120).

The implementation process was planned from the perspective that learning whilst being at work, including developing skills and competences, was a main and core aspect for this implementation process to succeed and they were planned for in close and continuous collaboration with nursing and medical staff, as well as with hospital managers.

Trustworthiness in qualitative research

Participant observations

Participant observation is originally a method for data-collection used by anthropologists to interpret a social phenomenon (122;123), but the methodology has gradually over the past decades found its way into studies within nursing and clinical practices. In research within these fields it may also be used in more quantitative ways still being a method within qualitative research when observing actions carried out and interactions between individuals. Participant observation may often be combined with other qualitative data-collection methods, and may range from very structured observations in a laboratory to the unstructured observations in natural settings of the participants. Several combinations within these two extremes are used in clinical research. In many original studies of interactions of participants in natural settings the true identity of the researcher remained unknown to the participants throughout the study period whereas in observation studies of e.g. nurses' interaction with patients or patients' interactions with relatives, the identity of the observer was known to the participants.

There is no one best way of observation, but the researcher's choice of structuring or using natural setting and especially how deeply to get involved and interact with

the participants depends on the observed phenomenon, the research question and the knowledge which is looked for (122;123.). It is though argued that the more the researcher structures his or her observations in natural settings the more he or she puts limits to the view on the setting, therefore only seeing what he or she planned to see.

Semi-structured interviews

The semi-structured research interview is a method of data-collection with a long tradition within qualitative research. The semi-structured interview seeks to understand issues from the daily lives of the participants, from the perspectives of the participants and therefore it is more than merely a conversation between two persons. The semi structured interview has been described as an active process and a social practice involving the interviewer and the person being interviewed, and during the relation between the two persons knowledge is produced – if the interviewer possesses the skills to interview and engage in the relation (121).

Trustworthiness

Trustworthiness in qualitative research deals with the issues of credibility - transferability – and dependability (122;123).

Findings of a trustworthy study represent as closely as possible the experiences of the participants. There are three types of threats to trustworthiness; reactivity, researcher bias and respondent bias (122;123) These threats will be addressed when describing the issues within trustworthiness.

Credibility and Confirmability

Credibility relates to how well the study findings can be trusted to represent the views and perceptions of the participants. The researcher must seek to make visible that the findings presented are not merely an interpretation and conclusion by the researcher on very limited grounds, but are grounded in open-minded analysis of the data.

Investigator triangulation was used in the process of analysis (**I-II).** By using investigator triangulation we aimed at strengthening both credibility and confirmability. The latter refers to the risk of researcher bias and deals with reducing the possibility of a one-sided interpretation of data, seeking to demonstrate that the study's findings were not imagined, but are firmly linked to the data. Discussions in our research team of the qualitative findings represented in categories, sub-themes and themes, involving four different professional backgrounds, supported the avoidance of the pre-understanding of one or two team members becoming very influential.

The credibility was furthermore strengthened by using data-triangulation (**I**). We combined two data-collection methods, participant observation and interviews to compile what was said and what was observed to get a most varied picture of the monitoring process. It would have benefited the issue of credibility to use data triangulation (124) by interviewing ward nurses on their experience of the implementation process (**II**).

Our choice of using mixed methods or methodological triangulation (125;126) (**II**) had, besides the intention to help understand the quantitative results, also several methodological challenges or issues to address. The fact that the interviewer and the four participants (**II**) knew each other professionally beforehand must be taken into concern, and so must the fact that I, the interviewer, had conducted the implementation process myself and had partly designed the components of the intervention. These realities may have been a threat to trustworthiness as they may have influenced the participants' willingness to answer honestly not to hurt or criticize me or to harm the relationship between us.

The influence of the researcher on the setting or individuals is named reactivity, and in qualitative research the goal is not to eliminate this influence, but to understand in which ways the influence is present. It is argued that in interviews, what is said is always influenced by the interviewer Reactivity is addressed (121) and it is argued that the qualitative interview has been a double aspect. There is the aspect of the relationship between the two parts in the interview, and there is the aspect of the knowledge, which is constructed during the interview. The willingness of the interviewees to answer honestly may be affected by a possible asymmetrical power relation between the interviewer and interviewee, something that must be taken into consideration when analysing the interviews and interpreting findings (121).

During all interview, I strived to be aware of my doubled sided role when conducting the interviews. I aimed at using a neutral and open-minded interview technique and to have an open-minded access to the text when analyzing it, besides using researcher triangulation. Having completed the analysis of the four interviews of the nurse ward managers (**II**), we consider that the relationship between researcher and nurse ward mangers was not influenced by any asymmetrical power. It is our judgement that because of the equality in the relationship between us, and because of the nurse ward managers being very involved in their ward, the knowledge constructed in these four interviews was of a deeper and more valuable kind than would have been possible had we not known each other.

Long-term involvement is believed to help ameliorate reactivity and respondent bias (127). It is, however, the researchers that decide on the number of observations and interviews. To maintain a balance of distance and closeness we

decided on the 13 observations and interviews (**I**). When ending each interview the participants were asked if and how my presence had affected them during the observations and interviews – and they all answered that they had not been affected in any significant way.

Dependability

Dependability means that the procedures of the study are documented and traceable, and have a logic, which makes sense to others (127). Rich data transcribed verbatim, not just notes, plus detailed observation notes enhance credibility and dependability as it reduces researcher bias. I transcribed all interviews and struggled to take detailed notes. The participants (**II**) mentioned that too much time had passed and that this may have affected their memory of the process. This could be an issue when talking about dependability as stability of data over time.

Transferability

Transferability refers to generalizability of the study's findings to other settings and this is thought to be achieved by detailed descriptions of sample and sample selection and of setting, context and data-collections procedure. These descriptions are meant to provide the reader of qualitative studies with enough knowledge for her to decide, if the findings are transferable to a setting known to her. The setting of our study represents a general medical and surgical ward at an urban university hospital, and the participants are nurses with a wide range of experiences and of different ages.

Content analysis

Content analysis was originally a way of quantitatively analysing the manifest content of text material, but gradually, and especially within nursing research, the method has evolved to become more qualitative also including interpretations of latent content (111;128;129). The manifest content is defined as the visible content describing the obvious components of the text whereas the latent content is the underlying and subtler content. Analysis of the latent content requires a deeper interpretation and an abstraction to a higher level than analysis of the manifest content (111;128;129).

An inductive content analysis of the interviews was performed (**I-II**) in order to look at the text emerging from the interviews open-minded and examine it for content being complementary of the interview guides. A more deductive approach (111;128;129) was applied to the observational notes, as the structure of the observations had already guided me to look for some aspects not seeing others

Validity and reliability in quantitative research

Validity and reliability

Study design

We conducted an experimental study and chose the design of the non-randomized intervention study with historical control, notwithstanding the fact that the randomized controlled study (RCT) is believed to be of the highest scientific standard. Despite problems establishing causal relationship in non-randomized interventional studies this design was chosen for two specific reasons.

Firstly, in the history of evaluating MET, a large cluster-randomized study was conducted in Australia (17). No differences between intervention and control hospitals were found mainly due to what was believed to be contamination of control hospitals. This particular study was followed by discussions of which design was believed to be the best when studying MET, EWS etc. not pointing in the direction of RCT, but warning against it (79). We considered there to be a risk of contamination. Secondly randomization on an individual or even on group level would not be ethical acceptable.

Internal validity

Internal validity deals with to what extent the conclusions drawn, depends on what the researcher says it depends on and nothing else and so refers to the confidence, that the design, conduct and analysis has minimized or avoided biases in the comparison. In our study we might need to address the following possible threats to the internal validity (130).

Events during study periods, such as other initiatives aiming at optimizing patient safety also contributing to reduced mortality may have influenced internal validity. We know for sure that the WHO guidelines for safe surgery (www.who./int/entity/patientsafety/safesurgery) were implemented in the hospital to minimize possible risks of going through surgery, although not targeting unexpected deaths.

The catchment area of the hospital was enlarged during the study periods. We tested for differences regarding the prevalence of cardiopulmonary or cerebral chronic diseases in the populations before and after the enlargement and found no statistical significant differences between the population of the catchment area before and after the intervention. We do not consider non-significant demographic differences in prevalence of chronic diseases between inhabitants of the original

and expanded catchment areas to have accounted for our findings, although small differences in health profiles, potentially influencing our results in either direction, cannot be ruled out. However, the possibility exists that our samples differ in some respect. We have not tested for such difference, and so they might have contributed to explanations accounting for the results rather than the intervention itself.

The available number of beds in the high-intensity patient monitoring area of the gastroenterological ward as well as in the intensive care unit was expanded during the post-interventional study periods. This might have made it easier for physicians to transfer deteriorating patients to better equipped and staffed units providing higher standards of medical care. We have taken this into account by also including all cases of death in the intensive care unit within 24 hours of arrival from the study setting.

The possibility of measured vital parameters not being recorded in clinical practice might be a threat to the internal validity of the study. From the qualitative study (**I**) we know that nursing staff had an established practice of recording all measured vital parameters and we therefore regard this threat to be minimal.

I conducted myself the manual data-collection (**II**) without involving a second researcher in collecting the data. This may be an issue conflicting with reliability or researcher bias. For practical reasons it was not possible to deal with this aspect besides being very honest and thorough. Still, it may have affected results (**III**) In the process of collecting data (**II-IV**) there was a risk of affecting internal validity regarding accuracy in data collecting. Three different people were taught how to collect data from patients' medical and nursing records and how to record these in a paper database. The same three people plus yet another person were the ones typing data into an electronic database. We did not make use of double entry of the electronic data, but a data-manager conducted after the typing had been finished, several checking of data identifying typing errors etc., where after patient files were revisited as needed and corrections in the data file were made.

External validity

External validity deals with the extent to which the results of the study can be generalized to other individuals, samples or settings (130).

This study was carried out in everyday practice over a wide time span whereby reflecting realistic, every day outcomes which is a strength to the external validity. Data was used from patients who at least once during their hospitalization had deteriorated in their clinical state to a total MEWS value of 2 (**II,IV**). These patients counted for 42% of all admitted patients. External validity would have been strengthened if we had included data from patients never worsening beyond total MEWS of 0 and 1.

We believe that study results are transferable to other study settings of mainly surgical patients, as these accounted for the largest reduction in mortality of unexpected deaths. However, before adopting this intervention to another setting analysis of the existing mortality rate of unexpected deaths would reveal the size of the problem and which benefits to expect.

Construct validity

Construct validity includes the aspect of several active components in one intervention (130).

In a multi-components intervention where the different components are both acting independently of each other and interdependently it will never be possible to conclude which specific component contributed the most to the results (95). We aimed at strengthening our intervention and the implementation activities by designing them guided by research from various contributing areas and by the knowledge we obtained in the qualitative study (**I**). We believe this may have strengthened the construct validity of all study parts.

Considerations

To analyse the mortality rate of unexpected deaths, which are regarded as rare events, occurring independently of each other, we used the Poisson regression, (112;113). Furthermore, we chose to include the risk time that patient sample spent in hospital and not only the number of patients. By this we believe to include realistic, clinical measures enabling more realistic results. The mortality rates are adjusted to 100 patient-years as such figures are transferable to clinical departments.

Power

When designing this study in 2009 only little - if any - knowledge was available of the incidence of unexpected deaths in a Danish setting, making truthful power estimation difficult. We therefore decided on the sample size of this study based on very practical assumptions of what would be a reasonable amount of data to collect in a realistic amount of patient admissions.

A general discussion of the qualitative findings and quantitative results

From the perspective of patient safety we considered, when designing this thesis in 2009, that the safety net, in respect to daily monitoring practice of general ward patients, was insufficient, particularly taking the development within demographics of the in-hospital patient population and the re-organization of hospital structures and care facilities into consideration. In recent years (2009-2013) a perspective on nursing monitoring practice and the use of EWS has been subjected to further research. Nurses have been reported to look at trends in their patients, when visually assessing them, instead of using and understanding the value of EWS as intended (9;10;58;131;132), and nurses' recordings of all vital parameters preceding life-threatening events were still in the late zeroes found to be lacking (9;10;131;132).

Professionalism impacts nursing monitoring practice and patient safety

Before altering monitoring practice by the intervention of this thesis we explored nurses' monitoring practice including intra- and interprofessional collaboration and communication (**I**). Nurses' monitoring practice was found to be influenced by the level of professionalism of the individual nurse.

This may occur to be very logical and not particular valuable knowledge when understood as *cleverer and more skilled nurses look after patients in a better way*. However, such interpretation may not reflect the entire picture of professionalism as the concept is complex and entails the characteristics of intellectual and individual responsibility, autonomy and collaboration besides formal education, knowledge, and skills (133).

Only little research on patient safety and its relation to professionalism is reported and so far professionalism has not been reported to significantly influence patient outcome. However, others have found in-hospital mortality to be impacted by the number of registered nurses on the ward, their level of specialized education, but also by the organization of the hospital (134;135). Being a registered nurse entails some of the characteristics of professionalism. Our findings illuminate how more detailed characteristics of a well-educated person may contribute further to patient safety.

We identified components of nursing monitoring practice associated with theoretical knowledge. How well nurses realize the potential use and predictive

value of assembled vital signs is likely to have been influenced by their level of knowledge hence, insufficient clinical knowledge might have prevented nurses from reacting appropriately to potential deterioration in patients.

Individuals possess different levels of knowledge and skills, and both the individual nurse and physician but also the organization in which professionals work must take responsibility to establish and maintain professionally relevant knowledge to optimize patient safety.

The issue of interprofessional collaboration and communication in relation to patient safety has been addressed by others, reporting a negative impact on patient safety when collaboration and communication is far from optimal (66). We found a very acknowledging working environment but also findings of less optimal communication at times of nurses being worried about a patient. The use of EWS systems has been found to establish a mutual language between nurses and physicians empowering correct communication about the physical state of the patient (61;70) and optimizing patient safety.

Implementation outcome and process

As part of this thesis implementation outcome and implementation process was evaluated (**II**) addressing the issues of adherence and sustainability. We considered it necessary to know implementation outcome to judge and interpret interventional effect (**III**) correctly.

Our results of 70-77% of all measurements with a total MEWS value of 0-4 being re-scored within 8 hours (II) may not seem convincing at first. However, when taking into account that these figures entail all measurements of all included patients, also calculating time to re-measurement in patients who were away for x-ray, surgery, physical training, had visitors, were a sleep, eating etc., we believe these figures present an extensively optimized monitoring practice. The Kaplan-Meier calculations of time to re-measurement for each individual parameter and the comparison of time-intervals between measurements in 2009 and 2011, supports this interpretation by showing a significant reduction in time to re-scoring for all the three parameters; heart rate, blood pressure and temperature at three different value levels. Only in patients having a blood pressure deviating to a MEWS value of 3, which is at the level of 70mmHg and below, staff re-measured the blood pressure just as quickly before as after the intervention (**II**). Insight of implementation outcome regarding EWS systems is only reported in a few very recent studies (132) which support our results of adherence to the intervention or report very low adherence at night (136).

Supported by results by other (57;58), it seems likely to interpret that some nurses only used their clinical gaze to assess patients who had previously scored 2-4, whereby not finding any signs of deterioration, and therefore they skipped re-scoring patients within 4 hours. Optimizing nurses' individual level of professionalism including knowledge, reflection and interprofessional communication and collaboration is mandatory to achieve significant effects of an EWS instrument. Any EWS system is a coarse instrument and, when used in clinical practice, never better at preventing unexpected deaths than the level of professionalism in the individual nurse using EWS.

Sustainability, understood as long-time adherence to an intervention, was found to be high, although sustainability in the literature (137;138) is described to be of at least two years past initial implementation efforts. We evaluated adherence 1½ years past the beginning of implementation activities directly involving staff.

We found clinical relevance and meaningfulness to be a motivating factor when implementing this clinical intervention (**II**). This is supported by most research on implementation (100;101). Participants' perception of this intervention as being meaningful supports and explains the achievement of 70-77% of all measurements with a total MEWS value of 0-4 being re-scored within 8 hours. Additionally, studies into how observation chart design may affect recognition of the deteriorating patients have, after the finishing of our study, found that charts including a EWS scoring system and colours to guide staff, improve decision accuracy and the response time of staff (139;140).

Reduced adjusted mortality rate of unexpected death

We evaluated short and long term effects of our intervention on the adjusted mortality rate of unexpected death, and found it to be significantly reduced, mainly in patients found dead (**III**). Only very few studies have solely evaluated the effect of using EWS, as most studies evaluate the effect of MET or entire RRS, making comparison to our study difficult. Several studies have reported significant effects of MET and RRS on overall hospital mortality (18;141;142). Our results resemble the results of a few other studies (16), also identifying reduced numbers of unexpected death, although analysed without taking notice of the time each patient spent in hospital.

This main finding of reduced adjusted unexpected in-hospital patient MR is likely to have resulted from more appropriate in-hospital monitoring practice and initial management of deteriorating patients, as well as from more extended clinical use of the hospital medical emergency team in the study setting. The rise in medical emergency team calls may partly be due to increased numbers of patients and in-hospital risk time. However, the intervention may have resulted in higher

awareness among nursing staff upon early signs of deterioration, making them call for the medical emergency team more frequently than before the intervention. However, nurses only called the MET in 25% of cases in which the patient scored a total MEWS or 5 or above, but nurses may have called the MET at an earlier stage in the deterioration of the individual patient.

Our results of a significant reduction in mortality rate of unexpected deaths was found despite only 36% of patients scoring total MEWS values of 2-4, were re-scored within the recommended 4 hours. Further reduction in mortality rate may be possible if nursing staff accomplished to re-score patients with total MEWS values of 2-4 according to the algorithm and to act adequately towards these scores and additional visually clinical symptoms of instability.

The number of ICU admissions was not altered by our intervention (III), as has been found by others (16;141). It seems likely, that some deteriorating patients in our setting, who before the intervention typically were not detected and therefore found dead, would by means of the intervention, be identified and transferred to the ICU, and patients who before the intervention were transferred to the ICU would after the intervention be managed on the ward with assistance from the MET. We find it very likely that a reshuffle of patients like this has taken place.

EWS in prevention of patients dying alone

Another aspect of using EWS and MET is that the MET is reported often to be involved in discussions of setting individual limits to treatment and care in the most fragile patients and also to support ward staff in providing adequate care and comfort to these patients (143). Besides assisting staff in identifying patients at risk of an adverse event, a structured monitoring practice may also support nursing staff in their clinical assessment of patients who are too fragile to receive aggressive life-saving treatment, so to ensure that no one dies alone.

From an ethical point of view, no patient should risk dying alone. When nurses aim at alleviating suffering and securing patients of dying in dignity, nurses must seek to be present at the bedside of dying patients. We believe that the significant reduction in patients found dead (**III**) reflects that nurses in our study setting used all means, besides their intuition and clinical gaze, to ensure that their assessment of the clinical state of the patient, and the risk of potential worsening within a short time limit, was optimal, thereby preventing patients of dying alone.

Association between early deviations in heart- and respiratory rate and severe deterioration

Associations found between early deviations in vital parameters and severe deterioration (**IV**) provides additional knowledge about the respiratory rate as not only being a predictor of mortality, as reported by others (34;35), but also to be associated with gradual bedside deterioration from less to more severe vital organ dysfunction in the general ward medical and surgical patient. The respiratory rate has previously been found to be the first vital sign to deviate in the deteriorating patient (34;35). All together these results emphasize the clinical need to interpret early deviations of the respiratory rate and the heart rate and as signs of the patient being in need of special attention, especially if the patient is of older age. Clinicians need to be encouraged to assess heart rate and respiratory rate with appropriate sincerity. Neither of these vital parameters should stay a neglected or less prioritized vital sign.

An important aspect of preventing unexpected death and harm to occur to patients is the need for action and not only measuring. Knowledge of the perspective of time between the first measurement of a total MEWS value of 2 and the first measurement of a total MEWS value of 4 or above (IV) would support both nurses and physicians in how to interpret and when to react to total MEWS values of 2.

In this study we found that time to react to prevent further deterioration may be very short in some patients. This is in accordance with a recent study (144) describing that increasing MEWS values measured 30 hours after admission was clearly associated with corresponding in-hospital mortality.

Conclusions

Based on results obtained in this thesis it is concluded that

- individual levels of professionalism among nurses influence clinical practice of bedside monitoring and possibly also patient safety, considering that delayed bedside recognition and management of clinical deterioration was found in patients cared for by nurses with lower levels of professionalism (**I**).

- nurses seem to rely also on their clinical gaze in interpreting slightly elevated early warning scores, considering that rescoring four-hourly in patients with higher scores was found to be less well implemented than routine scoring at eight-hour intervals (**II**).

- modified early warning scoring is believed by nursing staff to promote patient safety, considering that it was reported to have facilitated earlier detection of severe deterioration in general ward patients (**II**).

- nursing staff may considerably promote and facilitate an in-hospital multi-component intervention, as shown by high adherence of nurses and nursing assistants to compulsory and systematic early warning scoring in general ward patients (**II**).

- clinical relevance of and belief in a multi-component intervention are key issues for successful implementation, considering that earlier bedside detection of patient deterioration by the intervention itself was reported to have promoted adherence to the intervention (**II**).

- structured and mandatory interprofessional use of early warning scoring promotes earlier and more appropriate in-hospital management of serious clinical deterioration in general ward patients, since the unexpected patient mortality rate was found to be significantly lower after implementation of our clinical intervention (**III**).

- in-hospital patients with slightly increased early warning scores brought on by tachycardia or tachypnoea should be particularly closely monitored, since significant relationships were found between slightly increased heart rate or respiratory rate in marginally deteriorated general ward patients and later deterioration (**IV**).

- older patients with marginal deviations in their bedside vital parameters are at particular risk of further deterioration and should be carefully monitored, since patient age was found to be significantly associated with higher MEWS values within 48 hours of scoring 2 or 3 (**IV**).

- compulsory in-hospital early warning scoring contributes to patient safety, considering that it was reported to facilitate earlier detection of severe medical deterioration (**II, IV**), and to be significantly associated with lower in-hospital patient mortality (**III**).

Implications for practice and future research

National, regional and local initiatives are required at both individual and organizational levels to support and further develop professionalism in nursing to enhance in-hospital patient safety. Among required initiatives are the need for nurses to involve themselves in education to improve their knowledge and skills, and the responsibility for employers to provide facilities for learning and training. However, educational measures alone have not yet been shown to influence patient survival. Considering the impact of professionalism on nursing monitoring practice, we suggest that formal education is supported by provision of an improved working environment enabling reflection on clinical practice as an essential and natural part of daily work.

Knowledge of adherence to an intervention and sustainability over time might be of interest and value to clinicians and hospital managers who plan to implement mandatory EWS scoring and/or other multi-component interventions in clinical settings. Furthermore both clinicians and researchers might want to know implementation outcome when reading and interpreting clinical intervention outcome. Such knowledge might be most useful to clinicians aiming at improving patient safety by optimizing the use of EWS systems and corresponding guidelines for rapid bedside management.

Our results of a reduced mortality rate of unexpected deaths implicate that organizations might have a multi-component tool at hand by which optimization of patient safety is possible. However organizations should not focus exclusively on the EWS instrument but facilitate implementation of mandatory early warning scoring and interprofessional daily use of scoring results in combination with enhanced levels of professionalism. Thus EWS systems should be implemented with an interprofessional approach focusing on collaboration and communication through education and training.

By determining the heart rate and the respiratory rate as being associated with deterioration implicates that further optimization of the use of these parameters might benefit patient safety. Particularly closer supervision (for up to 48 hours) of older patients, scoring MEWS values of 2 or 3, with respect to changes in respiratory rate or heart rate and appropriate management until their scores are no longer considered to reflect clinical deterioration might be needed.

Extended knowledge of the beneficial effect of EWS in individual patient populations besides the general ward medical and surgical patient is still lacking, and further research should focus on how to improve the use of EWS.

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