Communication in Critical Care

Measuring and monitoring quality of care
to improve patient safety

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ISBN: 978-90-9029826-9
Cover photo: Benedict Campbell (2015). Rouleur.cc [Online afbeelding]. Gedownload op 20 juni 2016, van https://rouleur.cc/journal/racing/robert-millar-cyclocross
Design cover by M. Wijnen and A.H. Brunsveld-Reinders
Printed by Grafische Producties: UFB, Grafimedia, Leiden

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Proefschrift

ter verkrijging van
de graad van Doctor aan de Universiteit Leiden,
op gezag van Rector Magnificus prof.mr. C.J.J.M. Stolker,
volgens besluit van het College voor Promoties
te verdedigen op donderdag 13 oktober 2016
klokke 15:00 uur

door

Aleida Henriët Brunsveld-Reinders
geboren te Gramsbergen
in 1971

Promotiecommissie

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General introduction and Outline of the Thesis

Anja H. Brunsveld-Reinders

M. Sesmu Arbous

General Introduction and outline of the thesis

Introduction

In the last decades, in- and outpatient healthcare systems have become more effective but have also become more complex with greater use of new technologies, medicines and a multitude of interventions. [1] As a result of this, patients who are hospitalized are particularly vulnerable to suffer incidents or Adverse Events (AE) during their hospitalization. [2-5] Twenty-seven to 50% of these events were judged as preventable. [5] Adverse events can eventually result in life threatening events such as cardiac arrest, unplanned admission ICU and unexpected death. If these events occur, patient safety and quality of healthcare of the patient will be affected.

Patient safety and Quality of care

During the last twenty years there has been an increasing interest to monitor and improve patient safety and to determine to which extent harm is preventable. [3,6]

Patient safety can be defined as "a discipline in the health care sector that applies safety science methods with the goal of achieving a trustworthy system of health care delivery. Patient safety is also an attribute of health care systems; it minimizes the occurrence and impact of, and maximizes recovery from, adverse events". [7]

Patient safety can be measured and improved by assessing the quality of care. Quality of health care is defined by the Institute of Medicine as "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge". [8] This definition of quality of health care made it appear that quality was just a listing of quality indicators, which expressed the standards in care. [9] More recently, the Institute of Medicine focuses on conceptual components of quality instead of on measured indicators. Accordingly, "high quality" of care comprises care that is safe, effective, patient centered, timely, efficient and equitable. [10]

Donabedian developed a model to assess the quality of care. In this model, structure (how care is organized) and process (what we do) both influence patient outcomes and the results achieved. [11,12] Another aspect, context, also called 'safety culture' has been specifically added for patient safety models to evaluate the context in which care is delivered. [13] (Figure 1.)

To improve healthcare quality and safety these four domains (structure, process, outcome and culture) should be considered in conjunction with the best available clinical evidence. Quality improvement activities identify and address gaps in the four domains, between the four domains and between knowledge and practice. [14]

Figure 1 adapted from Pronovost [13]

How to optimize and improve quality of care for critically ill patients on wards or the ICU?

Quality of care and patient safety can be improved in hospitals by focusing on the following aspects of care: safety, effectiveness, patient centeredness, timeliness, efficiency, and equitability. This will eventually result in meeting better patient needs and higher patient satisfaction. [10]

In hospital wards this can be done by standardization of the processes of care. This means that guidelines and clinical protocols should be introduced which promote best practices and optimize the standardization of care in patients who have clear presenting symptoms or acute diagnoses. [15] Besides standardization of care, early recognition and treatment of the deteriorating patient is also important. Rapid response systems aim to improve the safety of hospital-ward patients whose condition is deteriorating. This system is based on identification of patients at risk (calling criteria and method of activation), and rapid intervention by the response team. [16] Another aspect to improve the patient safety on the ward is the improvement of communication between physicians and nurses. Nurses and physicians often communicate over the phone and this form of communication is prone to errors. [17] Communication is reported as an important contributing factor to the occurrence of serious adverse events. Effective communication increased when the nurse used a standardized method to communicate with the physician, i.e. the Situation-background-assessment-recommendation (SBAR) tool. [18]

When the patient becomes more critically ill and the effect of the therapy instituted on the hospital ward is not sufficient, the patient will be admitted to the intensive care unit (ICU) for extensive care. Patients in the ICU are particularly vulnerable due to their

illness but also because of the multitude of invasive diagnostic and therapeutic interventions and the use of numerous potent drugs. Furthermore, the ICU is a complex, high technology health care system and a high risk environment with intensive use of new technologies, medicines and equipment, a diverse range of physicians and nurses, many hand-over moments and many communication layers. [1] Thus, ICU patients are very prone to incidents and errors which eventually can result in serious adverse events and complications. [19]

In the ICU several strategies can be implemented to enhance and improve patient safety. One of the strategies is the use of a daily goal form to improve clear communication. From studies by different disciplines such as aviation and chemical industries, but also in health care, it is well established that communication is to date still the most important single factor contributing to the occurrence of near-misses, incidents and complications. Particularly in the ICU effective communication between the ICU physicians and nurses is imperative. Both have to understand the goals of care which include the tasks to be performed and the care and communication plan. It was shown that by the use of a daily goal form, the communication between ICU physicians and nurses became more effective and nurses understood better the goals of care for the day. [20]

However, although the use of a daily goal form can improve the communication, humans are fallible and incidents and errors are to be expected. An incident reporting system that identifies hazardous systems is another strategy that can give insight in causative factors related to the occurrence of incidents and errors in the ICU. [21] By reporting these incidents in an incident reporting system, the incidence of incidents becomes visible. By analyzing incidents the causative patterns and conditions under which nurses and physicians work will be uncovered and improvement strategies can be installed. [22,23] Most importantly, potential strategies should be checked for their actual effectiveness in clinical practice, thereby closing the PDCA (Plan-Do-Check-Act) cycle, since this is the ultimate tool to actually change clinical practice and improve quality. [24-26]

With respect to prevent errors, reduce incidents and improve quality, checklists are an important tool to increase patient safety, by improving communication and structuring care. [27,28] Checklists are particular helpful in the complex processes on the ICU. A checklist highlights the essential criteria and will help the user not to forget important items but it also achieves standardization of the process and enhances objectivity and reproducibility. [29,30]

Another important aspect of quality of health care is patient and family satisfaction. Although maybe a proxy, patient and family satisfaction affect timely, efficient and patient-centered health care, and they even affect patient outcome. Thus, it is essential

to monitor and evaluate delivered care. Because often critically ill patients on the ICU cannot make decisions themselves, family members are involved in the care process as surrogate decision-makers. Assessing the satisfaction of the family with the delivered care to ICU patients can be measured by using family satisfaction questionnaires. In itself family satisfaction is an aspect of quality of care, but these questionnaires can also give a reliable impression of the way the care was given by the ICU professionals to their relative. Thus, asking family is a way to assess the quality of delivered care.

Aim and outline of the thesis

The aim of the work summarized in this thesis is to assess which tools are available to measure and monitor quality of care in critically ill patients and to study the effect of implementing some of these tools to increase patient safety and quality of care.

Chapter 2 describes the COMET study rationale and design. In this before-after study the Modified Early Warning Score (MEWS) and the Situation-Background-Assessment-Recommendation (SBAR) communication tool was implemented followed by the introduction of the Rapid Response Team (RRT). The primary outcome was the incidence of the composite endpoint including cardiopulmonary arrest, unplanned ICU admission or death. **Chapter 3** presents the results of the pragmatic before-after study of the introduction of the RRS in Dutch hospitals. A generalized linear mixed model (GLMM) was used to compare the primary outcome and the individual endpoints between the before phase and the RRT phase. **Chapter 4** describes the effect of a RRT on the mortality of patients on the wards that did not have a limitation of medical treatment (LOMT) order and the effect of a RRT on the change of these LOMT orders over time. **Chapter 5** reports the level of satisfaction of nurses and physicians with the introduction of the Rapid Response System in Dutch hospitals. **Chapter 6** presents the influence of the introduction of daily goals form in the ICU on ICU-length of stay. **Chapter 7** reports the development of an intra-hospital transport checklist by using a comprehensive method with the aim to increase patient safety during transportation of ICU patients to the radiology department. **Chapter 8** describes a review of the medical literature of the available incident and error reporting systems (IRSs) in the adult ICU and the extent to which the IRSs comply with the PDCA cycle. **Chapter 9** reports on a review of the medical literature of the available questionnaires to measure family satisfaction on the ICU and provides an overview of the quality of these questionnaires by evaluating their psychometric properties. A general discussion and summaries in English and Dutch are provided in the last two chapters (**Chapter 10 and 11**).

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Chapter 2

Cost and Outcome of Medical Emergency Teams (COMET) study. Design and rationale of a Dutch multi-center study

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British Journal of Medicine & Medical Research 3(1):13-28, 2013

Abstract

Aims: Description of a study protocol to analyze the effectiveness of the sequential implementation of a Rapid Response System (RRS) on the incidence of the composite endpoint of cardiac arrest, unplanned Intensive Care Unit (ICU) admission, and mortality rates.

Study design: The COMET trial is a before-after, non-randomized multi-center trial.

Place and Duration of Study: The COMET trial was held in the Netherlands in fourteen Dutch hospitals from April 2009 until November 2011. Each hospital included two surgical and two general medicine nursing wards.

Methodology: Prior to the introduction of the RRS, endpoints were collected for 5 months as part of a baseline assessment. The RRS was introduced in two steps. Initially, two tools were introduced during 7 months for early detection of the deteriorating patient: the Modified Early Warning Score (MEWS) and for structured communication, the Situation-Background-Assessment-Recommendation (SBAR) tool. During the next 17 months the Rapid Response Team (RRT) was operational in addition to both the detection and communication tool. Generalized Estimating Equations (GEE) analysis of trends in outcomes will be performed. The cost description will primarily focus on the program costs associated with training and education sessions and the time invested in all consultations originating from patient care on the study wards.

Conclusion: The COMET study will provide evidence on the clinical outcomes and costs of the implementation of Rapid Response System. This will include an analysis to explore the possible effect of a Rapid Response Team as add-on to the MEWS and SBAR tools for early recognition of the deteriorating patient on the nursing ward.

Introduction

Patient deterioration into critical illness on general nursing wards is generally preceded by alterations in the physiological condition hours before an event occurs. This has been demonstrated for cardiac arrests [1,2], unplanned ICU admissions [3,4] and (unexpected) death. [5] The determinants of these events can potentially be recognized by measurement of readily available vital parameters. Therefore, early recognition and intervention in this patient group could potentially prevent adverse events from occurring. As a direct consequence of these findings, RRS have been developed and were first described in 1995 by Lee et al. [6] Up to this point, conclusive evidence regarding the effectiveness of the system is absent. [7]

Rapid Response Systems are built up from three distinct, but interacting components or limbs. [8] The afferent limb is designed to detect the deteriorating patient by the use of Track and Trigger (TT) systems. These are based on measurement of vital parameters and by deviation of either a single or a combination of parameters (including scores) from a norm which determines if a patient is at risk for deterioration. The efferent limb, the RRT, is subsequently activated. An RRT is a combination of personnel originating from the ICU which responds directly to the patient at the bedside. Finally, an administrative component oversees data registration and analysis together with education of the care takers which are required to operate the system components. These limbs are designed to protect the patient, structure care processes to prevent patient deterioration and serious adverse events including cardiac arrest. Taken together, they form a "chain of prevention" which should ensure adequate response by all care-providers. [9]

Despite the unproven nature of RRS, in 2009, a nationwide patient safety initiative has been started in the Netherlands which describes the compulsory implementation of RRS in all Dutch hospitals. This is further acknowledged by the Dutch government and Health Inspectorate. The governmental directive of implementing RRS as soon as possible left no room for the conduct of a randomized trial, but as hospitals needed time to prepare the introduction and implementation of RRS type systems, the opportunity arose to conduct a before-after multicenter trial into the clinical outcomes and costs of RRS type systems in the Netherlands. This manuscript describes the corresponding study protocol.

Methodology

Objectives

The primary objective of this multicenter study is to evaluate the composite clinical outcome of Rapid Response Systems, defined as the impact on cardiac arrest, unplanned ICU admission, and mortality rate. Also, a secondary analysis will investigate to what extent the impact on clinical outcome may be attributed to the afferent (early detection by a Track and Trigger tool) or efferent (RRT) limb during the phased introduction. Furthermore, the satisfaction of the primary applicants (nurses and doctors) will be assessed and a program cost description (from a hospital perspective) will also be performed.

Four steps in a before-after design

The COMET study is a pragmatic before-after trial enabling a GEE (Generalized Estimating Equation) analysis of trends in clinical outcome, based on monthly cardiac arrest, ICU admission and mortality data. The study design is depicted in Figure 1. The before period consisted of 5 months in which baseline data were collected. Most hospitals were able to provide these data prospectively. The implementation of RRS was divided into its two limbs.

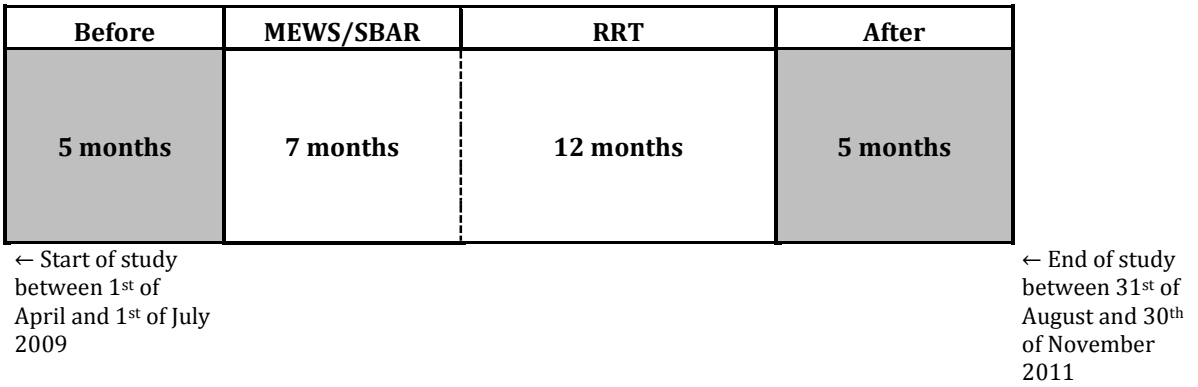

Figure 1. Design of the COMET study.
The COMET study was designed as a before-after study. Hospitals were able to start the study in a three months time span based as logistics within each hospital was different. Following the baseline period of 5 months, the MEWS/SBAR was implemented for 7 months and subsequently followed up by 17 months in which the RRT was available. During this phase and also the after period the entire system was complete. During the entire study, all the endpoints were measured. Besides the before-after comparison, time trend analysis on a monthly basis was also performed.

Initiation of the study was partly left at the discretion of participating hospitals because the time constraints and inter-hospital variation in logistics wouldn't allow a single starting point. Within a restricted three month time frame, starting at the first day of each month between April 2009 and July 2009, the baseline recordings were commenced. Within that same timeframe, a minimum of four participants were trained in the ALERT™ [10] course at the Radboud University Nijmegen Medical Center. In short, this course teaches how to anticipate, recognize, and prevent critical illness at an early stage by providing classroom sessions for theory followed up by multidisciplinary scenario practice. The first intervention phase lasted 7 months during which the MEWS (Modified Early Warning Score) together with the SBAR communication tool (Situation-Background-Assessment-Response instrument) were implemented (Table 1). [11,12] The MEWS and SBAR tools, and later on the RRT, were introduced using a standardized toolkit in which the system was taught to each care-giver. Applicants were also provided with plasticized handheld cards and implementation was continued throughout the study period with posters on the wards, in patient charts, feed-back session and face-to-face communication with personnel. During the MEWS/SBAR phase, the RRT was not available and awareness of the subsequent introduction of the team was absent since the MEWS/SBAR toolkit didn't mention anything regarding the next phase. The RRT as add-on to the MEWS/SBAR tools continued for the next 15 months, of which the final 5 months constituted the after measurement period. This design enabled ample time for implementation of the system and would also provide insight in the differential effectiveness of the MEWS/SBAR on the one hand and the RRT on the other.

Further details on the interventions

Throughout the entire study period and therefore irrespective of the phase in the study, the physicians and nurses adhered to the following procedure. Measurement of the vital parameters, including frequency of measurements and MEWS, was not specifically protocolized within the trial. It was defined 'as clinically indicated' in which the nurses and physicians were instructed (using standardized toolkits for each study phase) to determine the full MEWS (Table 1), whenever a patient's vital parameter was outside normal range, for example had a heart rate outside the 51-100 range, or a systolic blood pressure outside the 101-200 range, or a respiration rate outside the 9-14 range, or a temperature outside the 36.6-37.5 range, or whenever a patient was not alert or the nurse was worried about the patient condition. Also the physicians could demand measurement of the MEWS at specific intervals, when required.

Table 1. The Modified Early Warning Score (MEWS).

MEWS score	3	2	1	0	1	2	3
Heart rate		<40	40-50	51-100	101-110	111-130	>130
Systolic blood pressure	<70	70-80	81-100	101-200		>200	
Respiration rate		<9		9-14	15-20	21-30	>30
Temperature		<35,1	35,1-36,5	36,6-37,5	>37,5		
AVPU score				A (**A**lert)	V (response to **V**oice)	P (reacting to **P**ain)	U (**U**nres-ponsive)
Worried about patient's condition: 1 point							
Urine production below 75 milliliter during previous 4 hours: 1 point							
Saturation below 90% despite adequate oxygen therapy: 3 points							
Upon reaching 3 or more points → call resident in charge							

The MEWS score was implemented as the tool for ward staff to identify the patient at risk of deterioration. The described method was adapted from Subbe et al. [11]

Whenever the score passed the threshold of 3 or more points, the physician (on call) had to be directly notified and the communication had to be structured using the SBAR tool (Table 2). This physician was a postgraduate resident in charge of all patients at the ward or a (supervising) medical specialist and was at least trained and certified according to the Fundamental Critical Care Support (FCCS) guidelines.

Figure 2 shows the algorithm used for activation of the RRT during the RRT phase of the study. It entailed that the physician had a maximum of 30 minutes to evaluate and set-up a treatment plan for the patient after the nurse detected a patient with a MEWS of 3 or more. After initiation of treatment (which may also contained direct notification of the RRT), a maximum of 1 hour was available to evaluate the treatment effect. If the patient continued to deteriorate or did not respond to treatment, the physician was instructed to activate the RRT. Within the system, an override option was incorporated. The nurse was able to directly activate the RRT if the physician did not keep to the protocol (e.g. exceeding the prescribed time limits for review and management of the patient) or in case the patient's health status did not improve (according to the nurse) an hour after initial treatment initiation.

In the MEWS/SBAR phase, the staff provided routine patient care. In response to the detection of a patient with a MEWS of 3 or more, the physician would manage the patient "as this would normally be performed" which could include assessment and consultation with other specialties. No protocol or guidelines for initiation of treatment or consultation of the ICU was available. Therefore this phase enabled the analysis of the ability early detection of the deteriorating patient employing the described tools specific tools without the specific protocol for managing the patient after identification (i.e. time lines for treatment options including the RRT).

Table 2. The SBAR (Situation-Background-Assessment-Recommendation)communication instrument.

SBAR communication instrument	
S	**Situation:** I'm calling about (*name of patient, ward and room number*) The problem I'm calling about is (*problem*) The vital parameters are (*Heart rate, Blood pressure, Breathing rate, Saturation with/without suppl. Oxygen, Temperature, AVPU scale, Urine production, other non-specified parameters*) MEWS score (*score*) I'm concerned about (*define problem*)
B	**Background:** Admissions diagnosis and admission date If relevant: Medical history and other clinical information
A	**Assessment:** I think the problem is (*describe problem*) or I'm unsure what the problem is, but the patient (*is deteriorating/unstable*)
R	**Recommendation:** I think that you should (*describe exactly what needs to happen at this moment*) 1. You should evaluate the patient now and/or 2. You should evaluate the patient (*set specific time interval*) and/or 3. Determines medical policy What should I do now? How often do you want the vital parameters checked and at which thresholds do you want to be called again? **Repeat-back:** We have agreed on the following (*repeat the medical policy systematically and who does what and when*) Write the determined policy up into the patients records

The SBAR method was introduced to facilitate complete and systematic handover over patient data between the nurse and physician (on call) especially whenever a patient reached a MEWS of three or more. [12]

Deviation from the MEWS threshold was allowed in specific circumstances. For instance, in case of a patient with chronic obstructive pulmonary disease with altered respiratory status (e.g. maximum peripheral saturation of 85% with supplementary oxygen), a physician was able to adjust the MEWS criteria accordingly because such patient would trigger at any time. This could enclose alteration of thresholds for the MEWS cut off point of three points, but also changes in thresholds for specific vital parameter(s). These adjustments had to be documented in the nursing and medical charts for clear and an undisputable medical policy.

Setting and participants

The COMET study is a multicenter study in which 14 Dutch hospitals participated. Two are university hospitals (Academic Medical Center Amsterdam and Leiden University Medical Center), nine are large teaching hospitals (BovenIJ Hospital, Catharina Hospital, Gelre Hospital, Kennemer Gasthuis, Medical Center Alkmaar, Medical Spectrum Twente, Rijnland Hospital, Sint Lucas Andreas Hospital and Zaans Medical Center) and three are

smaller regional hospitals (Diaconnessenhuis Leiden, Ikazia Hospital and Rivas Beatrix Hospital). Each hospital included four study wards, 2 surgical and 2 medical based wards. The surgical type wards include general surgery wards, oncology type surgery, vascular, orthopedics etc. Medical wards include internal medicine, nephrology, infectious diseases, pulmonology and neurology.

All patients (age 18 or above), both electively and acutely admitted from home or from another nursing ward onto the 4 study wards, were eligible for inclusion.

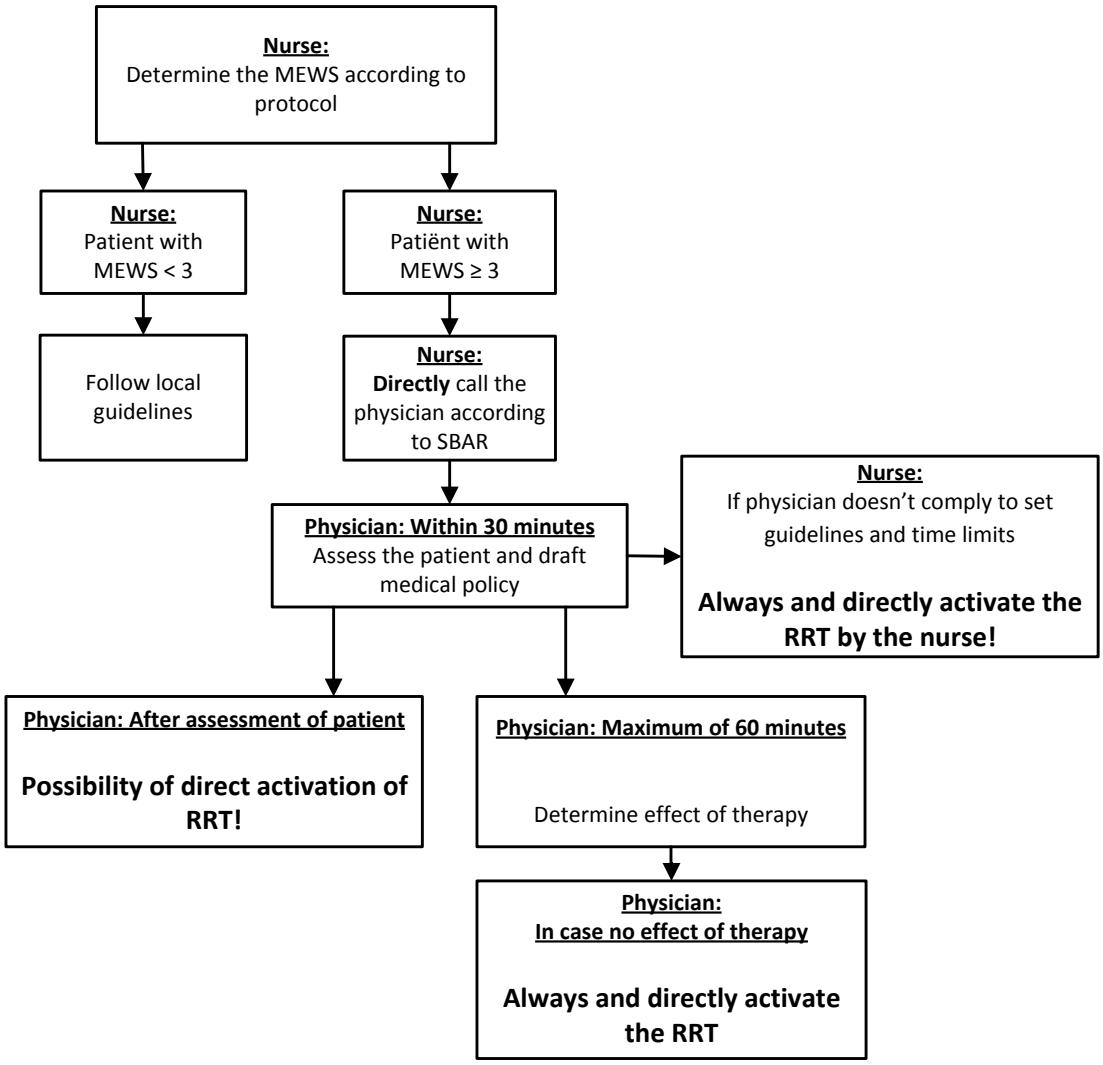

Figure 2. Algorithm for RRT activation.
The algorithm displays the protocol of handling positive MEWS values and all subsequent actions which either nurse or physician has to undertake together with set time limits

Outcome measures and definitions

The primary outcome is the composite endpoint of the first occurring cardiac arrest, unplanned ICU admission or death per 1000 admitted patients on the four wards participating in the COMET study. The same composite endpoint per 1000 inpatient days at these wards is considered a secondary outcome. The components of the

composite endpoint will also be assessed separately as secondary endpoints. Cardiac arrest was defined as an event in which a respiratory and/or cardiac activity was absent and for which the cardiac arrest team was called and started Cardio Pulmonary Resuscitation (CPR), either using chemical resuscitation and/or manual chest compressions and/or respiratory ventilation (irrespective of type). An unplanned ICU admission was defined as a situation in which admission could not be delayed for the following 12 hours without risk. This data field is a component of the Dutch national ICU registry (National Intensive Care Evaluation (NICE), which comprises a continuous and complete registry of all patients admitted to the ICU's of all participating hospitals. [13] Being a member of the NICE registry was mandatory for hospitals to be able to participate in the COMET study.

Analysis of the secondary endpoint includes, according to the MERIT study, the incidence of all cardiac arrests, unplanned ICU admissions, and deaths on the participating wards. [14] Thus, multiple endpoints per patient are possible with the exclusion of a subsequent unplanned ICU admission after successful treatment following a cardiac arrest which is deemed "appropriate care." For these three endpoints, additional information such as APACHE II and IV scores were collected upon admission to ICU and also whether chest compressions and/or artificial ventilation was carried out with patients experiencing a cardiac arrest.

Other secondary outcomes include: (1) Unexpected death defined as death without the presence of any form of a Do Not Attempt Resuscitation (DNAR) order, which primarily includes any form of restriction of active treatment, (2) Hospital Length of Stay (LOS), (3) ICU length of stay, (4) numbers of RRT calls per 1000 admitted patients and per 1000 inpatient days and (5) program costs from a hospital perspective based on team composition and duration of activation during a cardiac arrest, ICU or RRT consultation. Other process parameters will be measured which include a multiple choice written test to be made after each education session in which (based on a case description) the correct action needs to be chosen. Also, at three set time points during the COMET study, a questionnaire will be administered among the nurses and physicians on the included wards regarding their satisfaction with the protocol and its components and perceived benefit of the system. These items were anonymously administered, processed and analyzed. Finally, the number of patients with a primary endpoint without RRT call in the preceding 24 hours per 1000 admitted patients will also be calculated to analyze for possible delay and protocol deviations.

Sample size

This study is powered to determine the effectiveness of an RRS. First of all, the incidence of cardiac arrest presumably ranges between 4 and 11 per 1000 admissions. [14,15] The

incidence of unplanned ICU admissions in patients on general hospital wards has been estimated at 5/1000 admissions. [16]

At the Academic Medical Center (AMC), from 2005 to 2009 (4 years), 100,000 patients were admitted to the hospital. In that same time period, 686 patients (6.9/1000 admissions) were admitted (unplanned) from the general ward to the ICU (re-admissions excluded). Based on the literature and historical AMC data, we anticipate that in the control period 10/1000 admitted patients will reach the primary endpoint (resuscitation, unplanned ICU admission and death) and that this number decreases to 6/1000 during the intervention period, a reduction by 40%. Fourteen hospitals will participate in this study, each with four wards. In the pre-post study design, these four wards will be clustered by two (surgery versus general wards). The study will thus contain 28 (2*14) clusters. With 28 clusters and a total of 5 time periods in the control (phase 1) and 5 time periods during the RRT intervention (phase 3), 99 patients are needed per cluster per time period to reject the null hypothesis that the difference between the intervention period and the control period is smaller than 0.004 [17] with a power of 80% and a one-sided significance level of 0.05. The total number of eligible patients to be included amounts to 27,720 (2*28*5*99). The intra-class correlation coefficient (ICC) used for this calculation is 0.00254. This ICC was derived from the ICC observed (0.00127) in a non-randomized study of three hospitals [18], but it was doubled to account for higher ICCs than one anticipates. [14]

The training in MEWS in phase 2 may also exert influence on the primary outcome measure, but probably less than the combined intervention including the RRT. [8] For lack of power to detect a difference between MEWS only and MEWS+RRT phase, the data gathered during the MEWS phase will only be used for exploration and hypothesis generation. To this end, data will be gathered during 7 time periods with a total of 19,404 (7*28*99) admitted patients.

Data acquisition and analysis

Data for the COMET study were taken from multiple existing hospital and nationwide (NICE registry) databases. Hospitals were primarily conducting their own data acquisition, registered the data on Case Record Forms (CRF) and entered the source data into an internet database. This enabled data monitoring by the study coordinators while not on site. Most data were prospectively collected, except for baseline data in some hospitals. However, this partial retrospective data gathering did not result in a loss of information, because the procedures and extent of data extraction from the existing databases were identical to procedures during prospective data collection.

The main analysis will focus on the before-after comparison of the primary composite endpoint in which all separate events are presumed to be potentially

avoidable. This includes the earlier mentioned exception of an unplanned ICU admission after cardiac arrest.

The total number of 28 clusters over 10 time periods justifies the use of generalized estimating equations (GEE) for statistical analysis of the data. Generalized estimating equations can flexibly handle normal or non-normal endpoints, tend to be more robust to misspecification of the variance structure than (generalized) linear mixed modelling. It is a natural choice for individual-level binary outcomes and may automatically account for variable cluster sizes if they occur. [19]

The analysis will account for the segmented pre- and post-intervention phases into the 5 distinct time periods per phase. The generalized model will include terms for the baseline level of occurring events, the pre-intervention trend over time, the impact of the intervention, the post-intervention trend over time, autocorrelation over time within clusters, and error. [20] Additional analyses include a descriptive of the first endpoint encountered by patients by study phase and by time period, as well as GEE-based exploratory analyses contrasting the MEWS/SBAR phase against the RRT phase. Moreover, possible learning curves in the recognition of deteriorating patients will be studied through test and questionnaire, which are part of the toolkits for each phase of the trial. Satisfaction with the RRS and its components is assessed by regular distribution of questionnaires among the users of the system. The results from these questionnaires will indicate the perceived boundaries in using the system (e.g. ease of use MEWS, activation of RRT).

Dose response analysis according to Chen et al. [21] will be performed to examine possible impact of early review of critically ill ward patients in relation to RRT activation. Taken together, these analyses will portray a clear image of the RRS system within each hospital and by meta-analysis in all COMET hospitals.

Cost description

A partial economic evaluation will be performed, restricted to the description of the direct medical costs of the index admission. This provider (hospital) perspective has been chosen because of the high number of patients to be included and the low incidence of the primary outcome measure in the study. For the same reasons no patient outcome analysis concerning quality of life is planned. The time horizon of the study is the index admission.

The cost components include (i) the training of nurses and physicians in recognizing early warning signs, (ii) installation of RRTs, (iii) (intensive) monitoring and treatment of (vitally threatened) patients, (iv) (ICU) inpatient days, and (v) resuscitations. Volume data will be retrieved from hospital information systems and the NICE database. Unit costs of hospital activities will be derived from national guidelines for costing in health

care research [22,23] or, if these guidelines seem unsuitable for that purpose, from available local unit costs in participating reference hospitals. Activity based costing of RRT will be applied for all hospitals and based on the detailed monitoring of RRT activities. The costs of MEWS and subsequent RRT training will be based on pre-calculation of the related program costs, including the time investment of trainees. Costs will be estimated for the base year 2011 after price indexing.

Based on the cost description and the difference in event rate between the pre- and post-intervention periods, we will tentatively perform an incremental cost-effectiveness analysis showing the extra provider costs per resuscitation, unplanned ICU-admission and death prevented. Sensitivity analyses will be performed for different levels of economies of scale and capacity utilization which influence the availability costs of rapid response teams. The unit costs of an RRT per admission or per recognized vital threat depend on the total number of admissions for which the team is available. The present study will contribute to determine optimal levels of RRT capacity, relative to its unit costs.

Ethics and informed consent

The medical ethics committee (METC) of the Academic Medical Center in Amsterdam waived the need for formal evaluation of the study due to the obligatory nature of the intervention and the observational nature of the study. Consequently, the need for informed consent was not applicable. The trial was registered at the Dutch Trial Register under number TC2706. All authors hereby declare that all experiments have been examined performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki.

Discussion

The COMET trial is a multicenter, non-randomized before-after trial with the ability to perform GEE analysis to evaluate the effectiveness and costs associated with implementation of an RRS within the fourteen participating Dutch hospitals. The COMET trial consists of the phased implementation of RRS. It starts with the use of MEWS/SBAR tools to detect and communicate about a clinically deteriorating patient. Seven months later the second component of RRS, the physician based RRT which can be warned by ward personnel, is introduced. This phased implementation enables not just the evaluation of the RRS as the combination of MEWS/SBAR and RRT (comparing the after and before measurements); it also allows for exploration of the impact of the RRT as add-on to the use of only the MEWS/SBAR tools (comparing the measurement during the MEWS/SBAR period with the before measurement and with the after measurement).

To our knowledge, this has never been fully attempted on this scale although Priestley et al. have shown reduction in hospital LOS and in-hospital mortality in the training group which had just been trained in the use of the afferent limb. [16] The COMET study is held within the Netherlands where mandatory implementation of an RRS is required by the Health Inspectorate. This enabled a unique opportunity to initiate a multicenter study in which a representative population of Dutch hospitals is present and external validity of the data is perceived to be high. Recently, an editorial by Bellomo et al. has shown that single center trials often show positive results which are not held up in multicenter trials. [24] Much of the scientific knowledge regarding RRS is derived from many mono center or even mono ward trials with less rigorous study designs. Therefore, reticence should be present regarding these data. The COMET study, despite absence of randomization but including an innovative time phased introduction over a substantial timeframe of a RRS, should provide new insight in the effectiveness of the system and, to a lesser extent, each of its components, the MEWS/SBAR and RRT.

The internal validity of research into 'complex interventions', is often at stake and optimal trial design is challenging. [25,26] Randomized controlled trials, in respect to RRS, are merely impossible to conduct. Several reasons for this are present. Prior to the governmental directive on RRS implementation, the COMET study was set up as cluster randomized controlled trial (RCT) following the methodology of a stepped wedge trial. [19] Within this design, not hospitals but the two pairs of wards were randomized for the initiation of the RRS so that there was always a parallel control group from the same hospital present. In the end, all four wards of each hospital would have taken up the intervention. This design or an RCT in which hospitals would be randomized as either placebo or intervention hospital (MERIT study), were too hard to accomplish due to the mandatory nature of RRS in the Netherlands in which every hospital at a certain time point should have an RRS, but also due to problems encountered in the MERIT study including potential contamination in a parallel design. [26]

Furthermore, complex interventions are difficult to study because they are built up from components that may act both independently and inter-dependently. Also, they are adaptive to changes in their local environments, and behave in a non-linear fashion. [25] Standards of nursing care, education and commitment of all associated health care workers within an RRS are required to be able to correctly assess the program's effectiveness.

The COMET trial is a pragmatic trial in which RRS has to proof itself in the flexible and real-time workspace of general practice. It lacks the sometimes "artificial nature" of more stringent, protocolized studies, thereby gaining in clinical relevance against, perhaps, a slightly increased risk of a lower internal validity. One manifestation of the pragmatic approach is that the MEWS is determined 'on indication' rather than set at

specific intervals and on all patients. This mirrors the clinical practice to a large extent in which no specific guidelines are present regarding measurement of vital signs. On the surface, frequent measurement of complete sets of vital signs should hypothetically increases the chance of identifying a deteriorating patient, but the clinical relevance of our pragmatic approach is supported by two papers showing that fixed measurements of vital signs show low positive predictive power on adverse events. [27,28] Furthermore, the COMET study employs a physician based RRT rather than a nurse led team or a step up procedure in which a physician is called when indicated by the RRT nurse. No evidence exists what composition is more effective; however, it is generally perceived that a physician led team is able to directly initiate therapy which nurses aren't allowed to. The RRT within the COMET study is staffed 24/7 and the minimal competency level of the RRT physician is Fundamental Critical Care Support (FCCS) trained. This ensures, together with the ICU nurse, adequate knowledge and skills levels regarding assessment and treatment options at the bedside of the patient at risk. A final possible limitation of the study lies in the starting point of the study. Because the pressure on hospitals in 2009 to initiate the implementation of the RRS, led to logistical issues for the hospitals which participated in the COMET study. For some hospitals, the organization of also entering the study was minimal. For some it was a bit more challenging. To account for this, hospitals were entitled to initiate the study within a three month time frame, allowing them to start the RRS while being equally well prepared. This minimized the risk of different learning curves early in the study, which would have influenced hospital performance during the MEWS/SBAR phase.

The COMET study is innovative, because it will investigate for the first time, the degree of satisfaction of the care-givers in all participating hospitals and at ward level. This will support the interpretation of possible differences in outcome parameters among hospitals and/or wards, that directly relate to the care givers' opinions regarding (ease) of use of RRS components, perceived effectiveness, but also issues regarding past experiences of RRT members. Finally, because of the sequential introduction of the afferent limb prior the RRT, the additive effect of the RRT on sole, hypothetically earlier recognition of the deteriorating patient, can be studied. Recent evidence suggests that this may indeed be beneficial. [29]

An RRS can potentially take up much effort during its implementation in hospital organizations, as suggested by a recent postal survey in the Netherlands. [30]
Implementation depends on the willingness among many health care workers to contribute, despite interference with "normal day-to-day" routines. Hence, implementation outcome measures were incorporated in our study design to facilitate the interpretation of the findings. In contrast with the MERIT trial and the trial by

Priestley [14,16] accounting for these implementation outcome measures will increase the study duration up to 2.5 years.

Conclusion

In conclusion, the COMET trial will provide new and important insights into the functioning of an RRS and has incorporated as much insights regarding the analysis of complex interventions.

Acknowledgements

We would like to thank P.F. de Maaijer (expert in development of educational tools) for the assistance in the development of the educational tools (COMET toolkits).

Competing Interests

The Radboud University Nijmegen Medical Center (B.G. Fikkers, MD, PhD) is a satellite center for the ALERT™ course within the Netherlands.

Authors contributions

This work was carried out in collaboration between all authors. Authors JL, SS, SR and EJ were involved in the design of the study. Authors JL, MD and EJ were primarily involved in the subsequent conceptualization of the study protocol and drafting of this manuscript. Management and logistics were carried out by authors JL and ABR. Author BF and PT participated as individual experts regarding their RRS knowledge. All authors read the final version of the manuscript.

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Chapter 3

Outcomes associated with the nationwide introduction of Rapid Response Systems in the Netherlands

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Critical Care Medicine 2015 Dec;43(12):2544-2551

Abstract

Objective: To describe the effect of implementation of a Rapid Response System (RRS) on the composite endpoint of cardiopulmonary arrest, unplanned ICU admission, or death.

Design: Pragmatic prospective Dutch multicenter before-after trial, Cost and Outcomes analysis of Medical Emergency Teams trial.

Setting: Twelve hospitals participated, each including two surgical and two non-surgical wards between April 2009 and November 2011. The Modified Early Warning Score and Situation-Background-Assessment-Recommendation instruments were implemented over 7 months. The rapid response team was then implemented during the following 17 months. The effects of implementing the rapid response team were measured in the last 5 months of this period.

Patients: All patients 18 years old and older admitted to the study wards were included.

Measurements and main results: In total, 166,569 patients were included in the study representing 1,031,172 hospital admission days. No differences were observed in patient demographics between periods. The composite endpoint of cardiopulmonary arrest, unplanned ICU admission, or death per 1,000 admissions was significantly reduced in the rapid response team versus the before phase (adjusted odds ratio 0.847; 95% CI, 0.725-0.989; p=0.036). Cardiopulmonary arrests and in-hospital mortality were also significantly reduced (odds ratio, 0.607; 95% CI, 0.393-0.937; p=0.018 and odds ratio 0.802; 95% CI, 0.644-1.0; p=0.05, respectively). Unplanned ICU admissions showed a declining trend (odds ratio 0.878; 95% CI, 0.755-1.021; p=0.092), whereas severity of illness at the moment of ICU admission was not different between periods.

Conclusions: In this study, introduction of nationwide implementation of rapid response systems was associated with a decrease in the composite endpoint of cardiopulmonary arrests, unplanned ICU admissions and mortality in patients on general hospital wards. These findings support the implementation of rapid response systems in hospitals to reduce severe adverse events.

Introduction

Patients who experience adverse events during their hospital stay, including cardiopulmonary arrest, unplanned ICU admissions and unexpected death, show clear signs of deterioration in the hours preceding the event. [1,2] Rapid Response Systems (RRSs) have been developed for timely identification and treatment of patients on general wards at risk for clinical deterioration. [3] RRSs are designed as a three-component system. [4] The two primary components are the afferent and efferent limbs. The afferent limb comprises the early detection of the deteriorating condition by systematic measurement of vital signs using a track and trigger system. [5-7] When measures reach a certain threshold, the efferent limb is activated and the Medical Emergency Team or Rapid Response Team (RRT) is called and responds to the patient's bedside. These teams are most often composed of ICU physicians together with ICU nurses. [8] The final component is the education, data collection and analysis limb to aid in (sustained) implementation within the institution.

Up to this moment, only two randomized studies have been performed investigating the effectiveness of RRSs. A large randomized trial from Australia, the Medical Early Response Intervention and Therapy (MERIT) study, failed to show an impact of introduction of an RRT on a composite endpoint including death, cardiac arrest and ICU-admission. [9] The second study from the United Kingdom demonstrated a reduction in hospital mortality after introduction of an RRT. [10] Apart from these studies, many smaller less well-controlled studies have been published generally reporting a decline in cardiac arrest rates following introduction of an RRT. [11]

In 2008, implementation of RRS was mandated by the Dutch government. [12] We took the opportunity to study the effects of this nationwide implementation of RRS on outcome of patients admitted to general hospital wards. Primary endpoint was the incidence of the composite endpoint of cardiopulmonary arrest, unplanned ICU admission, or death.

Methods

Trial design

The study protocol has been described previously. [13] In short, the Cost and Outcomes analysis of Medical Emergency Teams (COMET) multicenter study was designed as a prospective, pragmatic before-after multicenter trial enabling the analysis of clinical outcomes after sequential introduction of the RRS components. Twelve of the originally planned 14 Dutch hospitals participated throughout the study. Two hospitals were withdrawn during the study after major local reorganizations with changes in case-mix

from surgical to medical patients on COMET-wards. The withdrawal of study centers was performed without knowledge of incidence of study endpoints. Therefore, these two hospitals were excluded from final analysis.

Two large university hospitals (number of beds, 882-1,000), eight large teaching hospitals (number of beds, 359-1,070) and two smaller regional hospitals (number of beds, 290-325) completed the study. Each hospital included four study wards, two surgical and two medical wards. All patients were 18 years or above.

Patients who were readmitted to the hospital were not excluded from the analysis. These patients were considered to be a new hospital admission. The trial design was determined a priori and is shown in Figure 1.

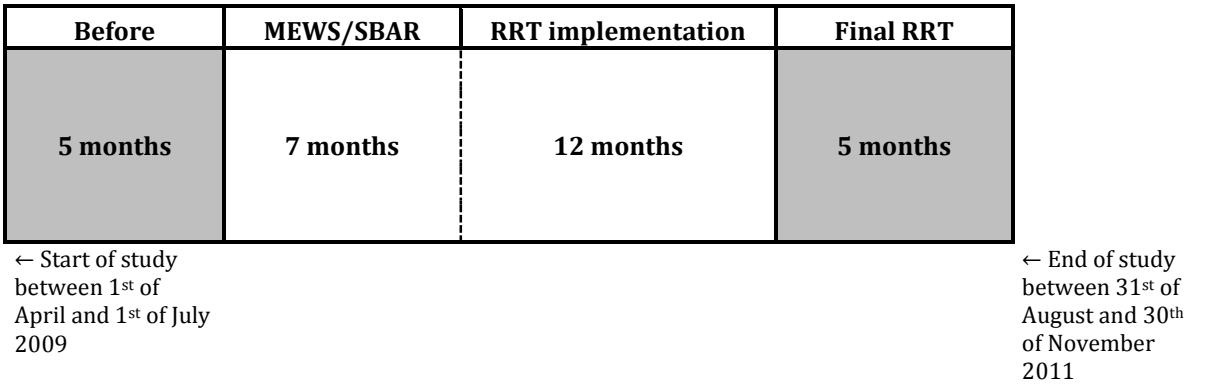

Figure 1. Design of the COMET study.
Following the baseline period of 5 months, the Modified Early Warning Score (MEWS)/Situation-Background-Assessment-Recommendation (SBAR) was implemented for 7 months and subsequently followed up by 17 months in which the rapid response team (RRT) was available. Effects of the RRT on outcomes were measured during the last 5 months and compared with the 5-month baseline period. During the entire length of the study, data were collected on all the endpoints. For further clarification, hospitals were able to start with the study in a 3-month time period. The total study took 30 months, in which each hospital participated for 27 months.

The before period consisted of 5 months in which baseline data was prospectively collected. The implementation of RRS was divided into two phases. Within the first phase (7 months) the MEWS (Modified Early Warning Score) and the SBAR communication tools (Situation-Background-Assessment-Response instrument) were implemented (Appendix A). In the second phase, lasting a total of 17 months, the RRT was introduced. The last 5 months of this phase were used to measure the effects on outcome of patients compared to the before period and will be referred to as "final RRT period". These 5 months comprise the same months of year as the before period.

Outcomes

The primary outcome is the composite endpoint of cardiopulmonary arrest, unplanned ICU admission, or death while being admitted on a COMET ward per 1,000 admitted patients. Intensive care admission did not include medium care or other high

dependency units. Intensive care was defined according to the criteria from the Dutch National Intensive Care Evaluation (NICE) registry. [14] The composite endpoint was chosen in accordance with previous studies [9] because of the low number of patients anticipated to reach the individual components of this endpoint.

Secondary endpoints were the individual components of the composite endpoint and the outcomes per 1,000 admissions days. Cardiopulmonary arrest was defined as an event for which the cardiopulmonary arrest team started cardio pulmonary resuscitation (CPR), using chemical resuscitation and/or manual chest compressions and/or respiratory ventilation (irrespective of type). Unplanned ICU admissions were registered according to the definitions of the Dutch NICE registry as admissions that were unscheduled and could not be delayed for at least 12 hours without risk. All hospitals had followed training in data collection and data definitions as used in the NICE registry. [14]

Details of the interventions

Within each participating hospital, all physicians and nurses working on a COMET ward were trained using standardized toolkits, including pocket cards and posters provided by the primary investigators. Specifically, during the MEWS phase, participants were trained in using the MEWS [15] and SBAR communication tool. [16] Determination of the MEWS was mandatory whenever at least one of the measured vital signs was outside its normal range or when considered necessary by the treating physician or nurse. Upon reaching the threshold of three or more points of the MEWS, the responsible physician on that ward was directly notified with communication structured using the SBAR tool. Deviation from the MEWS threshold was allowed in specific circumstances based on patient characteristics for instance in a patient with chronic hypoxemia, but should be clearly mentioned by the physician within the patient chart.

The RRT included both an ICU nurse and a physician who was at least trained in Fundamental Critical Care Support (www.fccs.nl). Description of activation of RRTs is presented in Figure 2. During the study, no structural changes in data collection charts, medical record keeping or treatment guidelines were introduced.

Sample size

The calculation of the sample size has been described in detail previously. [13] About twice the originally planned number of 27,720 admissions, equally divided over the before and RRT periods, was available for analysis. The actual analysis to detect if the RRT period would show a lower incidence of patients experiencing the composite endpoint or its components by at least 4 (from 10 to 6) per 1,000 admissions, was based on 54,479 admissions, 26,659 stemming from the before period and 27,820 from the final

RRT period. Considering increased numbers of admissions available for analysis, the level of significance was set at a two-sided rather than the originally planned one-sided α of 0.05.

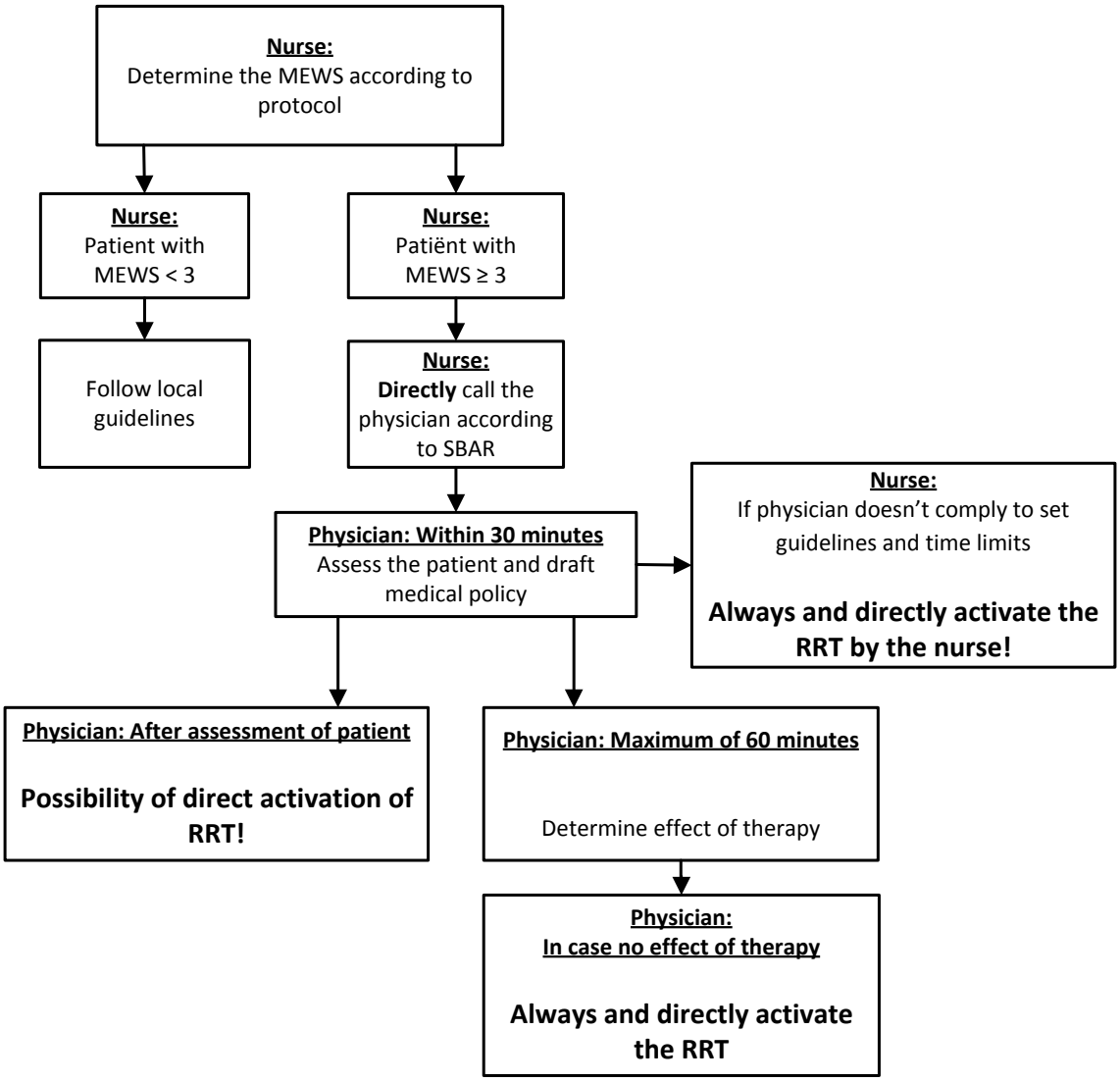

Figure 2. Algorithm for RRT activation.
The algorithm displays the protocol of handling positive MEWS values and all subsequent actions which either nurse or physician has to undertake together with set time limits.

Data acquisition

Admission data of patients who had spent time on a COMET ward at any time during the study observation period were provided by the information departments of participating hospitals. Data on cardiopulmonary arrest, unplanned ICU admission, and death and RRT activations on COMET wards were collected with clinical report forms.

Data presentation and statistical analysis

Incidences of cardiopulmonary arrest, unplanned ICU admission and death, both as composite endpoint and each separately, are presented graphically over time for the before, MEWS, RRT implementation, and final RRT periods respectively. Incidences were calculated per 1,000 admissions. Admissions were counted when a patient had spent at least 1 day of his admission on a COMET ward. Inpatient days were counted when a patient had spent some part of the day on a COMET ward.

Generalized linear mixed modelling (GLMM) was applied to assess differences in outcomes per 1,000 admissions between the before and final RRT periods while correcting for potential confounding following the before-after study design.

Potential confounders were identified following 1) cross-tabulation of categorical variables (sex, emergency admission, hospital) with the before and final RRT periods or *t* testing for the difference in patients' age between the before and final RRT periods and 2) simple univariable logistic regression analyses on the composite outcome with the same variables (sex, emergency admission, hospital, age). Seasonality - reflecting differences in risk of cardiopulmonary arrests, unplanned ICU-admission, or death by calendar month [17,18] – could be ignored, because in each hospital the included months of the year were identical for the before and final RRT periods.

In the GLMM, a binomial distribution was assumed for the composite primary endpoint and for deaths. For unplanned ICU admissions, a binomial distribution was assumed after recoding the original count variable into a dichotomous one, expressing whether patients were at least once admitted to the ICU or not during their stay (no convincing model fit could be achieved under the assumption of Poisson distributed original ICU admission counts). For cardiopulmonary arrests a Poisson distribution was assumed because of its observed (extremely) low incidence. No offset variable was taken into account. Potential confounders were included in GLMM as fixed or random variables. Hospitals were modelled as a random variable, accounting for differences in background incidence (level) and varying impact of the intervention (slope) while simultaneously controlling for the differentially distributed numbers of admissions by hospital during the before and final RRT periods. Age of patients was modelled as a random component, whereas patients' sex and admission type (planned vs unplanned/emergency) were modelled as fixed variables. All analyses were performed in SPSS version 20.0.0.1 (SPSS INC, Chicago, II).

The uncorrected odds ratios (ORs) and ORs after correction for confounding are reported along with their CIs and corresponding *p* values. In deviation from the published study protocol [13], the decision was made to simplify the analyses. We first nested admissions within hospitals rather than within the ward types as clusters because during the introduction, implementation, and maintenance of the RRSs at the

local level, hospitals seemed more distinct than ward types. Secondly, it was decided to compare the before and final RRT periods as whole periods and to refrain from the analysis of data by successive months, because the latter approach introduced complex dependencies over time, in case admissions included two or more months.

Ethics approval

The medical ethics committee of the Academic Medical Center in Amsterdam waived the need for formal evaluation of the study due to the obligatory nature of the intervention and the observational nature of the study. Consequently, the need for informed consent was not applicable. The trial was registered at the Dutch Trial Register (www.trialregister.nl) under number NTR2706. All authors hereby declare that all experiments have been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki, updated October 2008.

Funding for the primary investigators of the study was provided by the Academic Medical Center and Leiden University Medical Center. Each participating hospital provided staff for training of their personal personnel and acquisition of study data.

Results

Characteristics of the study population from the 12 hospitals are presented in Table 1. Patients could be transferred during their hospital admission between non-COMET wards to COMET wards and vice versa. Therefore, the ratio of COMET admission days to the total length of hospital admissions was calculated, ranging from 0.97 to 0.98 in the different study periods.

Table 1. Characteristics of study population

	Before	MEWS	RRT implementation	Final RRT
No. of months	5	7	12	5
No. of hospitals	12	12	12	12
No. of hospital admissions	28,298	40,499	68,212	29,560
Percentage emergency	47.2[a]	47.1[b]	47.4	49.7
Mean overall length of stay	6.42	6.57	6.34	5.81
COMET part of admissions	0.981	0.972	0.984	0.983
No. of COMET admission days	178,156	258,710	425,558	168,748
Male patients	49.2	50.1	49.9	50.1
Mean age of patients (SD)	62.2 (18)	62.3 (18)	62.4 (18)	62.3 (18)

RRT = Rapid Response Team, COMET = Cost and Outcomes analysis of Medical Emergency Teams.
[a] Based on 26,659 admissions, excluding one hospital without provided information on emergency.
[b] Based on 37,883 admissions, excluding one hospital without provided information on emergency.

Figure 3 shows the primary outcome, that is, the number of patients per 1,000 admissions with a cardiopulmonary arrest, unplanned admission to the ICU, or death while being admitted to a COMET ward. The number of patients who reached the primary outcome decreased from 37.14 (95% CI, 34.94 – 39.34) per 1,000 admissions in the before period to 32.92 (95% CI, 30.88 – 34.95) in the final RRT period (Figure 3). The unadjusted OR of reaching the primary endpoint was 0.88 for the last 5 months of the RRT phase relative to the before phase. The number of patients reaching the primary endpoint in the MEWS and the RRT implementation period (Figure 3) were 39.14 (95% CI, 37.24 – 41.03) and 37.28 (95% CI, 35.86 – 38.70) respectively. Per 1,000 COMET inpatient days, the composite endpoint was reached 5.90, 6.13, 5.98, and 5.77 times in the before, MEWS, RRT implementation phase, and final RRT periods respectively.

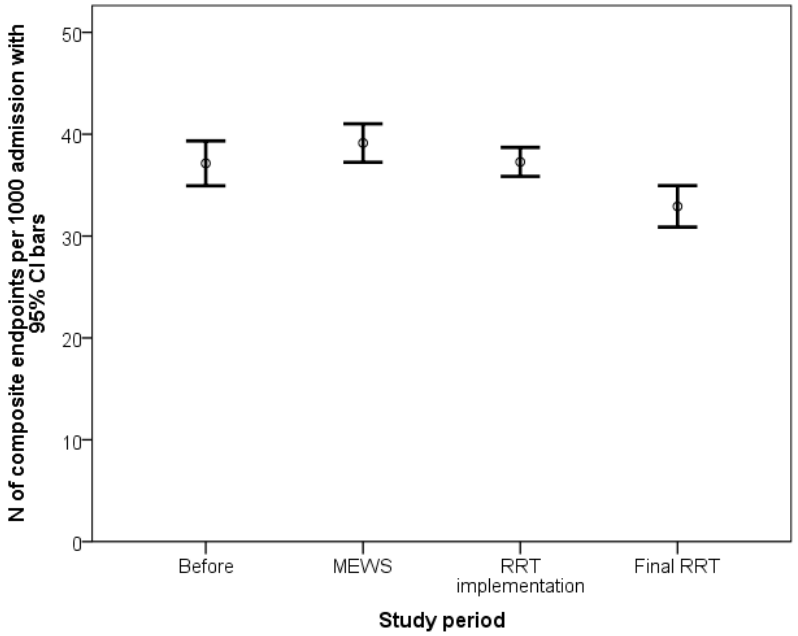

Figure 3. Composite endpoint per 1,000 admissions.
The primary endpoint, that is, the number of patients per 1,000 admissions with a cardiopulmonary arrest, unplanned admission to the ICU, or death while being admitted to a COMET ward, is shown. The incidence of the composite endpoint is shown including its 95% CI. MEWS = Modified Early Warning Score, RRT = rapid response team.

The results for the individual components of the primary outcome presented per 1,000 admissions are given in Table 2. The number of cardiopulmonary arrests remained stable in the before and MEWS periods and gradually declined in the RRT implementation and final RRT periods. The number of unplanned ICU admissions was similar in the before, MEWS and RRT implementation periods, but dropped in the final RRT period. Mortality increased from the before to the MEWS period and fell back again to the baseline level in the RRT implementation period, before it further decreased in the final RRT period.

Table 2. Secondary outcomes per 1,000 admissions

	Before	MEWS	RRT implementation	Final RRT
Cardiopulmonary Arrest, *n*/1,000 (95%CI)	1.94 (1.43-2.46)	1.93 (1.50-2.35)	1.54 (1.25-1.83)	1.22 (0.82-1.61)
ICU admission,[a] *n*/1,000 (95%CI)	19.8 (18.1-21.6)	19.6 (18.1-21.0)	19.5 (18.3-20.6)	17.1 (15.5-18.6)
Death, *n*/1,000 (95%CI)	20.4 (18.7-22.0)	22.5 (21.0-23.9)	20.5 (19.5-21.6)	17.7 (16.2-19.2)

RRT = Rapid Response Team.
[a] Including multiple unplanned ICU admissions per patient.

Interestingly, the composite endpoint was almost entirely composed of unplanned ICU admissions and deaths; cardiopulmonary arrest was a less frequent event. Per 1,000 COMET inpatient days, the point estimates for the before, MEWS, RRT implementation and final RRT periods are 0.31, 0.30, 0.25, and 0.21 for cardiopulmonary arrests, 3.15, 3.06, 3.12, and 2.99 for unplanned ICU admissions, and 3.23, 3.52, 3.29, and 3.09 for deaths respectively.

Table 3 shows the ORs for the primary and secondary endpoints. The unadjusted ORs of having a cardiopulmonary arrest in the final RRT period relative to the before period was 0.626 (95% CI, 0.41-0.95), of being admitted unexpectedly at least once to the ICU 0.881 (95% CI, 0.77–0.99) and of dying 0.865 (95% CI, 0.76–0.97). Adjustment for case-mix variables was performed for potential confounders gender, age, individual hospital, and urgency of admissions, while simultaneously accounting for clustering of admissions within hospitals. Preparatory analyses revealed associations of these variables with the composite endpoint, whereas sex, hospital and emergence level were also differentially distributed over the before and after periods (data not shown). The benefits of the RRT turned out slightly better after correcting for confounding variables while taking into account clustering of admissions within hospitals.

Table 3. Odds ratios of composite endpoint and its individual components for the Rapid Response Team final period versus the before period, corrected for sex, age, hospital and emergency of admission.

	Uncorrected OR	95% CI of uncorrected OR	Corrected OR	95% CI of corrected OR	*p* value corrected OR
Composite endpoint	0.882	0.807-0.964	0.847	0.725-0.989	0.036
Cardiopulmonary arrest, *n*/1,000 (95%CI)	0.626	0.411-0.953	0.607	0.393-0.937	0.018[a]
ICU admission[b], *n*/1,000 (95%CI)	0.881	0.777-0.999	0.878	0.755-1.021	0.092
Death, *n*/1,000 (95%CI)	0.865	0.768-0.975	0.802	0.644-1.0	0.05

OR = odds ratio.
[a]A generalized linear model (GLM) model based on Poisson-distributed cardiopulmonary arrest with identity link converged during its iteration and showed a *p* value of 0.018; the corrected odds ratio reported stems from a nonconverging Poisson-based GLM model with a log link which is slightly more conservative (*p*=0.024).
[b] Odds ratio presented for being unexpectedly admitted at least once to the ICU.
Number of admissions in before period = 26,659; number of admissions in rapid response team period = 27,820.

Appendix B shows the characteristics of patients reaching the individual components of the primary endpoint for all study phases. Statistical comparisons were restricted to the before and RRT periods of the study only. During the before period, more patients were transferred to the coronary care unit and less patients to other hospitals or other destinations after a cardiopulmonary arrest (p=0.013) when compared to the RRT period. Patients who died were younger in the RRT phase (75.0; SD, 14) compared with the before phase (76.8; SD 12) (p=0.021).

Only in the RRT implementation and final RRT phases, the RRT was available for the care providers. The call rate in the RRT implementation phase was 6.8/1,000 admitted patients and increased to 7.3/1,000, see Appendix C. In this study, the RRT was primarily called by the responsible physician. However, in the RRT implementation phase, 15% of the RRT calls were initiated by a nurse which decreased to 9% in the RRT phase with a seemingly corresponding increase of activations by the resident. Rarely, do not attempt resuscitation (DNAR) orders were instituted after an RRT was called.

Discussion

The COMET study is the largest trial which has been performed investigating the effectiveness of RRSs. [9] Eventually, 12 Dutch hospitals participated in this trial in which an approximately 15% adjusted risk reduction in severe adverse events, including cardiac arrests, unplanned ICU admissions and in-hospital mortality, was found.
Regarding the individual components of the primary endpoint, full implementation of the RRS resulted in lower rates of death and cardiac arrest and only a trend for unplanned ICU admissions. It has been argued that effective RRS may lower the rate of ICU admission by earlier detection and treatment of deteriorating patients but also may increase ICU admission if deteriorating patients are transferred to the ICU for treatment. Therefore, ICU admission rates may underestimate the beneficial effect of RRSs.

As recently reviewed, 42 studies have been published describing the effectiveness of RRSs. [19] Many of these studies were relatively small and underpowered to find effects on clinically relevant endpoints. Methodological quality was suboptimal in most studies. [19] In some studies, a reduction in the incidence of cardiac arrests was reported. [20-23] However, interpretation of this reduction is difficult as no adjustment was made for DNAR policies. It cannot be ruled out that institution of RRTs lead to an increase of DNAR orders and consequently to less registered CPR attempts. [24,25]

Two large, randomized, well-designed studies have been published on the effects of RRSs on outcome of in-hospital patients. The first study by Priestley et al [10] used a stepped wedge design and was performed in United Kingdom and included 7,450 patients. Introduction of a RRT lowered in-hospital mortality, with an odds ratio of 0.52.

By contrast, the MERIT trial randomizing 23 Australian hospitals to introduce RRS or to continue usual care did not show an improvement on a composite endpoint consisting of unexpected death, unplanned ICU admission or cardiac arrest after introduction of an RRS. [9] Several possible explanations for these negative results have been suggested, including contamination of the control group and secondly, lack of power in this cluster randomized design. Maybe more importantly, the time taken for implementation of RRSs may have been too short for optimal functioning. [26-30]

Interestingly, a marked difference was present in the proportion of patients reaching the endpoints. In the Australian MERIT study, at baseline, almost 5 per 1,000 admitted patients were transferred unplanned to the ICU, in the COMET study, 20 per 1,000 were admitted to the ICU. Most likely explanation for this difference is the fact that in the COMET study only patients that were admitted to four selected surgical and medical wards per hospital were included, whereas all hospital patients were included in the MERIT trial. Alternatively, we cannot exclude that differences in ICU admission policies or availability of ICU beds may account for the different ICU admission rates. Death rates were also considerably lower in the MERIT study, but this can be explained by the fact that only unexpected deaths were included in the MERIT study in contrast to all deaths in the present study. It may well be that the effects of RRSs depend on the severity of illness and other characteristics of the population it is introduced to.

In 2007, the Dutch government demanded that RRSs should be instituted in all hospitals in the Netherlands. Due to this mandatory nature of RRS in the Netherlands, any form of a randomized trial, including a stepped wedge design, was not feasible. Therefore, the COMET study was designed with a prospective before-after methodology, with the inherent risk that associations between intervention and outcome may not be causal. [31] For instance, severity of illness may have changed over time, potentially influencing the rates of mortality, cardiac arrest or ICU admission. Although baseline characteristics were very similar in the different study periods, we cannot fully rule out this possibility. Also, simultaneous interventions - which may include the SURgical Patient Safety System checklist in surgical patients [32] - or general background trends during the study could also influence our findings. Consequently, caution should be taken in this respect when interpreting the study results.

In our study, a slightly increased death rate was shown in the phase in which the MEWS data were collected but without institution of a RRT. No clear explanation can be given for this finding. It could be related to seasonal effects. In this respect, it should be emphasized that the primary comparison between baseline and full implementation of the RRS is not influenced by seasonal factors because both periods comprised the same months of year in all participating hospitals. Several arguments do support a causal interpretation of the association between the RRS and the studied severe adverse

events. First, the working mechanism of RRSs makes a positive impact on incidences of severe adverse events plausible, and proactive monitoring of patients is very likely to be beneficial. [33] Second, we improved the internal validity of our before-after design by adjusting for potential confounders including gender, age, individual hospital and urgency of admissions. The strength of the association of the RRS with the composite endpoint increased with ORs being 0.85 (95% CI, 0.72-0.99) and 0.88 (95% CI, 0.77 – 0.99) with and without adjustment for confounders respectively. Third, during the study and also in 11 of the 12 hospitals (data not shown), the effect of sequential introduction of the RRS resulted in a consistent and gradual decline of the proportion of patients reaching the endpoints over time.

Interestingly, our study was the first to perform the analysis of sequential introduction of the components of an RRS. Our data may suggest that instituting only the afferent limb of the RRS, which is the MEWS/SBAR, may not be as effective in decreasing the number of cardiac arrests, unplanned ICU admissions, or deaths. This suggestion should only be interpreted as hypothesis formulation also because these findings were not corrected for seasonal influences. It is very likely that increased utilization of the system and its components is likely to result in improved clinical outcome during the entire study period. [34]

The results of the COMET study support the continuing efforts regarding implementation of RRS and optimization of current systems. A more mandatory nature of implementation and measurement of outcomes would assist in the continual optimization and research into RRS.

Based on the results of this study, introduction of an RRS with the MEWS and SBAR for early identification and a RRT for early management of patients at risk for deterioration was associated with a decrease in the incidence of severe adverse events including death, unplanned ICU admission and cardiac arrest. As part of the COMET study, a budget impact analysis will be performed in further analyses.

Authors contributions and Acknowledgements

JL and ABR are both primary authors and share responsibility for the logistical process together with data entry, validation and analysis. Principle design of the study was performed by JL, EdJ and MD. Data analysis was performed primarily by MD and writing of the manuscript by JL and ABR with supervision of EdJ and MD. All co-authors read and acknowledge the content of this manuscript.

JL and ABR had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

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Appendix A. Modified Early Warning Score and Situation-Background-Assessment-Recommendation communication tool

Modified Early Warning Score (MEWS)

MEWS score	**3**	**2**	**1**	**0**	**1**	**2**	**3**
Heart rate		<40	40-50	51-100	101-110	111-130	>130
Systolic blood pressure	<70	70-80	81-100	101-200		>200	
Respiration rate		<9		9-14	15-20	21-30	>30
Temperature		<35,1	35,1-36,5	36,6-37,5	>37,5		
AVPU score				A (**A**lert)	V (response to **V**oice)	P (reacting to **P**ain)	U (**U**nresponsive)
Worried about patient's condition: 1 point							
Urine production below 75 milliliter during previous 4 hours: 1 point							
Saturation below 90% despite adequate oxygen therapy: 3 points							
Upon reaching 3 or more points → call resident in charge							

The MEWS score was implemented as the tool for ward staff to identify the patient at risk of deterioration. The described method was adapted from Subbe et al. [15]

The SBAR communication instrument.

SBAR communication instrument	
S	**Situation:** I'm calling about (*name of patient, ward and room number*) The problem I'm calling about is (*problem*) The vital parameters are (*Heart rate, Blood pressure, Breathing rate, Saturation with/without suppl. Oxygen, Temperature, AVPU scale, Urine production, other non-specified parameters*) MEWS score (*score*) I'm concerned about (*define problem*)
B	**Background:** Admissions diagnosis and admission date If relevant: Medical history and other clinical information
A	**Assessment:** I think the problem is (*describe problem*) or I'm unsure what the problem is, but the patient (*is deteriorating/unstable*)
R	**Recommendation:** I think that you should (*describe exactly what needs to happen at this moment*) 1. You should evaluate the patient now and/or 2. You should evaluate the patient (*set specific time interval*) and/or 3. Determines medical policy What should I do now? How often do you want the vital parameters checked and at which thresholds do you want to be called again? **Repeat-back:** We have agreed on the following (*repeat the medical policy systematically and who does what and when*) Write the determined policy up into the patients records

The SBAR method was introduced to facilitate complete and systematic handover over patient data between the nurse and physician (on call) especially whenever a patient reached a MEWS of three or more. [16]

Appendix B. Distributions of Characteristics of secondary outcomes

	Before	MEWS	RRT implementation	Final RRT	*p* value
No. of cardiopulmonary arrests	55	78	105	36	
Male patients	62	68	68	58	0.18
Mean age of patients (SD)	70.6 (13)	68.6 (17)	72.2 (12)	70.7 (12)	0.95
Chest compression	89	86	80	89	0.54
Defibrillation	29	23	22	22	0.38
Tracheal intubation	73	82	74	83	0.074
Direct outcome					0.015
Death during CPR	53	33	35	41	
Transfer to Intensive care Unit	35	55	46	50	
Transfer to Coronary Care Unit	11	10	9	0	
To other hospital	0	0	2	6	
Stay on ward	2	1	9	3	
Survival to hospital discharge	13	30	31	28	0.075
No. of ICU admissions	561	792	1,328	504	
Male patients	61	57	58	57	0.47
Mean age of patients (SD)	67.0 (14)	67.5 (14)	67.8 (14)	65.7 (14)	0.13
Mean SAPS II (SD)	41.2 (19)	42.7 (18)	41.4 (18)	41.4 (18)	0.87
Mean APACHE II (SD)	19.1 (9)	19.8 (8)	19.5 (9)	19.5 (8)	0.44
Mean APACHE IV (SD)	66.8 (34)	69.9 (34)	68.1 (34)	68.0 (32)	0.59
Median ICU Length of stay in days (IQR)	19 (10-37)	19 (10-39)	19 (10-37)	18 (9-32)	0.30
ICU survival	85	84	85	84	0.63
Survival to hospital discharge	75	74	76	76	0.14
No. of deaths	576	910	1,400	522	
Male patients	55	53	55	52	0.36
Mean age of patients (SD)	76.8 (12)	77.1 (13)	77.6 (12)	75.0 (14)	0.021
Median Length of hospital stay in days (IQR)	6 (2-15)	7 (3-14)	7 (3-14)	7 (2-12)	0.25

Unless stated otherwise, numbers represent percentages. Statistical comparisons were performed between the before and RRT phase. The Chi-square test, Fisher's exact test, T-tests were performed as appropriate.
CPR = cardiopulmonary resuscitation; SD = standard deviation; IQR = interquartile range; SAPS = simplified acute physiology score; APACHE = acute physiology and chronic health evaluation.

Appendix C. Rapid Response Team call rate and interventions

	RRT implementation	Final RRT
No. of months	12	5
No. of RRT calls	468	217
No. of hospital admissions	68,212	29,560
Rapid Response Team, *n*/1000 (95% CI)	6.8 (6.2 – 7.5)	7.3 (6.4 – 8.3)
Mean age of patients (SD)	70.0 (14)	67.4 (16)
Male patients	65	54
Rapid Response Team activated by		
Specialist	9	9
Resident	70	77
Nurse	15	9
Other	6	6
Indication for Rapid Response Team call		
Respiratory	55	61
Circulatory	21	18
Arrhythmia	2	0
Alteration in consciousness	6	5
Metabolic disorder	2	2
Other	15	14
Initiation of Do-not-attempt-resuscitation order	5	3
Direct outcome after RRT		
Transfer to Intensive Care Unit	42	44
Transfer to Coronary Care Unit	2	1
Remained on the ward	53	51
Death	1	1
Other	3	4

This table represents the activation of RRTs. Due to unreliable administration of the consultations by the RRTs; these numbers are an underestimation of the real time RRT activations. Unless stated otherwise, numbers represent percentages. The category 'other' includes direct outcome after RRT consultation. This includes Medium Care or High Care transfer, transfer to other nursing ward and miscellaneous.

Chapter 4

"Unexpected" versus all-cause mortality as the endpoint for investigating the effects of a Rapid Response System in hospitalized patients

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Accepted for publication Critical Care

Abstract

Objective: To assess the effect of replacing all-cause mortality by death without limitation of medical treatments (LOMT) as endpoint in a study on Rapid Response Teams in hospitalized patients. Furthermore, to describe the time-course of LOMT orders in patients dying on a general ward and the influence of RRTs on such orders.
Design: This study is a secondary analysis of the COMET-trial, a pragmatic prospective Dutch multicenter before-after study.
Setting: We repeated the original analysis of the influence of RRTs on death before hospital discharge by replacing all-cause mortality by death without LOMT-order. In a subgroup of all patients dying before hospital discharge, we documented patient demographics, admission characteristics and LOMT orders of each patient.
Patients: All patients 18 years or above admitted to the study wards were included.
Measurements and Main Results: In total, 166,569 patients were included in the study. The unadjusted ORs were 0.865 (95% CI 0.77-0.98) in the original analysis using all-cause mortality and 0.557 (95% CI, 0.40-0.78) when choosing death without LOMT as endpoint. In total, 3,408 patients died before discharge. At time of death, 2910 (85%) had an LOMT order. Median time from last change in LOMT status and death was 2 days (inter quartile range (IQR) 1-5) in the before phase and median 1 (IQR 1-4) after introduction of the RRT (p=NS).
Conclusions: The improvement of survival in hospitalized patients after introduction of an RRT in the COMET-study was more pronounced when choosing death without LOMT, rather than all deaths as endpoint. Most patients who died during hospitalization had LOMT orders instituted, often shortly before death.

Introduction

Patients who are admitted to general wards in hospitals may deteriorate which may result in unplanned ICU admission, cardiac arrest or even death. [1] Rapid Response Systems have been developed for timely identification and treatment of patients on generals wards at risk for clinical deterioration. [2] In the literature, these systems have different names, including Rapid Response Team, Outreach Team or Medical Emergency Team. In this paper we will use the term Rapid Response Team (RRT) for both the actual outreach team and the rapid response system as a whole.

Three large controlled studies investigated the effects of the introduction of an RRT on clinical outcomes. [3-5] Endpoints of these studies were mortality, unplanned ICU admission and cardiac arrest rates. While studies in the United Kingdom and the Netherlands reported improved survival [4,5] and decreased cardiac arrest rates [4], an Australian study could not demonstrate improvement of a composite endpoint including mortality, unplanned ICU admission and cardiac arrests. [3]

Crude mortality may not be the optimal endpoint to study effects of an RRT on survival. Patients with untreatable diseases may be admitted to a hospital for palliative end-of-life care. Clearly, RRTs are not set up to prevent death in those patients. For this reason, unexpected death has been proposed as a more suitable endpoint for studying the effects of RRTs on survival. [3] Death was considered 'expected' if a patient had limitations of medical treatment (LOMT) orders present at time of death. This, however, may not be a correct definition for expected death. First, some patients may prefer not to undergo life-sustaining treatments in case of cardiac arrest, but this does not mean that death is imminent or that these patients don't want optimal treatment. Furthermore, treatment limitation orders are sometimes instituted shortly before death when the clinical condition has deteriorated progressively to a point that survival is no longer considered possible. Clearly, RRTs could have been beneficial in these patients if called in an earlier phase when the clinical condition was not yet hopeless.

Aim of our study was to explore the association between treatment-limitation orders and hospital death in a multicenter study on RRTs in the Netherlands. First, what is the effect of an RRT on mortality if 'all cause hospital mortality' was replaced by 'death without LOMT-order'? Second, what proportion of patients dying on a general hospital ward is given a LOMT-order, how do these LOMT-orders change over time during hospitalization and are LOMT-policies influenced by the introduction of an RRT.

Methods

Design, setting, participants

This study is a part of the Cost and Outcomes analysis of Medical Emergency Teams (COMET) multi-center study. The COMET study was designed as a prospective pragmatic before-after trial enabling the analysis of clinical outcomes after sequential introduction of the Rapid Response System components. Twelve Dutch hospitals participated in this study. Four study wards, two surgical and two medical wards were included in each hospital, the so called COMET-wards. Included patients were 18 years or above. The full design of this study has been described previously [4,6] and is shown in Figure 1.

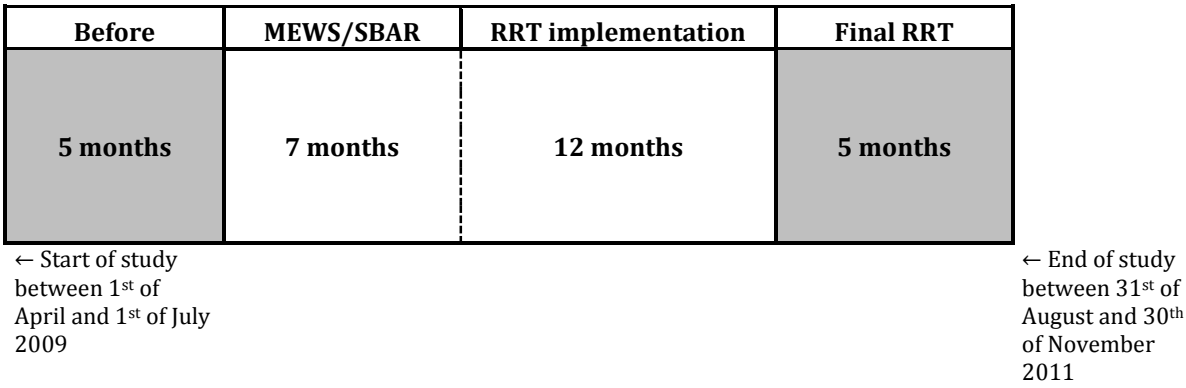

Figure 1. Design of the COMET study.
Following the baseline period of 5 months, the Modified Early Warning Score (MEWS)/Situation-Background-Assessment-Recommendation (SBAR) was implemented for 7 months and subsequently followed up by 17 months in which the rapid response team (RRT) was available. Effects of the RRT on outcomes were measured during the last 5 months and compared with the 5-month baseline period. During the entire length of the study, data were collected on all the endpoints. For further clarification, hospitals were able to start with the study in a 3-month time period. The total study took 30 months, in which each hospital participated for 27 months.

The study consisted of a before period followed by two study phases. The before period comprised of five months in which baseline characteristics were collected. After that a two-steps implementation of the RRT was performed. The first phase lasted seven months in which the Modified Early Warning Score (MEWS) and the Situation-Background-Assessment-Recommendation (SBAR) communication tool were implemented. In the second phase, which consisted of 17 months, the Rapid Response Team (RRT) was introduced. This phase was divided into the RRT implementation phase and the final RRT phase. The before period and the final RRT phase were used to compare the effects on outcome of patients. To exclude seasonal effects on the outcome, the before period and the final RRT phase in each hospital covered the same calendar months.

Definitions

Unexpected death was defined as all deaths without a pre-existing limitation of medical treatment (LOMT) order. [3,7] Definitions of the limitations of medical treatment (LOMT) in this study were: *Code A* for 'full active care', *Code C* "do not perform cardiopulmonary resuscitation" and/or "do not admit to ICU"; *Code D* "only palliative care". Code B was used in the past, but was no longer used in any of the participating hospitals. In this study, if no LOMT was recorded in the charts, this was considered equivalent to code A "for full active care".

Ethical consideration

The medical ethics committee of the Academic Medical Center in Amsterdam waived the need for formal evaluation of the study due to the observational nature of the study. Consequently, the need for informed consent was not applicable.

Intervention

Incidences of all death were collected during the study period using a clinical report form. All deaths included the patients who were admitted on the COMET ward and transferred at a certain point to a non-COMET ward and died. Clinical information systems in the hospitals were used to identify death during this study. We collected the following data: basic patient demographics (age, gender), admission characteristics (date of admission, transfer date to COMET ward, COMET ward specialty, length of hospital stay, date and time of death), and limitation of medical treatment (date of recorded LOMT). After implementation of the RRT, members of the RRT collected the following data during consultation: who activated the RRT?, the indication for RRT call, direct outcome after RRT and treatment code before and after consultation.

Statistical analysis

Data analysis was performed using SPSS version 20.0 (Armonk, New York, USA). Generalized linear mixed modeling (GLMM) was applied to assess differences in outcomes per 1,000 admissions between the before and final RRT periods while correcting for potential confounding following the before-after study design. In the GLMM, a binominal distribution was assumed for death. Potential confounders were included as fixed or random variables. Hospitals were modeled as a random variable. Age of patients was modeled as a random component, whereas patients' sex and admission type (planned vs unplanned/emergency) were modeled as fixed variables. The uncorrected odds ratios (ORs) and ORs after correction for confounding are reported along with their CIs and corresponding *p* values. Descriptive analyses are presented as raw numbers and percentages. Continuous data were presented as

medians with inter quartile range (IQR) due to non-normally distributed data. To compare groups the non-parametric Mann-Whitney *U*-test was used for non-normally distributed continuous variables. Categorical variables were compared between groups by χ^2 tests. The level of significance was set at $p < 0.05$.

Results

In total 166,569 patients were included in the COMET-study, of whom 2,345 patients died on a medical ward and 1,063 patients on a surgical ward. Of the patients who died, surgical patients were older, median 81.4 years [IQR 73.6 to 87.0] in comparison to medical patients, median 78.4 years [68.3 to 85.6]. The median hospital length of stay (LOS) was 7 days (IQR 3 to 16 days) for surgical patients compared to 6 days (3 to 13 days) for medical patients. In 13% of patients who died and for whom an RRT was called, a LOMT was instituted or changed after consultation of the RRT. Baseline characteristics of patients are presented in Table 1.

Table 1. Demographics

		Medical	**Surgical**
Deaths		2345	1063
Implementation phases of the	Before	387 (17)	189 (18)
Rapid Response System, n (%)	MEWS	643 (27)	267 (25)
	RRT implementation	940 (40)	460 (43)
	Final RRT	375 (16)	147 (14)
Gender, male, n (%)		1261 (54)	1084 (54)
Age (median, IQR)		78.4 (68.3-85.6)	81.4 (73.6-87.0)
Death on Intensive Care Unit, n (%)		48 (2)	43 (4)
Time of death, n (%)	00:00 - 05:59	701 (30)	302 (28)
	06:00 - 11:59	555 (24)	255 (24)
	12:00 - 17:59	530 (23)	245 (23)
	18:00 - 23:59	508 (22)	241 (23)
	Unknown	51 (2)	20 (2)
Hospital Length Of Stay (median, IQR)		6 (3-13)	7 (3-16)
Number of RRT consultation before death		56 (45)	68 (55)
	0-24 hours	45 (80)	62 (92)
	24-48 hours	3 (5)	5 (7)
	> 48 hours	8 (14)	1 (1)
Initiation of LOMT order by RRT		7 (13)	9 (13)

The odds-ratio's for death before hospital discharge for patients admitted during the last 5 months of the RRT phase (n=27820) were compared with the baseline period before implementing the RRT (n=26659). The originally reported unadjusted OR for all-

Table 2. Comparison of effect of RRT on all-cause in-hospital mortality vs. death without LOMT in hospitalized patients

	Uncorrected OR	95% CI of uncorrected OR	Corrected OR	95% CI of corrected OR	*p* value corrected OR
Death, n/1,000 (95%CI)	0.865	0.768-0.975	0.802	0.644-1.0	0.05
Death without LOMT, n/1,000 (95%CI)	0.557	0.397-0.782	0.549	0.385-0.784	0.001

Odds ratio (OR) represent differences between final RRT phase versus the before phase. Corrected ORs are adjusted for sex, age, hospital and emergency of admission. Number of admissions in before period = 26,659; number of admissions in rapid response team period = 27,820.

cause mortality in the final RRT period compared to the before period was 0.865 (95% CI, 0.77–0.97). [4] In the same cohort of patients, the unadjusted OR for death without LOMT ('unexpected death') was 0.557 (95% CI, 0.40-0.78). Likewise, the ORs after adjustment for age, gender, individual hospital and urgent vs. planned admission were 0.802 (95% CI, 0.64-1.0) in the original analysis using all-cause mortality and 0.549 (95% CI, 0.38-0.78) when choosing death without LOMT as endpoint (Table 2).

Table 3. Treatment limitations (LOMT status) at different time points in patients who all died during hospital admission

		Medical		**Surgical**	
All deaths		**n (%)**	**Days***	**n (%)**	**Days***
	All	2345	2 (1 - 5)	1063	1 (1-5)
LOMT at time of admission	A	736 (31)		459 (43)	
	C	1278 (55)		464 (44)	
	D	331 (14)		140 (13)	
LOMT at time of death	A	280 (12)	5 (1 - 10)	218 (21)	4 (1 - 11)
	C	790 (34)	3 (1 - 8)	352 (33)	3 (1 - 8)
	D	1275 (54)	1 (0 - 2)	493 (46)	1 (0 - 2)
Change in DNR status between admission and death	A-A	279 (12)		217 (20)	
	A-C	137 (6)	3 (1 - 8)	79 (7)	3 (0 - 7)
	A-D	320 (14)	1 (0 - 2)	163 (15)	1 (0 - 2)
	C-C	649 (28)		273 (26)	
	C-D	629 (27)	1 (0 - 2)	190 (18)	1 (0 - 2)
	C-A	0 (0)	NA	1 (0)	n=1
	D-D	326 (14)		140 (13)	
	D-C	4 (0)	5 (2 - 30)	0 (0)	NA
	D-A	1 (0)	n=1	0 (0)	NA
Length of Hospital stay	0 - 3 days	762 (32)	1 (0 - 2)	324 (30)	1 (0 - 2)
	4 - 7 days	541 (23)	2 (1 - 5)	228 (21)	3 (1 - 5)
	8 - 14 days	517 (22)	3 (1 - 9)	217 (20)	2 (1 - 9)
	15 - 21 days	219 (9)	3 (1 - 12)	101 (10)	2 (1 - 15)
	>21 days	306 (13)	3 (1 - 20)	193 (18)	3 (1 - 26)

*Days: delta time between last code change and time of death. Data presented in median and IQR.

Table 3 shows the treatment limitations at different time points in patients who died during hospital admission. In both medical and surgical patients, most of patients who subsequently died already had a LOMT at hospital admission. The median time between last LOMT order and death was three days in patients who had a Code C and one day in patients with code D. A short time between LOMT order and death was also found in patients who had a prolonged hospital-length of stay. Unexpected death was defined as death without a pre-existing LOMT order. In 12% of medical and in 20% of surgical patients no LOMT was present at time of death.

Table 4. Effects of implementation of Rapid Response System on LOMT status

		Before	**Final RRT**	
		N=576	N=522	*p-value**
LOMT at time of admission, n (%)	A	221 (38)	187 (36)	0.31
	C	271 (47)	269 (52)	
	D	84 (15)	66 (13)	
LOMT at time of death, n (%)	A	99 (17)	64 (12)	0.06
	C	170 (30)	174 (33)	
	D	307 (53)	284 (54)	
Delta time (days) between last change in LOMT status and death, median, IQR [n]		2 (1-5)	1 (1-4)	0.09
Stratified by hospital-length of stay, median, IQR [n]	0-3 days	1 (0-2) [195]	1 (0-2) [178]	0.74
	4-7 days	3 (1-5) [130]	2 (1-5) [110]	0.27
	8-14 days	3 (1-9) [100]	2 (1-7) [125]	0.09
	15-21 days	2 (1-10) [54]	3 (1-15) [38]	0.55
	> 21 days	5 (1-25) [97]	2 (1-12) [71]	0.12

Medical and surgical patients are combined. * Chi-square or Mann Whitney U test if appropriate.

In Table 4 the effect of RRT implementation on treatment limitations in patients who died during hospital stay is presented. No differences were found in institution of LOMT after introduction of the Rapid Response System. The delta time between last code change and death was 2 days (median 1-5) in the before phase and 1 day (median 1-4) in the Final RRT phase, this was not significant.

Discussion

In this study we demonstrate that the effects of introducing an RRT on in hospital death is more pronounced if death without LOMT is used compared to the original COMET analysis using all-cause mortality as endpoint. [4]

The underlying hypothesis why 'death without LOMT' might be a better endpoint than all deaths, is that patients with LOMT are expected to die and for these patients an RRT call will not be initiated. Thus, it has been argued that the true effects of an RRT are underestimated if all patients are analyzed as was done in the original analyses of the COMET-study. [6] In one earlier controlled trial on the effects of an RRT in Australian hospitals, 'unexpected death', i.e. death while having no LOMT, was included in the composite endpoint consisting of unplanned ICU admission, or cardiac arrest, or unexpected death. However, the negative findings in this study may be related to factors such as insufficient statistical power and contamination of the control group. [3,8,9]

In this cohort of patients all dying before hospital discharge, 85% had some LOMT at the end of life. At hospital admission LOMT was present in 65% of patients dying in the hospital. We are not the first to show that most hospitalized patients who eventually die have limitations of medical treatment. In a study from Canada and the USA, in a cohort of patients with community-acquired pneumonia who required admission to a hospital, 51 from 65 patients (78%) who died had do-not-resuscitate orders instituted before death. [10] In 1995 in the United States, among a representative sample of Medicare patients hospitalized with congestive heart failure, acute myocardial infarction, pneumonia, cerebrovascular accident, or hip fracture, 49% of patients who died had LOMT orders. [11] In a study in Saudi Arabia, after implementing an RRT, of 3191 patients dying in the hospital, 2793 (88%) died on the general ward with LOMT orders instituted. [12]

Patients with a LOMT are believed not to benefit from an RRT because death is 'expected'. This, however, is not necessarily true. First, there may be many reasons for limiting medical treatments. Patients may prefer not to undergo some invasive procedures, such as mechanical ventilation, or physicians may consider treatments inappropriate due to a patient's poor prognosis. In both circumstances, patients may still be successfully treated and discharged from the hospital. Moreover, in our study, we found that 84% of patients who died had some limitation of medical treatments at the time of death. However, in most of these patients that LOMT-order was instituted in the last days before death, sometimes even less than one day earlier. Thus, having treatment limitations at the time of death cannot be interpreted as death being expected during the entire hospital stay. It appears that LOMT instituted shortly before death is more a reflection of deteriorating condition of the patient during hospital stay, eventually leading to the clinical conclusion that death is inevitable and that some treatments be

better withheld. It does not imply that RRT could not have improved outcome in the earlier period in these patients.

RRTs have been installed in hospitals with the aim for timely identification and treatment of patients deteriorating on general wards preventing morbid outcomes. An additional role for the rapid response team is to be involved in decisions and discussions with the physicians on the ward about palliative care, and LOMT if patients have no real prospects of surviving with reasonable quality of life. [13] In an earlier study, an RRT was associated with improved documentation of comfort care orders, pain scores, patient distress, and chaplain visits. [14] In a recent review, Jones and coworkers mentioned several reasons why RRTs may need to be involved in end of life decisions. Firstly, the usual care team may not have recognized or may not accept that 'the patient is dying'. Secondly, the usual team may not be comfortable or skilled in having end of life care discussions with patients or families. Lastly, the usual team may have difficulty in accepting a LOMT despite the presence of advanced comorbidities and an irreversible new illness due to personal or religious reasons. [15] Also, RRTs may confront situations in which LOMT orders are postponed awaiting discussion with team or family members. [16]

In our study 13 % of RRT-calls were followed by the institution of LOMT orders. This is less than found by others. Smith and coworkers reported that 28% of RRT activations were associated with new LOMT orders. [17] Casamento and coworkers observed a LOMT order in 32% of RRT calls. [18] In a study by Jones et al 31% of RRT activations were associated with LOMT. [19] A possible explanation for the low rate of LOMT orders after RRT calls in our study is the already high prevalence of LOMT orders at hospital admission. It appears that most patients at the end of life already had a LOMT before the RRT was called. Accordingly, in our study, we found no differences in the institution of LOMT before and after implementation of an RRT, although the relatively low number of patients cannot exclude a small effect in favor of the RRT period.

In this study there are some limitations. First, during the review of the medical charts of the patients who died, we assumed that if there was no LOMT recorded in the patient charts medical treatments were not limited. However, it is possible that implicit limitations of medical treatment were present in some of these cases. Therefore, we cannot exclude some underestimation of the LOMT during this study and consequently an overestimation of the number of patients dying unexpectedly. Second, to estimate the effect of replacing "all cause hospital mortality" by "death without LOMT" when studying the effects of an RRT, patients dying with an LOMT were considered as not having reached the endpoint just as patients surviving up to hospital discharge. Preferentially, patients with LOMT orders should be excluded from the study population. However, as information about LOMT was only present for patients who died, this was not possible. When excluding only patients who died with a LOMT, we found ORs that were almost

identical to those presented here. As relatively few patients surviving up to hospital discharge have LOMT orders, we believe that it is unlikely that these patients have major influence on our findings. Lastly, we have a relatively low percentage of RRT calls recorded during this study. This may be due to administrative concerns. It was not always clear to the physician of the ward when to call the RRT or to call the ICU for rapid consultation. Thus, the real number of RRT calls may have been higher than documented.

Conclusion

We found higher improvement of survival up to hospital discharge when choosing death without LOMT, rather than all deaths as endpoint in a study on the effect of implementation of RRTs in Dutch hospitals. Implementation of Rapid Response Systems was not associated with significant change in LOMT. Most patients who died during hospitalization had LOMT orders instituted, often shortly before death. The presence of LOMT does not necessarily mean that death is expected and that these patients could not benefit from Rapid Response Teams.

Conflict of interest

The authors declare that they have no conflict of interest.

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Chapter 5

Satisfaction of nurses and physicians with the introduction of a Rapid Response System in Dutch Hospitals

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Submitted

Abstract

Objective: To measure the degree of satisfaction of nurses and physicians with the implementation of a Rapid Response Team.

Design: This study is a secondary analysis of the COMET-trial, a pragmatic prospective Dutch multicenter before-after study.

Setting: Questionnaires were distributed among physicians and nurses of the medical and surgical wards participating in the COMET-study at 7 and 14 months after introduction of a Rapid Response Team (RRT). The questionnaires included 24 questions with respect to how respondents used the MEWS/SBAR tools and RRT, their level of satisfaction with MEWS/SBAR and RRT and the characteristics of the respondents.

Measurements and Main Results: The response rate was 1005/1920 (52%). Satisfaction with implementation of the RRS was generally higher at t=14 compared to t=7 months and in respondents working on surgical versus medical wards. In a multivariate analysis, independent predictors of high satisfaction were timing of the questionnaire (14 months versus 7 months after start of an RRT), the support of the RRT system by local ward management, and having an RRT that was considered to be open and approachable.

Conclusions: Our findings show that healthcare workers generally are very satisfied with RRTs in their hospital and that satisfaction increases over time. In addition to direct beneficial effects on relevant patient outcomes, this in itself is an argument in favour of implementing RRTs in hospitals.

Introduction

Rapid Response Systems (RRSs) have been introduced in hospitals to improve recognition of and response to deteriorating hospital ward patients. [1] An RRS can be seen as an intensive care-based, organization-wide preventive approach to the management of deteriorating patients, and implementing the RRS requires more than just standardization of 'calling criteria' and the rapid response of a dedicated acute care team. The RRS consists of three important components. The afferent limb is designed to identify the deteriorating patient by using calling criteria such as the Modified Early Warning Score (MEWS) card and to trigger a response. The efferent limb involves directed action of the Rapid Response Team (RRT) and the third component includes measures to improve the quality of care on the ward, training and feedback. [1,2]

An optimal RRS should ensure 1) the support of all physicians and nurses, 2) leadership and support from senior hospital executives, 3) 24/7 response by staff with appropriate skills, knowledge and experience, and 4) the promotion of hospital-wide awareness of the system. [3]

The effectiveness of RRSs has not yet been proven conclusively. So far, the effectiveness of the introduction of RRSs in hospitals was shown only in two studies. The study by Priestly [4] showed a reduction in hospital mortality, while the study of Ludikhuize et al [5] showed a reduction of the composite endpoint including cardiac arrest, death and unplanned ICU admission. Another multicenter randomized study executed by Hillman [6] in Australia could not demonstrate a benefit from the introduction of a Medical Emergency Team based RRS.

Besides effects on relevant patient outcomes, the value of an RRS also depends on how satisfied nurses and physicians are with the system. Satisfaction of healthcare workers with the RRSs not only a subjective measure of contentment with the support the RRS offers to the care for their patients, it also is a prerequisite for proper implementation and performance of the RRS. Nurses will only call a Rapid Response Team if they expect to be supported by it. Fear of being criticized by members of an RRT for their care for deteriorating patients was reported to be a barrier for implementing an RRS. [7-9] In the Netherlands, we recently implemented an RRS in 12 hospitals.

Aim of this study was to measure the degree of satisfaction of nurses and physicians with the implementation of an RRS and the perceived benefit of the system.

Methods

Design, setting, participants

This study is part of the Cost and Outcome Medical Emergency Team (COMET) study which was executed in the Netherlands from 2009 until 2011. The COMET study was a pragmatic prospective before-after multicenter study in which 12 Dutch hospitals participated. The before period lasted five months in which baseline characteristics were collected. Subsequently, the RRS was introduced in a 2-steps fashion. First, in the MEWS/SBAR phase, which lasted seven months, the Modified Early Warning Score (MEWS) card and the Situation-Background-Assessment-Recommendation (SBAR) communication tool were introduced to identify patients at risk and to facilitate communication between nurses and physicians. Secondly, the RRT was implemented and this phase lasted 17 months; it was divided into two periods namely RRT implementation and the Final RRT phase. In every hospital, patients of 18 years and older who were admitted on two surgical and two medical wards, the so called COMET wards, were included. A full description of the study design (Figure 1) was previously published. [5,10]

During the second phase of the COMET study, questionnaires were distributed to nurses and physicians in all 12 participating hospitals to measure the satisfaction with the RRS on two different time points: 7 and 14 months after introduction of the RRT. On each occasion, participating hospitals distributed 80 questionnaires on the four COMET wards to nurses and physicians. The questionnaires were completed anonymously.

Intervention

The questionnaires included 24 questions covering three aspects; 1) questions on how respondents used the MEWS/SBAR tools and RRT, 2) level of satisfaction with MEWS/SBAR and RRT, 3) characteristics of the respondents (physician/nurse, working on medical/surgical ward, gender, age, experience since graduation (years), employment in the hospital and current ward (years)). Responses to the questions were scored on a scale from 0 – 10 (0 = totally disagree or never, 10 = totally agree or always). A full description of the questionnaires can be found in the Appendix A.

Ethical consideration

The medical ethics committee of the Academic Medical Center in Amsterdam waived the need for formal evaluation of the study due to the observational nature of the study. Consequently, the need for informed consent was not applicable.

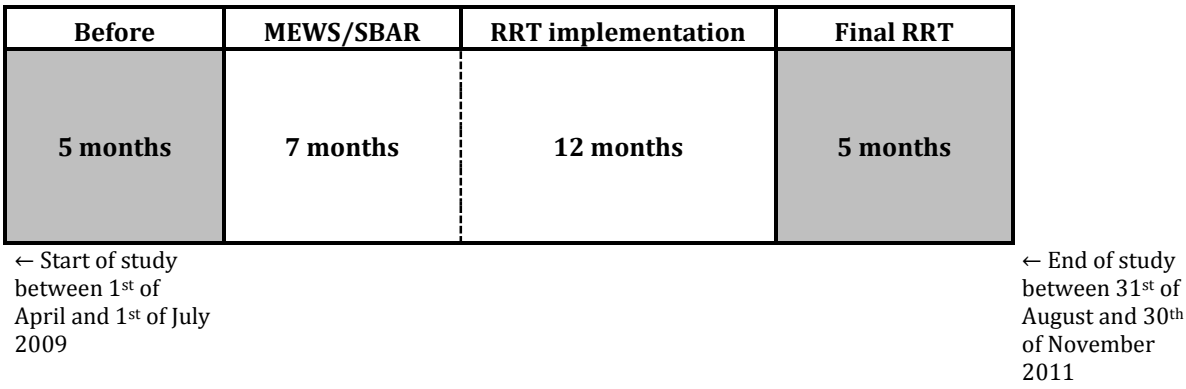

Figure 1. Design of the COMET study.
Following the baseline period of 5 months, the Modified Early Warning Score (MEWS)/Situation-Background-Assessment-Recommendation (SBAR) was implemented for 7 months and subsequently followed up by 17 months in which the rapid response team (RRT) was available. Effects of the RRT on outcomes were measured during the last 5 months and compared with the 5-month baseline period. During the entire length of the study, data were collected on all the endpoints. For further clarification, hospitals were able to start with the study in a 3-month time period. The total study took 30 months, in which each hospital participated for 27 months.

Statistical analysis

Descriptive analyses are presented as raw numbers and percentages. Continuous data were presented as medians with inter quartile range (IQR) due to non-normally distributed data. A bootstrap independent *t-test* was used for comparison of the time points, drawing 1000 samples of the same size as the original samples and with replacement, stratified by the timing of questionnaire. Generalized estimating equation (GEE) was applied to estimate the univariable association between predictors as measured by the questionnaire and satisfaction. Predictors that were used in GEE were 1) timing of questionnaire (7 and 14 months), 2) gender of respondent, 3) surgical/medical ward, 4) number of patients with MEWS ≥ 3 assessed by nurse or physician in the last 2 weeks, 5) age (years) of respondent, and 6) work experience (years) of respondent.

In the GEE, a binomial distribution was assumed after recoding the questions scored on a scale from 0 to 10 into a dichotomous one. Score from 0 to 5 meant never or totally disagree and score from 6 to 10 meant always or totally agree. We indicated the reference category as the one which contained the most answers. Furthermore, a GEE was applied to estimate the multivariable association between demographic and process related items and overall satisfaction with Rapid Response Team. Associations were reported as relative risks (RR). Associations with p-values > 0.1 were manually removed (backward stepwise) from the GEE. The level of significance was set at $p < 0.05$. Statistical analysis was done by using SPSS version 20.0 (Armonk, New York, USA).

Results

Demographic

The response rate was 51% at seven months and 53% at 14 months after RRT implementation. Eighty-five percent of returned questionnaires were filled in by nurses. Further details on the respondents are given in Table 1.

Table 1. Demographics

	RRT implementation phase	
Questionnaire	**7 months**	**14 months**
Respondent, n (% of total)	492 (51)	513 (53)
Gender, male, n (%)	55 (11)	73 (14)
Age, mean ± SD	32.8 ± 10.5	32.6 ± 10.5
Reporter, n (%)		
Physicians	52 (11)	56 (11)
Nurses	421 (85)	438 (85)
Other or unknown	19 (4)	19 (4)
Ward		
Non-surgical ward	231 (47)	248 (48)
Surgical ward	251 (51)	246 (48)
Not reported	10 (2)	19 (4)
Experience since graduation (years), mean ± SD	8.6 ± 9.2	8.15 ± 8.9
Employment in the hospital (months), mean ± SD	96.9 ± 105.2	81.57 ± 90.9
Employment on current ward (months), mean ± SD	65.9 ± 74.7	57.04 ± 66.3

Responses to the questionnaires at seven months and 14 months are given in Table 2. According to their own answers, respondents were more likely to call the RRT if patients had a MEWS > 3 point, and the Rapid Response System was more fully incorporated on the wards at 14 months compared to 7 months after its introduction.

Also, at 14 months compared to seven, support by the management on the ward was higher and it was more often considered “no problem” to explain the RRS to colleagues. Satisfaction with the RRS was generally higher at 14 months. Concerning the perceived attitudes of members of the RRT, respondents tended to be more positive at 14 months than at 7 months.

Table 2. Characteristics of questionnaires, answers given by professionals

Questionnaire	7 Months	14 Months	*p-value*
Use of MEWS/SBAR			
If my patient had a MEWS ≥ 3, I always call the physician of the ward immediately	6.44 (6.19-6.66)	6.87 (6.65-7.06)	0.006
I always use the SBAR communication tool in the communication between the nurse and physician	5.29 (5.05-5.54)	5.49 (5.23-5.73)	0.245
The RRS is fully incorporated in the daily care we provide to our patients on the ward	5.49 (5.28-5.68)	6.26 (6.06-6.46)	0.001
The management of the ward on my nursing ward supports the RRS concept	7.55 (7.36-7.74)	7.87 (7.71-8.03)	0.006
Explaining the MEWS/SBAR and RRT procedure to a new colleague is not a problem	6.52 (6.31-6.74)	6.91 (6.75-7.09)	0.006
Satisfaction using MEWS/SBAR and RRT procedure			
What is your general opinion about the MEWS tool?	7.17 (7.05-7.31)	7.55 (7.42-7.67)	0.001
What is your general opinion about the use of SBAR communication tool?	6.99 (6.85-7.16)	7.08 (6.93-7.21)	0.462
What is your general opinion about the RRT?	7.33 (7.18-7.47)	7.69 (7.56-7.81)	0.001
The use of the MEWS/SBAR tool and RRT procedure creates an unbalanced increase in workload	3.71 (3.46-3.93)	3.32 (3.11-3.54)	0.016
Using the MEWS/SBAR tool, deteriorated patients were identified earlier	6.74 (6.56-6.91)	7.16 (6.99-7.31)	0.002
The RRT is of an added value over using the MEWS/SBAR tool in early recognition and treatment of deteriorated patients	6.73 (6.55-6.91)	7.02 (6.87-7.17)	0.015
The presence of the RRT procedure in our hospital makes sure that physicians review deteriorated patients earlier than before	6.68 (6.49-6.88)	6.79 (6.63-6.95)	0.352
The RRS is very relevant for my daily activities and I will keep using this in the future	7.01 (6.82-7.18)	7.44 (7.28-7.58)	0.001
The RRS is an essential part of the daily care and should be employed in all hospitals	7.28 (7.12-7.43)	7.72 (7.58-7.84)	0.001
Rapid Response Team			
The members of the RRT are kind and helpful during consultation	7.19 (7.03-7.35)	7.54 (7.41-7.76)	0.001
The members of the RRT have a low threshold to contact and are approachable	7.22 (7.04-7.38)	7.48 (7.37-7.60)	0.017
The members of the RRT give sufficient and high quality bed-side teaching during consultation	6.43 (6.23-6.62)	6.51 (6.34-6.68)	0.583
Negative experiences with the members of the RRT in the previous three months?			
The members of the RRT were unfriendly and not cooperative to the ward nurse and physician during consultation	2.14 (1.90-2.41)	2.09 (1.88-2.31)	0.799
Members of the RRT gave the feeling that they were called unnecessarily	2.52 (2.29-2.77)	2.39 (2.18-2.60)	0.424
The members of the RRT give the impression that the daily care on the ward is insufficient	2.56 (2.32-2.80)	2.64 (2.45-2.86)	0.555
Possible delays in the RRS protocol			
Nurses frequently activate the RRT instead of physicians	3.27 (3.04-3.49)	3.74 (3.54-3.96)	0.005
The physicians of the ward adhere to the time frame to call the RRT	4.91 (4.72-5.09)	4.78 (4.57-4.97)	0.350
The RRT is always present within 10 minutes after the RRT call	6.87 (6.69-7.07)	6.98 (6.80-7.16)	0.142

Questionnaire 7 and 14 months after implementation of RRT. Response to questions was scored on a scale from 0-10 (0=totally disagree or never, 10= totally agree or always. All data are presented as mean and 95% CI. Data were derived from answers to questions 3-21 of the questionnaire (see appendix A).

Table 3. Association of characteristics of respondents with RRS-related behavior and satisfaction

	Timing^ (14 months versus 7 months)		Female versus male*		Surgical versus medical~		Experience with patients with MEWS >3°		Age (Years)		Work experience (years)	
Use of MEWS/SBAR	RR (95%CI)	*p-value*	RR (95%CI)	*p-value*	RR (95%CI)	*p-value*	RR (95%CI)	*p-value*	RR (95%CI)	*p-value*	RR (95%CI)	*p-value*
If my patient had a MEWS ≥ 3, I always call the physician of the ward immediately	1.182 (0.974-1.034)	0.091	*NS*		1.389 (1.168-1.650)	0.000	*NS*		*NS*		*NS*	
I always use the SBAR communication tool in the communication between the nurse and physician	*NS*		*NS*		1.157 (1.029-1.302)	0.015	*NS*		*NS*		1.008 (1.004-1.013)	0.000
The RRS is fully incorporated in the daily care we provide to our patients on the ward	1.429 (1.271-1.605)	0.000	*NS*		1.406 (1.179-1.678)	0.000	*NS*		*NS*		*NS*	
The management of the ward on my nursing ward supports the RRS concept	*NS*		*NS*		4.878 (2.597-9.091)	0.000	1.326 (0.959-1.835)	0.089	1.018 (0.998-1.038)	0.084	0.979 (0.959-1.000)	0.051
Explaining the MEWS/SBAR and RRT procedure to a new colleague is not a problem	1.311 (1.086-1.605)	0.005	1.383 (1.001-1.908)	0,049	1.585 (1.259-1.996)	0.000	*NS*		*NS*		*NS*	
Satisfaction using MEWS/SBAR and RRT procedure												
What is your general opinion about the MEWS tool?	1.479 (1.059-2.066)	0.021	*NS*		2.141 (1.277-3.597)	0.004	*NS*		*NS*		*NS*	
What is your general opinion about the use of SBAR communication tool?	*NS*		*NS*		*NS*		*NS*		0.982 (0.962-1.004)	0.110	1.024 (1.002-1.047)	0.036
What is your general opinion about the RRT?	1.887 (1.403-2.532)	0.000	*NS*		2.475 (1.479-4.149)	0.001	*NS*		*NS*		*NS*	
The use of the MEWS/SBAR tool and RRT procedure creates an unbalanced increase in workload	0.723 (0.873-0.598	0.001	*NS*		*NS*		*NS*		*NS*		0.985 (0.975-0.995)	0.004
Using the MEWS/SBAR tool, deteriorated patients were identified earlier	1.344 (1.044-1.733)	0.022	*NS*		1.451 (1.156-1.821)	0.001	*NS*		1.013 (1.002-1.025)	0.021	*NS*	
The RRT is of an added value over using the MEWS/SBAR tool in early recognition and treatment of deteriorated patient	1.460 (1.209-1.761)	0.000	*NS*		1.855 (1.600-2.146)	0.000	*NS*		*NS*		*NS*	
The presence of the RRT procedure in our hospital makes sure that physicians review deteriorated patients earlier than before	*NS*		*NS*		1.957 (1.634-2.347)	0.000	*NS*		*NS*		1.013 (1.003-1.024)	0.010
The RRS is very relevant for my daily activities and I will keep using this in the future	1.773 (1.294-2.427)	0.000	*NS*		2.793 (1.887-4.132)	0.000	*NS*		*NS*		*NS*	
The RRS is an essential part of the daily care and should be employed in all hospitals?	1.520 (1.224-1.887)	0.000	*NS*		2.801 (1.898-4.132)	0.000	*NS*		0.979 (0.956-1.003)	0.087	1.025 (1.002-1.049)	0.037
Rapid Response Team												
The members of the RRT are kind and helpful during consultation?	1.848 (1.253-2.725)	0.002	1.821 (1.295-2.564)	0,001	1.645 (1.095-2.463)	0.016	1.534 (0.980-2.398)	0.061	*NS*		*NS*	
The members of the RRT have a low threshold to contact and are easily reachable	1.555 (1.175-2.058)	0.002	1.502 (1.013-2.227)	0,043	1.563 (1.171-2.088)	0.002	1.412 (1.048-1.923)	0.028	*NS*		*NS*	
The members of the RRT give sufficient and high quality bed-side teaching during consultation	*NS*		*NS*		1.524 (1.181-1.969)	0.001	*NS*		*NS*		*NS*	

Table 3. (cont.)

	Timing^ (14 months versus 7 months)		Female versus male *		Surgical versus medical~		Experience with patients with MEWS >3°		Age (Years)		Work experience (years)	
In the last three months negative experiences with the members of the RRT?												
The members of the RRT were unfriendly and not cooperative to the ward nurse and physician during consultation	*NS*		*NS*		0.618 (0.321-1.190)	0.150	*NS*		*NS*		*NS*	
Members of the RRT gave the feeling that they were called unnecessarily	*NS*		*NS*		0.613 (0.421-0.894)	0.011	*NS*		1.018 (1.001-1.035)	0.040	*NS*	
The members of the RRT give the impression that the daily care on the ward is insufficient	*NS*		*NS*		*NS*		*NS*		1.000 (0.990-1.010)	0.962	*NS*	
Is there any delay in the process?												
Nurses frequently activate the RRT instead of physicians	1.073 (1.013-1.138)	0.017	*NS*		1.093 (0.999-1.196)	0.053	0.872 (0.822-0.925)	0.000	0.994 (0.991-0.997)	0.000	1.004 (1.000-1.008)	0.037
The physician of the ward stick to the time frame to call the RRT	*NS*		*NS*		*NS*		NS		1.008 (1.000-1.016)	0.045	0.993 (1.000-1.001)	0.097
The RRT is always present within 10 minutes after the RRT call	1.200 (0.996-1.449)	0.056	*NS*		1.307 (1.124-1.522)	0.001	NS		*NS*		*NS*	

Relative Risk of characteristics of respondents with RRS-related behaviors and satisfaction. RR > 1 indicates higher satisfaction or agreement with statement. Response to questions was originally scored on a scale from 0-1- (0=totally disagree or never,10=totally agree or always). For this analysis answers were dichotomously recoded in a way that scores from 0-5 means 'no' or 'disagree' and 6-10 means 'yes' or 'agree'. Data were derived from answers to questions 3-21 of the questionnaire (see Appendix A). ^Time of questionnaire – 14 months versus 7 months, * Gender – female versus male, ~Ward-surgical versus medical, °Observing patient with MEWS > 3 in the last two week, ≥ 1 patients versus 0 patients.

Table 3 reports the results of the generalized estimating equation analysis. In the table, the Relative Risk (RR) for agreement with a certain statement of the survey is given for time of questionnaire (14 months versus 7 months), gender (female versus male), ward (surgical versus medical), observing patients with a MEWS ≥ 3 in the last week (≥ 1 patient versus 0 patients), age and work experience (years) are reported. For almost all statements, compliance of respondents and ward managers with the RRS as well as satisfaction with the RRS was higher at 14 months compared to 7 months, and also higher in respondents working on surgical vs. medical wards. More years of experience as nurse or physician were associated with higher compliance and satisfaction for some but not all statements. Gender, age and experience with patients with MEWS > 3 showed no association with agreement with the given statements.

Table 4. Multivariate analysis exploring the association of different aspects of the RRS (demographic and process related items) and overall satisfaction with RRS

	RR (95% CI)	p-value
Support of RRS by management of my ward	3.497 (1.802-6.803)	0.000
Members of the RRT are kind and helpful during consultation	4.149 (1.825-9.434)	0.001
Members of the RRT has a low threshold to contact and are easily reachable	NS	
Members of the RRT give sufficient and high quality bed-side teaching during consultation	NS	
Members of the RRT gave the feeling that they were called unnecessarily	NS	
Members of the RRT give the impression that the daily care on the ward is insufficient	NS	
Nurses frequently activate the RRT instead of physicians	NS	
The physician of the ward stick to the time frame to call the RRT?	NS	
The RRT is always present within 10 minutes after the RRT call	NS	
Timing (14 months versus 7 months)	1.495 (0.959-2.331)	0.076
Surgical versus Medical ward	NS	

Relative Risk (RR) of characteristics of respondents with RRS-related behaviors and satisfaction. RR > 1 indicates higher satisfaction or agreement with statement. Response to questions was originally scored on a scale from 0-1-(0=totally disagree or never,10=totally agree or always). For this analysis answers were dichotomously recoded in a way that scores from 0-5 means 'no' or 'disagree' and 6-10 means 'yes' or 'agree'. Data were derived from answers to questions that were related in our opinion to the process (see Appendix A).

The multivariable analysis on factors associated with overall satisfaction with the RRT is shown in Table 4. Independent predictors of satisfaction were duration of experience with the RRS (14 versus 7 months after implementation of the RRS), support of the RRS by local ward management, and having an RRT considered to be 'open' and 'approachable'.

Discussion

In this study we found that nurses and physicians working on hospital wards in the Netherlands are generally very satisfied with the services offered by the RRT, with the MEWS instrument to recognize patients at risk and with the SBAR communication tool to improve communication about deteriorating patients between nurses and doctors. At 14 months after implementation of the RRT, respondents valued these components of the Rapid Response System even more than at 7 months after implementation. Accordingly, we found high agreement of respondents with the statement that RRTs should be installed in all hospitals and that they were willing to use it in the future.

Our findings from the Netherlands are in agreement with earlier reports on attitudes of healthcare workers regarding RRTs. Studies from Saudi Arabia [11], Australia [9,12], Italy [13] and Canada [8] and the USA [14] all reported very high satisfaction with RRTs by nurses and doctors. RRTs were believed to prevent cardiac arrests [8,12] and allowed nurses to seek help if they were worried about their patients. [8] We found that nurses and physicians at surgical wards expressed higher satisfaction with the RRT than colleagues at medical wards. The use of the different components of the RRT-system was also higher at surgical wards and the local leadership at the surgical ward was more supportive regarding the RRT than at medical wards. The same difference in attitudes towards the RRT between surgical and medical wards was also reported in studies from Italy, Australia and Canada. [8,13,15] It has been suggested that the benefits from an RRT may be more pronounced on a surgical ward because surgeons are more often busy at the operation room and not available for care at the ward. Furthermore, many doctors and nurses of surgical wards feel inadequate in managing critical patients and are accustomed to relying on external consultants for managing medical problems. [13] As severe adverse events are common after surgery, RRTs may be especially beneficial in these patients. Indeed, Bellomo and co-workers reported that an RRT resulted in a 58% relative risk reduction in adverse outcomes and a 44% reduction in emergency ICU admissions after major surgery. [16]

In general, no association was found between satisfaction with RRT and either gender, experience with more than one deteriorated patients in the last two weeks, age of the respondent or years of experience in healthcare. Only few individual statements did show such an association. More years of experience were associated with more agreement with the statement ‘I always use the SBAR communication tool in the communication between nurse and physician’, and also with the statement ‘an RRT in the hospital means that deteriorated patients are reviewed earlier’. In other studies seniority of nurses was shown to be associated with a higher appreciation of the RRT. [13] In our multivariate analysis, an RRT considered to be ‘open’ and ‘approachable’ during

consultation was associated with higher overall satisfaction with the RRT by healthcare workers. This can be a direct positive effect of being kind and helpful. If so, RRTs should be urged to be kind and helpful to help implement the rapid response system in hospitals. Alternatively, it is also possible that nurses and doctors who are satisfied with the RRT for other reasons also are more positive about how the RRT operates.

High satisfaction with an RRT found in our study is not necessarily representative for large-scale implementation in real life settings. We cannot exclude that implementation measures such as information and education were more intense and local leadership was more involved because our implementation of RRTs was part of a scientific study. However, we belief that this was unlikely. First, as this was a large study in 12 hospitals involving 166,569 patients, without external funding, implementation measures were mostly limited to informing all nurses and physicians and offering pocket cards with a MEWS and SBAR summary. This would not be very different in 'normal' implementations. Second, implementation was mostly done in the first months before and after the start of the RRT; if our study would have applied unrealistic implementation measures, one would expect highest appreciation of the RRT in the first period. In contrast, we found that satisfaction with the RRT actually increased over time between 7 and 14 months after start of the RRT. In our study questionnaires were distributed anonymously among physicians and nurses. As a limitation, because of the anonymity, we could not establish who returned the questionnaires during the two time points. Therefore, we considered the questionnaires as unrelated and used for analysis the independent samples t-test.

Conclusion

In conclusion, our findings show that healthcare workers generally are very satisfied with RRTs in their hospital. In addition to direct beneficial effects on relevant patient outcomes, this in itself is an argument in favour of implementing RRTs in all hospitals.

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Appendix A. Questionnaire used to assess satisfaction of nurses and physicians during the introduction of Rapid Response Systems in Dutch Hospitals during the RRT introduction phase (translation from Dutch version)

This questionnaire was used during the Rapid Response Team (RRT) implementation phase. Nurses and physicians obtained this questionnaire in the 7th and 14th month after introduction of the Rapid Response Team in their respective hospital.

Part A. Use of MEWS/SBAR

1. In the previous two weeks, how often did you have to deal with a patient who had a MEWS ≥3 or more? (one answer possible)
   - ☐ 0 patients (proceed to question 3)
   - ☐ 1-3 patients
   - ☐ 4-6 patients
   - ☐ 7-10 patient
   - ☐ More than 10 patients
   - ☐ Don't know

2. What is the percentage of patients with a MEWS ≥3 were the RRT was actually called for assistance? (one answer possible)
   - ☐ 0%
   - ☐ 1-25%
   - ☐ 26-50%
   - ☐ 51-75%
   - ☐ 76-100%
   - ☐ Don't know

Can you, on a scale from 0 - 10, describe your opinion regarding the following statements. Please circle your grade.

3. If a patient who I'm taking care for has a MEWS ≥3, I always call the physician of the ward immediately.

0	1	2	3	4	5	6	7	8	9	10

Never Always

4. Regarding the communication between the nurse and physician on the ward, if the patient has a MEWS ≥3, I always use the SBAR communication tool to discuss the situation of the patient.

0	1	2	3	4	5	6	7	8	9	10

Totally disagree Totally agree

5. The RRS (MEWS/SBAR and RRT) is fully incorporated in the daily care we provide to our patients on the ward.

0	1	2	3	4	5	6	7	8	9	10

Totally disagree Totally agree

6. The management of the ward on my nursing ward supports the RRS concept.

0	1	2	3	4	5	6	7	8	9	10

Totally disagree Totally agree

7. When training a new colleague on the ward, explaining the use of the MEWS/SBAR and RRT procedure, is not a problem and this colleague is able to use it immediately in daily practice.

0	1	2	3	4	5	6	7	8	9	10

Totally disagree Totally agree

Part B. Satisfaction using MEWS/SBAR and RRT procedure

8. What is your general opinion about the MEWS tool?

0	1	2	3	4	5	6	7	8	9	10

Poor Excellent

9. What is your general opinion about the use of SBAR communication tool?

0	1	2	3	4	5	6	7	8	9	10

Poor Excellent

10. What is your general opinion about the RRT?

0	1	2	3	4	5	6	7	8	9	10

Poor Excellent

11. The use of the MEWS/SBAR tool and RRT procedure creates an unbalanced increase in workload.

0	1	2	3	4	5	6	7	8	9	10

Totally disagree Totally agree

12. Employing the MEWS/SBAR tool, deteriorating patients were identified and/or managed earlier by the resident physician thus preventing a potential small problem would no escalate into a bigger problem such as cardiac arrest, unplanned Intensive Care admission or death.

0	1	2	3	4	5	6	7	8	9	10

Totally disagree Totally agree

13. The added value of the RRT compared to employing only the MEWS/SBAR tool, creates a significant clinical benefit in the early recognition and treatment of deteriorating patients by preventing small problems becoming large problems such as a cardiac arrest, unplanned Intensive Care admission or death.

0	1	2	3	4	5	6	7	8	9	10

Totally disagree Totally agree

14. The presence of the RRS procedure in our hospital makes sure that physicians review deteriorated patients earlier than before.

0	1	2	3	4	5	6	7	8	9	10

Totally disagree Totally agree

15. The RRS is very relevant for my daily activities and I will keep using in the future.

0	1	2	3	4	5	6	7	8	9	10

Totally disagree Totally agree

16. The RRS is an essential part of the daily care and should be employed in all the hospitals.

0	1	2	3	4	5	6	7	8	9	10

Totally disagree Totally agree

Part C. Rapid Response Team

17. In your opinion, how satisfied are you with the members of the Rapid Response Team with regard to
    a. The kindness and helpfulness during consultation

0	1	2	3	4	5	6	7	8	9	10

Totally dissatisfied Totally satisfied

    b. The RRT has a low threshold to contact and are easily reachable

0	1	2	3	4	5	6	7	8	9	10

Totally dissatisfied Totally satisfied

    c. They give sufficient and high quality bed-side teaching during consultation

0	1	2	3	4	5	6	7	8	9	10

Totally dissatisfied Totally satisfied

18. Did you have a negative experience in the last 3 months with members of the RRT?
    a. The members of the RRT were unfriendly and uncooperative to the ward nurse and physician during consultation.

0	1	2	3	4	5	6	7	8	9	10

Never Always

    b. The members of the RRT gave the feeling that they were called unnecessarily

0	1	2	3	4	5	6	7	8	9	10

Never Always

    c. The members of the RRT give the impression that the daily care on the ward is insufficient.

0	1	2	3	4	5	6	7	8	9	10

Never Always

Part D. Possible delays in the RRS protocol

19. Nurses frequently activate the RRT instead of physicians.

0	1	2	3	4	5	6	7	8	9	10

Totally disagree Totally agree

20. The physician of the ward adhere to the time frame to call the RRT (0.5 hour review patient and make a policy, 1 hour to evaluate treatment effect)

0	1	2	3	4	5	6	7	8	9	10

Totally disagree Totally agree

21. The RRT is always present within 10 minutes after the RRT call.

0	1	2	3	4	5	6	7	8	9	10

Totally disagree Totally agree

Part E. Education and information with respect to MEWS/SBAR tool and RRT procedure

22. Did you receive information by the study coordinators about the toolkit/presentation/email etcetera about the MEWS/SBAR tool and RRT procedure?
    - ☐ Yes (proceed to question 23)
    - ☐ No (proceed to question 24
    - ☐ Don't know (proceed to question 24)

23. If so, did you fill out a survey/exam after the training?
    - ☐ Yes
    - ☐ No
    - ☐ Don't know

24. How would you grade the quality of the education materials (toolkit, hand-outs, pocket cards and oral presentation) at the start of the RRT introduction phase?

0	1	2	3	4	5	6	7	8	9	10
Poor										Excellent

Part F. General questions regarding care provider demographic

1. Hospital name ……
2. Date of filling in questionnaire __/__/____ (dd/mm/yyyy)
3. Gender Male/Female
4. Age __
5. What is your profession?
    - ☐ Nurse
    - ☐ Student Nurse
    - ☐ Resident
    - ☐ Specialist
6. Name of current ward and speciality ……
7. Years post-graduation __ (yy)
8. Employment at current hospital __ (mm)
9. Employment at current ward __ (mm)

Legend

MEWS - Modified Early Warning Score, SBAR – Situation Background Assessment Recommendation, RRT – Rapid Response Team, RRS – Rapid Response System

Chapter 6

Incorporation of daily goals in daily care planning does not shorten length of stay in the intensive care unit

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Abstract

Objective: We hypothesized that incorporation of daily goals into daily care planning has the potential to shorten length of stay in the Intensive Care Unit (ICU).

Design: A prospective before-after study.

Setting: Four University hospitals in the Netherlands, two study "daily goal" ICUs and two control hospitals.

Participants: All patients with sufficient data admitted to the participating ICUs were included in the study.

Intervention: Daily goals were integrated in the care plan for patients but not in the control hospitals. In the control period in the study hospitals, daily goals were also formulated by the attending physician but kept confidential from doctors and nurses caring for the patient.

Main Outcome Measures: The primary endpoint was length of stay in the ICU. Secondary endpoint was the type of formulated daily goals and the number of deviations from formulated daily goals.

Results: The before-after cohorts, including the control hospitals consisted of 2,790 and 3,310 patients, respectively. The median number of evaluated daily goals per patient was 4 (2 to 5) and 5 (2 to 14) in the two study periods. The implementation of daily goals was not associated with a change in ICU length of stay when corrected for gender, grouped APACHE II reason for ICU admission, restricted cubic splines of age and APACHE II score. The percentage of daily goals that was '*succesfully met*' was in the first study period 79%, and in the second study period 75%, RR 1.05 (95% CI 1.04 to1.08). The percentage of daily goals *'not met with a documented reason'* was in the first and the second study period respectively 3% (123/3757) and 15% (1499/9842), RR 0.25 (95% CI 0.21 to 0.30). Daily goals *'not met without a documented reason'* decreased between the first and second study period from 18% (664/3757) to 8% (789/9842), RR 2.2 (95% CI 2 to 2.43).

Conclusions: Incorporation of daily goals in daily care planning does not shorten ICU-LOS of stay of mixed medical–surgical ICU patients but does improve documentation of care.

Introduction

Care for the critically ill depends, at least in part, on the quality of planning and communicating daily care. A strategy of defining and checking explicitly formulated patient-specific treatment targets, so-called 'daily goals', during each clinical round of the Intensive Care Unit (ICU) team, has been found to improve communication within ICU teams. [1] So far, there is a small body of evidence for the clinical advantage of daily goals. Recently a study, performed across 69 ICU's in the United States, reported a strong association between the use of daily goals and a lower ICU mortality. [2] The first study to report the advantage of daily goals was a single-center study in a North–American ICU specialized in oncologic surgery. [3] This study showed a significant decrease of ICU length of stay of one day after implementation of daily goals and the use of daily goal forms. Moreover, the understanding of the goals of care for patients by residents and nurses increased from 10% to more than 95%. It is uncertain whether these findings are generalizable, i.e., whether similar effects can be found in ICUs outside North–America that serve a mixed medical-surgical patient population.

We hypothesized that the incorporation of daily goals in daily care planning improves care for the critically ill in mixed medical-surgical ICUs and, hence, reduce ICU Length of stay (ICU-LOS). First, we analyzed the effect of incorporating daily goals on the ICU-LOS in ICUs in two "daily goal" and two control tertiary university hospitals. Secondly, we evaluated type of formulated daily goals and deviations from daily goals in the two "daily goal" ICUs in tertiary University hospitals.

Patients and Methods

Study design

This was a before-after design with two different analyses with respect to the first study aim: First, we analyzed the primary endpoint, ICU-LOS, in two mixed medical-surgical ICUs in tertiary University hospitals before implementation (study period 1) and after implementation (study period 2) of daily goals. Secondly, we compared ICU-LOS in the two study periods of the "daily goal" ICU's with ICU-LOS in two control hospitals. With respect to the second aim, we evaluated type of formulated daily goals and deviations from formulated daily goals in both study periods in the "daily goal" hospitals.

Outcomes

The primary endpoint was ICU-LOS. Secondary endpoint was the type of formulated daily goals and the number of deviations from formulated daily goals.

Daily goal evaluation

The daily goals were described on a pre-defined list, which contained 17 categories and were evaluated in two ICUs in tertiary University hospitals. Before the start of the study all attending ICU staff members were instructed and trained in formulating daily goals.

To be able to discern whether the essential part was (a) formulating daily goals, or (b) involving the whole team, or (c) actually meeting the formulated goals during the course of 24 hours, the daily goal evaluation consisted of study period 1 and study period 2 (e.g. in a before and after study design).

During study period 1 daily goals were formulated by the attending ICU physician without involvement of other ICU team members. These goals were kept confidential during clinical rounds and were not part of care planning so that these goals would not influence daily care planning and execution. For each patient the formulated goals were placed in sealed envelopes. Before the start of study period 2, the whole team was instructed how to formulate daily goals and to clearly state the reasons for abandoning a goal in the electronic Patient Data Management System (PDMS).

In study period 2, the daily goals were formulated and communicated during morning clinical rounds by the attending ICU physician in close corporation with all other ICU team members. Furthermore, the attending ICU physician and all other ICU team members were involved in execution and evaluation of the daily goals. Clinical rounds were done three times per twenty-four hours by the ICU team to discuss diagnosis and therapy, according to the closed format of these ICUs.

For both study periods, we evaluated compliance with daily goals in 10 randomly selected patients per week. In the first study period we choose 10 envelopes which contained the formulated goals of 10 patients. In the second study period, all daily goals were formulated in the electronic Patient Data Management System (PDMS) and we randomly choose 10 patients with their formulated goals using random tables based on the numbering of ICU beds. The randomization was managed by a member of the research team, not involved in daily clinical care. A member of the research team carefully checked for all the selected patients in the electronic PDMS whether daily goals were *'successfully 'met'*, *'not met but with a documented reason in the medical chart'* or '*not met without a documented reason'*.

During the two-year daily goal evaluation (in both study periods), there were no major changes in ICU staffing of both ICUs, neither in medical staff, nor in nursing staff. Full-time intensivists, fellows and residents staffed both ICUs. Nurse to patient ratios were one nurse to two patients, but typically with a one to one ratio in case of more severely ill patients. In addition, there were no major changes in local protocols regarding hemodynamic therapy, fluid regimens, ventilation strategies, sedation

strategies and sepsis treatment, and in both periods step down facilities were available to facilitate ICU discharge.

Data source

The ICU staff from the two control hospitals gave permission to use their data from the Dutch National Intensive Care Evaluation (NICE) registry, a voluntary quality registry that contains all consecutive admissions to participating hospitals. [4] In the Netherlands, consent from individual patients is not needed when registry data obtained from routine care and without patient-identifying data are used. The NICE registry is officially registered according to the Dutch Personal Data Protection Act.

Inclusion and exclusion criteria

We included admissions between 1st August 2006 and 31st July 2007 and between 1st January and 31st December 2008 to both "daily goals" hospitals and one control hospital. We included admissions between 1st January and 31st July 2007 and between 1st January and 31st December 2008 to the other control hospital, as this hospital starting participating in the NICE registry on 1st January 2008.

We excluded patients aged under 18 years on ICU admission, patients who were believed to be braindead and admitted to the ICU only for organ donation and patients for whom admission type, gender, age, APACHE II reason for ICU admission or ICU or hospital length of stay were unknown. In addition, we excluded patients admitted to the ICU following planned surgery, as these patients have a short anticipated ICU length of stay.

Power calculation

The power to detect a significant difference in the primary outcome was based on an hypothesized reduction in ICU-LOS of 15%. We would need 2,684 patients to have 80% power to detect a difference in ICU–LOS of 15% with a 0.05 two-sided significance level.

Statistical analysis

We present categorical data as number and percentage observed with Newcombes Hybrid Score confidence intervals for the differences in percentage between study periods. We present continuous data as median and interquartile ranges. We defined differences between study periods as the median difference between all possible pairs of individuals and obtained confidence intervals for these differences by inverting the Wilcoxon rank sum test statistic for independent groups. We performed linear regression with the natural logarithm of ICU length of stay as the dependent variable. We corrected for gender, APACHE II grouped reason for ICU admission, restricted cubic

splines of age and APACHE II score and factors indicating whether an admission was (I) in study period 1 or study period 2 and (II) to a control or "daily goal" ICU. Our main focus was on the interaction term between these factors.

We did not correct for the clustering of admissions within hospitals, because the introduction of a fixed or random effect per hospital would have hindered the estimation of the effects of main interest in this manuscript. We regarded p-values less than 0.05 as statistically significant and made no corrections for multiple testing. We performed the analysis in R version 3.1.0.

Study approval and informed consent

The institutional review board of the Academic Medical Center (AMC), Amsterdam, and the Leiden University Medical Center (LUMC), Leiden, The Netherlands approved the study protocol and statistical analysis plan, and waived the need for individual patient informed consent. The study was financed and endorsed by The Dutch Organisation for Health Research and Development (Zorgonderzoek Medische Wetenschappen, ZonMW, The Hague, The Netherlands) who had no influence on study design, data analysis or reporting.

Results

Inclusion of patients is shown in Table 1.

Table 1. Inclusion of patients

	Retained	Excluded
Total admissions	13217	
Aged ≥ 18 years	13093	124
Primary ICU admissions #	12033	1060
Known admission type *	11331	702
Medical or emergency surgery admissions ^	6100	5231

Readmissions are excluded * Exclusions of patients declared legally dead before ICU admission or unknown for: admission type; gender; age; APACHE II; reason for ICU admission and ICU or hospital length of stay ^ Excluded patients are elective surgical patients with a length of stay of 24 hours.

Patient characteristics are presented in Table 2. In the "daily goal" ICUs, patients in the second study period were significant older and showed higher Apache II scores compared to the first period. Control ICUs patients showed no differences between the two study periods.

Table 2. Patient descriptive for the two study periods for hospitals with daily goals and hospital with control patients

	Period 1	Period 2	Difference 95% CI, p value
Hospitals with daily goals			
Total patients	1410	1539	
Male, % (n)	61 (857)	62 (957)	-1.4 (-4.9 to 2.1), *p* 0.43
Age, median (IQR) years	60 (46 to 71)	61 (47 to 72)	-1 (-3 to 2.6), *p* 0.05
Apache score, median (IQR)	20 (14 to 26)	21 (15 to 27)	-1 (-2 to -1), *p* <0.001
Medical admissions, % (n)	68 (954)	70 (1081)	-2.6 (-5.9 to 1), *p* 0.13
Hospital as control			
Total patients	1380	1771	
Male, % (n)	61 (845)	59 (1052)	1.8 (-1.6 to 5.3), *p* 0.30
Age, median (IQR) years	59 (45 to 70)	59 (45 to 69)	1 (-1 to 2), *p* 0.28
Apache score, median (IQR)	18 (13 to 24)	18 (13 to 23)	1.8 (-6.1 to 10), *p* 0.37
Medical admissions, % (n)	71 (983)	73 (1293)	-1.8 (-5 to 1.4), *p* 0.27

ICU-LOS

In terms of outcome we found no reduction in ICU-LOS in "daily goal" hospitals or control hospitals between study period 1 and study period 2 (Table 3).

Following correction for gender, grouped APACHE II reason for ICU admission, restricted cubic splines of age and APACHE II score, the change in ICU-LOS between study periods 1 and 2 was similar in control (factor 1.01, 95% CI, 0.92 - 1.11, p-value=0.83) and "daily goal" hospitals (factor 0.93, 95% CI, 0.85 - 1.01, p-value=0.09, p=0.23 for the difference between 'daily goals' hospitals and control hospitals).

In a subgroup analysis on only medical ICU admissions and correcting for the same factors, ICU-LOS was similar in periods 1 and 2 in control (factor 1.01, 95% CI, 0.91 - 1.13, p-value =0.86) hospitals. However, in "daily goal" hospitals ICU-LOS was shorter in period 2 than 1 (factor 0.88, 95% CI, 0.79 - 0.98, p-value=0.02). When comparing control and "daily goal" hospitals, the implementation of daily goals was not associated with a change in ICU-LOS (factor 1.13, 95% CI, 0.97 - 1.32, p-value =0.12).

In a similar subgroup analysis on only emergency surgical ICU admissions, ICU-LOS was similar in periods 1 and 2 in control (factor 1.04, 95% CI, 0.88 - 1.22, p-value = 0.68) and "daily goal" hospitals (factor 1.03, 95% CI, 0.89 - 1.20, p-value=0.6851). When comparing control and "daily goal" hospitals, the implementation of daily goals was not associated with a change in ICU-LOS (factor 1.03, 95% CI, 0.82 - 1.29, p-value =0.79).

Table 3. Outcome measures for daily goals ICUs and control ICUs for study period 1 and 2

	Period 1	Period 2	Difference 95% CI, p value
Hospitals with daily goals			
Total patients	1410	1539	
ICU-LOS, median (IQR)	2.4 (0.9-6.9)	2.4 (1.0-6.0)	0.04 (-0.11 to 0.19), *p* 0.61
ICU mortality, % (n)	21 (292)	19 (294)	1.6 (-1.3 to 4.5), *p* 0.28
Readmission 24 hours, % (n)	2 (23)	2 (34)	-0.1 (-1.6 to 0.4), *p* 0.25
Hospital LOS, median (IQR)	12 (5-28)	11 (4-23)	1 (0 to 2), *p* 0.02
Hospital mortality, % (n)	29 (410)	26 (403)	3 (-0.3 to 6.1), *p* 0.08
Hospital as control			
Total patients	1380	1771	
ICU-LOS, median (IQR)	2.7 (1.0-7.3)	2.7 (1.0-8.2)	-0.04 (-0.20 to 0.12), *p* 0.66
ICU mortality, % (n)	19 (261)	17 (309)	-1.6 (-4.4 to 1.3), *p* 0.28
Readmission 24 hours, % (n)	2 (25)	2 (35)	-0.5 (-1.5 to 0.5), *p* 0.34
Hospital LOS, median (IQR)	14 (6-30)	14 (6-29)	0.22 (-1 to 1), *p* 0.59
Hospital mortality, % (n)	26 (360)	29 (444)	-3.3 (-6.5 to -0.1), *p* 0.04

Daily goals evaluation

In the first study period daily goals were formulated blinded for the team caring for a patient and in the second period daily goals were formulated in the PDMS. In total 3920 daily goals in 1008 patients in the first study period and 16487 in 1246 patients in the second study period were evaluated. The median number of daily goals per patient was in the first study period 4 (2 to 5) and 5 (2 to 14) in the second study period.

The top six categories of formulated daily goals in the first and second study period were: (a) Pulmonal care, (b) Fluid balance, (c) Cardiac Care, (d) Pain/sedation, (e) Infection and (f) Gastrointestinal care (Table 4).

The percentage of daily goals that was '*succesfully met*' was in the first study period 79%, and in the second study period 75%, RR 1.05 (95% CI, 1.04 - 1.08). The percentage of daily goals *'not met **with** a documented reason'* was in the first and the second study period respectively 3% (123/3757) and 15% (1499/9842), RR 0.25 (95% CI, 0.21 - 0.30). Daily goals *'not met **without** a documented reason'* decreased between the first and second study period from 18% (664/3757) to 8% (789/9842), RR 2.2 (95% CI 2 to 2.43).

Table 4. Categories of daily goals applied to the ICU patients in study period 1 and 2

	Study period 1		Study period 2	
	Frequency	**Percentage**	**Frequency**	**Percentage**
Pulmonal care	748	19.8	2983	18.1
Fluid balance	544	14.4	3437	20.8
Cardiac care	494	13.1	1737	10.5
Pain /sedation	430	11.4	1289	7.8
Infection	346	9.2	1005	6.1
Consults	264	7.0	687	4.2
Gastrointestinal care	256	6.8	1043	6.3
Renal care	182	4.8	634	3.8
DVT profylaxes	104	2.8	96	0.6
Family	100	2.6	444	2.7
Diagnostic procedures	86	2.3	664	4
Tubes and IV-lines	86	2.3	349	2.1
Discharge	52	1.4	488	3
Mobilization	32	0.8	386	2.3
Glucose regulation	20	0.5	58	0.4
Risk prevention	16	0.4	34	0.2
Inclusion in trials	14	0.4	14	0.1
Other and NAs	146	3.7	1139	6.9
Sum	3920	100.0	16487	100

Discussion

Statement of principal findings

The implementation of daily goals, when corrected for confounders, was not associated with a change in ICU length of stay. A secondary result, the improved administrative discipline, i.e. the recording of the reasons as to why a daily goals or a standard protocol were not accomplished is in favor of the daily goals implementation.

Study limitations

The before-after design of this study is associated with inherent limitations. First of all, time trends might have been influencing the outcome. Although we studied the effect of time by comparing length of stay of the two “daily goal” ICUs with control ICUs by using demographic and severity-of-illness data from the National Intensive Care Evaluation (NICE) registry, modelling ICU length of stay on these data is difficult. [5] Furthermore, although the two control and two “daily goal” hospitals were all academic hospitals, there still may have been differences in clinical practice or patient characteristics that have not been corrected for. Also, one control hospital contributed data for a shorter time period than the other hospitals. However, although a better approach might have been to randomize individual patients to having daily goals available or not available to nursing staff, still, this is a large multicentre cohort study comparing two study periods,

adjusting for several confounders adding to the knowledge on daily goals implementation.

Other studies

A study by Pronovost to improve the effectiveness of communication during patient care rounds in the intensive care using daily goals forms (DGF) was reported in 2003. [3] This prospective cohort study was performed in a 16 bed surgical oncology ICU. In this before-after study the understanding of goals of care for the day by nurses and residents increased from an initial less than 10% to more than 95%. The implementation coincided with a reduction of ICU-LOS from a mean of 2.2 days to 1.1 days. However, due to the limited data collection a causal relation between the use of DGF's and the ICU-LOS remained inconclusive.

The plausibility of these results are indirectly supported by earlier results of Donchin who investigated the nature and causes of human errors in the ICU and concluded that many of these errors could be attributed to problems of communication between the physicians and nurses. [6] A survey study (before-after comparison) showed that an explicit approach to clinical and educational responsibilities and to reporting assessments and plans during bedside rounds in the intensive care unit improved communication and satisfaction of health care providers. [7] The implementation of DGF's was evaluated by a questionnaire before implementation and after 6 weeks and 9 months in a medical ICU unit. [8] The questionnaire was designed to assess satisfaction with communication and the usefulness of the DGF. ICU-LOS was compared with the previous year for a period of 9 months. The questionnaire showed significant improvements in understanding of the goals of the day among nurses and physicians after 6 weeks and after 9 months. Nurses were willing to continue its use (71% before implementation and 93% after implementation) whereas physicians were less willing (100% before and 64% after implementation). Both nurses and physicians reported significant improvement in communication with each other. After the worksheet was implemented the mean length of stay declined from mean (SD) 6.4 (2.5) days during the pre-intervention period to mean 4.3 (0.63) days after implementation.

To investigate the perception of the communication from a nursing perspective before and after DGF's were implemented in a pediatric ICU, a questionnaire was used. [9] The majority of nurses (85%) felt that the daily goals form led to improved communications between nurses and physicians, and 73% also felt that the DGF improved communications among nurses between different shifts. Eighty-five percent of nurses expressed their impression that the use of DGF's improved the care.

So far three studies evaluated the implementation of DGF's. None of the studies provided sufficient information about the characteristics of the ICU unit over time nor

gave insight in possible mechanisms beside improved communication leading to the beneficial effect of the formulation of daily goals. In our study we could not confirm the beneficial effect of daily goals on length of stay that was found in the earlier studies. One of the reasons could have been that we corrected as optimal as possible for time trends and it is a known fact that LOS-ICU has been decreasing in the past decades. Obviously we have to be aware that the implementation of daily goals actually did not have a large effect on length of stay. Possibly, since improvement of communication has received so much attention lately, there may have been already some implicit communication of goals in the control period, making it difficult for explicit implementation of daily goals in our ICUs to improve outcome and to shorten length of stay significantly.

Strikingly, in period two documentation in case of deviation from a formulated earlier goal, or deviate from a protocol increased significantly. Both findings may have been signals of improved transfer of knowledge in a non-verbal way and of the awareness of the importance to note deviations from planned care.

Although we could not find a decrease of length of stay with the implementation of daily goal, we still are of the opinion that daily goals, as a way to improve communication and structure the transfer of knowledge, within a whole care team taking care of critically ill patients, is extremely important. Thus, a format whereby the care team focuses daily on important goals for every patient individually should be standard practice, particularly on ICUs

Conclusion

Incorporation of daily goals in daily care planning does not shorten ICU LOS of mixed medical–surgical ICU patients, but the use of daily goals does improve documentation of care.

Funding

Funded by the AMC, Amsterdam, the Netherlands, and Zorg Onderzoek Medische Wetenschappen (ZonMW).

Acknowledgement

We thank Dr. R. Holman from the “National Intensive Care Evaluation” for here help and advice in analyzing the data.

Conflict of interest

All authors have declared no conflicts of interest.

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Chapter 7

A comprehensive method to develop a checklist to increase safety of intra-hospital transport of critically ill patients

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Critical Care 2015 May 7;19:214

Abstract

Introduction: Transport of critically ill patients from the Intensive Care Unit (ICU) to other departments for diagnostic or therapeutic procedures is often a necessary part of the critical care process. Transport of critically ill patients is potentially dangerous with up to 70% adverse events occurring. The aim of this study was to develop a checklist to increase safety of intra-hospital transport (IHT) in critically ill patients.

Method: A three-step approach was used to develop an IHT checklist. First, various databases were searched for published IHT guidelines and checklists. Secondly, prospectively collected IHT incidents in the LUMC ICU were analyzed. Thirdly, interviews were held with physicians and nurses over their experiences of IHT incidents. Following this approach a checklist was developed and discussed with experts in the field. Finally, feasibility and usability of the checklist was tested.

Results: Eleven existing guidelines and five checklists were found. Only one checklist covered all three phases: pre-, during- and post-transport. Recommendations and checklist items mostly focused on the pre-transport phase. Documented incidents most frequently related to patient physiology and equipment malfunction and occurred most often during transport. Discussing the incidents with ICU physicians and ICU nurses resulted in important recommendations such as the introduction of a standard checklist and improved communication with the other departments. This approach resulted in a generally applicable checklist, adaptable for local circumstances. Feedback from nurses using the checklist were positive, the fill in time was 4.5 minutes per phase.

Conclusion: A comprehensive way to develop an intra-hospital checklist for safe transport of ICU patients to another department is described. This resulted in a checklist which is a framework to guide physicians and nurses through intra-hospital transports and provides a continuity of care to enhance patient safety. Other hospitals can customize this checklist to their own situation using the methods proposed in this paper.

Introduction

Critically ill patients are frequently transported between the Intensive Care Unit (ICU) and other sections of the hospital for diagnostic and/or therapeutic interventions. [1-3] Unfortunately there is an increased risk of an adverse event during intra-hospital transport (IHT). [4] The first documentation that IHT is potentially dangerous was shown in 1970: during transport, arrhythmia occurred in 84% of patients at high risk of cardiovascular events. [5] Subsequent studies reported incidents in between 4.2 to 70.0% of critically ill patients during IHT. [1-3,6-8] Incidents were mostly related to equipment failure (39 to 45%) [6-8], and physiological deterioration of the patient including hypotension up to 47% and hypoxia (20 to 29%). [3] Specific knowledge on the risk of particular incidents during IHT can contribute to improved safety but so far little is known about what kind of incidents occur during intra-hospital transport of critically ill patients.

Measures to reduce incidents include better pre-transport planning, the introduction of standardized procedures related to personnel, organisation and equipment during transport and the use of checklists during the preparation phase. [3,6-10] Indeed, some guidelines on optimal IHT [11,12] are available but they are not easily translated into practical measures to reduce incidents. As an alternative, checklists are practical and can provide tools to improve safety. [13]

The aim of our study was to develop a checklist covering the pre-transport preparation phase, the actual transport phase and the ICU reinstallation (post-transport) phase, to improve safety during intra-hospital transport of adult critically ill patients.

Methods

This study was conducted in a 29-bed, adult patient mixed tertiary ICU at the Leiden University Medical Center (LUMC), the Netherlands. Three complementary methods were sequentially applied to develop the checklist. These consisted of (1) a review of the available literature on IHT guidelines and checklists, (2) an analysis of incidents related to IHT at the LUMC and (3) an inventory of what could go wrong during IHT and how to prevent it accumulation through structured interviews with ICU doctors and ICU nurses. Based upon the study results, a checklist was developed and the feasibility and usability of the checklist were tested during a one-month period.

Definitions

For the purpose of this study we explicitly divided intra-hospital transport into three phases, and for the literature search we determined whether these three phases were addressed in the guidelines and checklists. Furthermore, we specifically focused on the separate phases when analysing the reported incidents and in the interviews with doctors and nurses. [14]

The *pre-transport phase* is the phase in which the patient is prepared for transport. The focus is on the patient's severity of illness and stability, on the kind of monitoring and therapy the patient currently requires and also on what the patient is likely to need during the transport process. The *transport phase* comprises the transport from the ICU to another department and vice versa as well as the period during the diagnostic or therapeutic procedure. The *post-transport phase* is the phase when the patient has returned to the ICU, in which ICU monitoring and earlier ICU therapies have to be reinstalled, and the patient has to be stabilised. This phase requires 0.5 to 1 h after transport and must be considered as part of the transport process. An incident is defined as 'any event or outcome which could have reduced, or did reduce the safety margin for the patient. It may or may not have been preventable and may or may not have involved an error on the part of the health care team'. [15]

Review of the literature

Our review of the literature focused on guidelines and checklists on intra-hospital transport of critically ill patients. We searched in PubMed, Embase, Web of Science, COCHRANE, CINAHL, Academic Search Premier and ScienceDirect; from inception until 12 January 2014. The databases were searched for medical literature with the following terms: 'intensive care', 'critical care', 'critically ill', 'intra-hospital transport', 'in-hospital transport', 'radiology department', 'guideline' and 'checklist'.

Reference lists of review articles and eligible primary studies were checked to identify cited articles not captured by electronic searches.

Study selection

Two authors (AB and SK) scrutinized titles and abstracts of all references for possible inclusion. Inclusion criteria were: transport of adult ICU patients in the hospital, checklist and/or recommendations for IHT. Excluded were articles related to paediatric critical care, inter-hospital transport, reviews and editorials. Full text articles were examined and any disagreement was resolved by a third author (SA).

Data abstraction

The following data were abstracted from the studies with guidelines or checklists: author/research group, year of publication, country and recommendations and checklist items related to the pre-transport-, transport- and post-transport phase.

Analysis of incidents related to transport

We collected and analysed IHT incidents in our hospital to learn about the types and contributing factors of IHT incidents. In our ICU all incidents are submitted to an electronic incident reporting system. All routinely registered transport-related incidents were analysed and categorized with respect to type, phase of occurrence and contributing factors in the period from 2006 to 2009. Subsequently, over a 12-months period in 2012 we specifically asked ICU physicians and ICU nurses to report all incidents occurring during intra-hospital transport. A questionnaire was developed to collect these incidents. Incidents were predefined and categorized as airway, breathing, circulation, disability, exposure and other. Also, a free-text field allowed the reporter to give a description of the situation during transport, perceived causes and actions that were taken. Incidents were analysed with respect to type, circumstances and contributing factors.

Interviews with experts in the field of intensive care

Structured interviews based on findings from the literature and collected incidents were undertaken with ten ICU physicians and fifteen ICU nurses. The interviews followed a questionnaire containing 53 questions on what could go wrong during the three phases of IHT and how to prevent it. Questions were related to equipment, patient physiology, monitoring, medication and fluid management; and covered all three transport phases. Additionally, for the transport phase questions focused on logistics and communication with the other department, and registration of vital signs. For the post-transport phase the focus was on the reinstallation of ICU therapies and monitoring and on the stabilization of the patient. A detailed overview of the questions used for the structured interview can be found in Appendix A.

Development of the checklist

The information gathered from the review of the literature, the analysis of transport-related incidents and the interviews with experts in the field were combined to develop the checklist. Checklist items were structured according to the different phases of transport. The checklist was introduced to ICU physicians and ICU nurses and was implemented in the Patient Data Management System of our ICU to be used in daily practice.

Feasibility and usability

The checklist was used by the ICU for one month, whereupon we collected data to investigate the feasibility and usability of the checklist. Nurses were asked to fill in a questionnaire after each transport documenting their experiences using this checklist. The following data were collected: overall rating of the checklist, the time it took to fill in the checklist, relevance of the questions, logistics of the filling in of the checklist, and questions that were felt to be lacking. The questionnaire is listed in Appendix B.

Ethical approval

The Medical Ethics Committee of the LUMC waived the need for ethical evaluation of the study due to the observational nature of the study. Consequently, the need for informed consent was not applicable.

Results

Review of the literature

In total eleven guidelines [11,12,16-24] and five checklists on IHT [25-29] were identified in the literature. The guidelines were developed in USA, Europe, India, Australia and New Zealand and described recommendations for intra-hospital transport as well as for inter-hospital transport. In the guidelines some basic principles regarding transport were defined for example, that a hospital transport protocol should be present [11,16-18,21,22,24] and that the patient should receive the same level of basis physiologic monitoring during IHT as they received in the ICU. [12,17-19,23] Three phases of transport were recognized. For each phase recommendations could be subdivided into categories namely (i) use of (monitoring) equipment, (ii) patient physiology, (iii) medication and fluids, (iv) organization and planning.

The pre-transport phase was most extensively described. In this phase, recommendations were related to the use of a transport trolley, equipment to secure airway, and preparation of monitoring, medication and fluids. With respect to patient physiology, a careful evaluation of the risk-benefit ratio should be made by the physician [11,16-24] and special attention should be paid to the indication for transport. [11,12,17,18,23,24] Other recommendations included: planning of personnel with the suggestion that a minimum of two qualified staff members, an ICU nurse and ICU physician, should accompany the patient [11,12,16-24] and the need for clear communication to ensure that the patient is expected at the destination department [16,20,22-24] and to confirm that the receiving party is ready. [11,12,20,23,24]

In the transport phase an important goal should be to continue monitoring during the transport as well as during the diagnostic or therapeutic procedure [11,17,18] and to

check and record the patient's vital signs on a regular basis, at least every 15 minutes. [16,24] Furthermore, medication and fluid management and maintenance of physiologic stability should be of key importance.

Back in the ICU, after installation and stabilization of the patient, it is essential to check monitoring and medication and to document the course of the transport in the medical chart. With respect to the latter, attention should be paid to the status of the patient during and after transport [11,12,16-18,23,24] and also to the events and interventions that occurred during transport. [12,16-18,20,24] All the transport equipment should be cleaned and plugged back in the main power supply to ensure that the equipment is available for another transport to the receiving department for a diagnostic or therapeutic intervention.

In the literature, five checklists for intra-hospital transport of critically ill patients were found [25-29], of which one was specifically developed for obese patients. [29] The main focus of the checklists was on the pre-transport phase. Only the checklist developed by Jarden [27] also described items for the transport and post-transport phase. Checklist items in the pre-transport phase related to the patient, monitoring equipment, communication and quality of the team. Before transport, the clinical stability of the patient [26-28] and the necessity of the transport should be assessed. [28] Medication, fluids and the equipment should be checked including transport trolley, monitoring devices, and additional equipment. [25-29] Items related to planning and organization should also receive attention. [26,28,29] For example, in order to guarantee a safe transport, items were formulated with respect to the composition of the transport team, namely the presence of a physician [27] and a minimum number of ICU nurses. [26]

During transport, when the patient has arrived at the destination department, various items should be checked and ensured. First, the continuity of the oxygen supply and the electronic supply for transport trolley and medication pumps should be checked. [27] Furthermore, vital signs and administration of medication should be registered frequently.

Upon return in the ICU, it is essential to reinstall respiratory support devices, medication and monitoring, and to describe in the medical chart the complications that have occurred during transport and to recheck the used equipment. [27] An overview of the content of the published checklists is shown in Table 1.

Analysis of incidents related to IHT

Over a 36-month period, a total of 5,937 incidents were reported in our incident registration system, of which 118 incidents (2.0%) were IHT related. Of the 118 IHT incidents 38% occurred in the pre-transport phase, 47% in the transport phase and 15% in the post-transport phase.

Table 1. An overview of the content of published intra-hospital (IHT) checklists

Author	Pope[28]	Fanara[26]	Jarden[27]	Roland[29]	Choi[25]	Current checklist ǂ
Year of publication	(2003)	(2010)	(2010)	(2010)	(2011)	LUMC
Pre-transport						
Necessity of transport is confirmed	+					
Patient assessment pre-transport		+	+			
Wrist band patient or consent form		+	+	+	+	
Transport team is notified	+	+	+			
Equipment and materials are gathered	+	+	+	+	+	+
Check sufficient oxygen level		+		+		+
Extra intravenous fluid and medication	+	+	+	+		+
Check sufficient intravenous medication	+	+	+	+		+
Stop enteral feeding and enteral insulin						+
Check tubes and lines		+	+	+	+	+
Check and set monitor alarms		+	+			+
Check and set transport ventilator alarms		+				+
Insert i.v. cannula in case of computed tomography with contrast						+
Preparation and equipment adapted to procedure (magnetic resonance imaging)		+				+
Fill in magnetic resonance imaging safety questionnaire						+
Register baseline vital signs		+/-	+			+
Receiving department is notified	+					+
Transport route is clear		+				
During transport						
Check and plug in equipment at destination			+			+
Registration of administered fluids/medication			+			+
Registration vital signs every 20 minutes			+			+
Post-transport						
Start enteral feeding and enteral insulin						+
Turn on humidifier						+
Change HME filter						+
Change suction bag if used			+			+
Complement transport bag						+
Report occurred incidents/events			+			+
Re-check equipment and materials			+			+

ǂ Current checklist Leiden University Medical Center (LUMC) refers to the final checklist that was based on reviewing the available literature on IHT checklists and guidelines, an analysis of transport related incidents and a structured interview with ICU physicians and ICU nurses. HME = Heat and moisture exchanger.

In the pre-transport phase most reported incidents were related to equipment and organizational issues. Examples of equipment-related incidents were: low battery of the ventilator and/or medication pumps, use of a mechanical ventilator not suitable for the MRI and an empty oxygen tank. Examples of organisation-related incidents were

inappropriate preparation of the patient leading to delay of transport or inadequate communication with the receiving department.

Also in the transport phase most reported incidents were related to equipment and organisation. Examples of equipment incidents during this phase included failure of the transport trolley and its monitor. Examples of the organisational incidents were in availability of CT or MRI equipment.

Post-transport, most reported incidents were related to airway and respiratory management, such as failure to install adequate oxygen level or to reconnect humidifier of the ventilator. An overview of the most common incidents is shown in Table 2.

Table 2. Top ten most commonly reported intra-hospital transport (IHT)-related incidents

Top 10 routinely registered IHT-related incidents[a]	**Pre-transport**	**Per-transport**	**Post-transport**	**Total**
Equipment dysfunction	9	24	1	34
Preparation before transport	30	0	0	30
Lack of communication with radiology department	1	5	0	6
Dislocation of intravenous lines and tubing	0	12	1	13
Oxygen tank empty	4	4	0	8
Increase need vasopressor or inotropics	0	3	0	3
Equipment not available radiology department	0	5	0	5
Lack of documentation in medical chart	0	0	2	2
Failure reconnect humidifier on ventilator	0	0	11	11
Hypoglycemia	0	0	1	1
Top 10 prospectively collected IHT-related incidents[b]				
Equipment dysfunction	7	24	2	33
Preparation before transport	6	5	0	11
Lack of communication with radiology department	5	5	0	10
Dislocation intravenous line	0	7	2	9
Oxygen tank empty	4	2	0	6
Increase need vasopressor or inotropics	5	15	6	26
Low blood pressure[§]	21	44	18	83
Hypoxia[§] /increased O_2 demand	5	18	12	35
Increased need sedatives or opiods due to agitation	2	17	2	21
Hypertension[§]	2	9	3	14

[a] Analysis of transport related incidents that were identified from routinely collected incidents in an electronic incident reporting system in Leiden University Medical Center. [b] For 12 months, all incidents occurring during intra-hospital transport were prospectively collected.
[§] No definitions were used to define hypotension, hypertension and hypoxia. Physicians and nurses were able to judge whether it was deviated.

In 2012, we prospectively collected transport-related incidents. In this period, 503 transports to the radiology department were undertaken. In 334/503 (66%) of IHTs an ICU physician and ICU nurse accompanied the patients to the radiology department. In 133/503 (27%) of IHTs three ICU staff members, an ICU physician and two ICU nurses and in 16/503 (3%) four ICU staff members, two ICU physicians and two ICU nurses accompanied the patient. When the patient was not intubated the nurses sometimes accomplished the transport without a physician 20/503 (4%). The median duration of

the transport was 55 minutes (range 10 to 305 minutes). In 77% the reason for the IHT was to perform a CT scan and in 10% an angiography.

In 133 of the 503 transports (26%), one or more incidents occurred, and in total, 358 incidents were reported. Incidents occurred in the transport phase (215/358, 60%), in the pre-transport phase (80/358, 22%) and in the post-transport phase (63/358, 18%). The ten most frequently reported incidents during transport are shown in Table 2. In the transport phase the incidents were related to hemodynamic instability, respiratory instability, equipment dysfunction and increased need of medication. In the pre-transport and post-transport phase incidents were related to hemodynamic instability. The lack of communication with the radiology department before and during transport also occurred regularly.

Interviews with experts in the field of intensive care

Ten physicians and fifteen nurses were interviewed to discuss the findings from the literature and the collected incidents. A transport protocol existed in our hospital but 90% of the physicians and 73% of the nurses were not familiar with the protocol. The protocol described the composition of the accompanying team, the monitoring and respiratory equipment to be used, and the medication and additional equipment that should be available during transport. Incidents considered most important by physicians and nurses in the pre-transport phase were an empty oxygen tank, lack of sufficient intravenous access, missing equipment, trolley failure, inadequate length intravenous tubing and miscommunication with the radiology department. In the transport phase, nurses and physicians mentioned potential incidents such as disclocation of an intravenous canulla or endotracheal tube, low battery of the pumps, impaired view of the patient in the radiology department and patient instability. In the post-transport phase patient instability and incorrect reinstallation of respiratory support and medication were commonly reported.

To enhance a safer transport, several improvement measures were suggested by physicians and nurses such as introduction of a checklist for the three phases of transport and standardization of the transport procedure and improved communication with the radiology department. A list of recommendations can be found in Table 3. Furthermore, the physicians and nurses indicated that they would feel more confident if they received more education and practical training.

Table 3. Recommendations from ICU physicians and ICU nurses

	Recommendations
Team	Ventilated patient at least one ICU physician and one ICU nurse
	Not ventilated patient and:
	o ≤ 1 inotropic, one ICU nurse
	o ≤ 1 inotropic, respiratory insufficient and arrhythmia, one ICU physician and one ICU nurse
Education	Focus on how to operate equipment of transport trolley
	More education for ICU physicians and ICU nurses to execute transport of ICU patients
Equipment and materials	Equipment on trolley is equal to equipment in the ICU
	Check equipment and materials prior to transport
	Check extra length of intravenous lines for MRI prior to transport
	Check and calculate oxygen level in oxygen tank
	Defibrillator is standard equipment on transport trolley
	Check all equipment on transport trolley
	Batteries are fully charged prior to transport
Organization and procedure	Introduction of an intra-hospital checklist
	Formal training in transport procedure to MRI
	Standard Operating Procedure
	Standardization of IHT procedure
Communication	Confirm appointment with the other department prior to transport
	Improve communication with the other department to prevent incidents during transport
	Debriefing with ICU physician and ICU nurse after transport
Medication	Check and prepare intravenous medication prior to transport
	Extra intravenous medication and intravenous fluids

Recommendations suggested by ICU physicians and ICU nurses when they were interviewed to discuss safety and hazards of IHT and the findings from the literature and the collected incidents.

Development of the checklist

Based on the literature, we chose the checklist of Jarden [27] as a base to develop our own checklist. The other four checklists were used to complement our new checklist. All the checklists had several items in common such as check equipment/materials [25-29], medication [26-28] and intravenous access. [25-29] We included these items in our checklist. One item, only found in the checklist by Pope was 'whether the receiving department is notified' and we included this item also in our checklist. [28] An overview of the items of the published checklists is shown in Table 1.

The final checklist developed as described above is presented in Figures 1 and 2. The basic principle of this checklist was to guide the physician and nurses through the different phases. In the pre-transport phase the focus is on required equipment, preparation of extra medication and intravenous fluids and checking of procedures such as the use of contrast fluid and kidney protection.

Patient label	Date (dd/mm/yyyy)		
	Time of start transport (hh/mm)		
	Time of arrival in ICU (hh/mm)		
	Procedure		
	☐ CT-Scan	☐ MRI	☐ Angiography
	☐ Other	.....	
	Purpose of transport		
	☐ Diagnostic	☐ Intervention	
	☐ Diagnostic and intervention		

Pre-transport

Equipment/materials	**YES**	**NO**	**NA**
Transport bag present			
Transport trolley fully charged			
Defibrillator present			
Manual resuscitation bag present			
Sufficient oxygen level			
Check length of i.v. tubes			
In case of MRI; extend length i.v. tubes			
Shut off necessary i.v. tubes			

Medication	**YES**	**NO**	**NA**
Sufficient intravenous medication			
Additional intravenous sedatives			
Additional intravenous inotropics			
Additional medication			
Additional infusion pump			
Additional intravenous fluids			
Stop enteral nutrition			
Stop enteral insulin			

In case of CT-Scan with contrast	**YES**	**NO**	**NA**
Intravenous cannula 18GA present			
Oral contrast administered			
If "YES":			
Renal protection according to protocol			

Monitor	**YES**	**NO**	**NA**
$EtCO_2$ monitoring present			
Check and set visual and audible alarm			

Transport ventilator	**YES**	**NO**	**NA**
Turn on the oxygen			
Put HME filter between ventilator and ET/TT			
Check and set visual and audible alarms			

ET/TT depth (cm)	

Administrative	**YES**	**NO**	**NA**
Register baseline vital signs overleaf			
Switch patient in PDMS to "Transport"			
Radiology department informed			
Fill in MRI safety questionnaire			

Figure 1. Newly developed Leiden University Medical Center (LUMC) checklist side one.
i.v., intravenous; MRI,Magnetic resonance imaging; $EtCO_2$, End Tidal CO_2; HME, Heat and moisture exchanger; ET/TT, Endotracheal tube/Tracheal tube; PDMS, Patient Data Management System.

In the transport phase the focus is on the destination department with attention for the following items: plugging in the oxygen, monitoring equipment and keeping sight on the monitor during the procedure and registration of vital signs, and medication and intravenous fluids.

In the post-transport phase it is important to connect the patient to the equipment in the ICU with specific attention to switching on the humidifier, nutrition, insulin and checking the correct dose of medication via the perfusor. Also, to assure that required equipment is ready for use for the next trip, the transport trolley and transport bag should be checked and connected to the power supply. Finally, documentation in medical charts including registration of incidents should be checked.

During transport

At destination	YES	NO	NA
Plug in oxygen			
Plug in air			
Switch off oxygen & air on trolley			
Plug in transport trolley			
Check visibility on monitor during procedure			

Medication and fluids administered

Medication	Dosage
Phenylephrine	
Midazolam	
Propofol	
.....	
.....	
.....	

IV fluids	ml
Saline solution	
Voluven	
Ringer's lactate	
.....	
.....	
.....	

Vital signs	Pre-transport	20 min	40 min	60 min	Post-transport
Time	...../.....	...../.....	...../.....	...../.....	...../.....
HR/Rhythm					
BP					
MAP					
CVP					
PAP					
Vent mode					
FIO_2					
PEEP/PS					
RR					
Tidal volume					
Minute volume					
SpO_2					
$ETCO_2$					
GCS					
Pupil L/R					

**Only the clinical parameters that are also recorded in ICU*

Post-transport

Connecting patient	YES	NO	NA
Turn on humidifier			
Stop extra sedatives			
Start enteral nutrition			
Start enteral insulin			
Untangle i.v. tubes			
Switch patient in PDMS to "Back in ICU"			
Check level i.v. pump with PDMS			

Transport trolley	YES	NO	NA
Complement transport bag			
Change Oxygen tank if level < 50 bar			
Change HME filter			
Plug in transport trolley			
Report procedure in medical chart			
Change suction If used			
Report incidents			

Specify:

Physician: ..... **Signature:** .....

Nurse: ..... **Signature:** .....

Figure 2. Newly developed Leiden University Medical Center (LUMC) checklist side two.

i.v., intravenous; HR, Heartrate; BP, bloodpressure; MAP, Mean aterial pressure; CVP, Central venous pressure; PAP, Pulmonary artery pressure; Vent mode, Ventilation mode, FIO_2, fraction of inspired oxygen; PEEP/PS, Postive End Expiratory Pressure/Pressure Support; RR, Respiratory rate; SpO_2, Peripheral cappillary oxygen saturation; $EtCO_2$, End Tidal CO_2, GCS, Glasgow coma scale; ICU, Intensive care unit; PDMS, Patient Data Management System; HME, Heat and moisture exchanger.

Feasibility and usability

In order to investigate the feasibility and usability of the checklist, data was collected over a one month period using the checklist. During this month, 41 transports were made to the Radiology department. In 29 of these transports, the checklist was used and a questionnaire was later filled in by the nurses about their experiences using the checklist. Reasons for not using the checklist during transport were either due to forgetfulness of the team to use it (5/29) or to the urgency of the transport (7/29). The time it took to fill in the checklist was on average 4.5 minutes per phase (range 3-10). Nurses stated that the user friendliness of the checklist was good, it was comprehensive and complete, it reduced the chance of forgetting things, and it was easy to apply because it was implemented in the Patient Data Management System. A point of criticism was the documentation of vital signs every 20 minutes on the paper-based checklist that was used in the transport phase. This was considered time consuming. Digitally input documentation was preferred. Items that were missed in the checklist were information on the completeness of the transport bag and patient assessment in the pre- and post-transport phase. Information on the transport phase and post-transport phase was filled in after the transport.

Discussion

We developed a checklist to improve safety of intra-hospital transport by using three complementary methods: a review of the available guidelines and checklists in the literature, an analysis of transport-related incidents and an inventory of what could go wrong during IHT and how to prevent it by interviews with ICU doctors and nurses. Importantly our checklist includes three phases of intra-hospital transport. Furthermore, we propose that our methods of local modification of an existing checklist on IHT may be a useful procedure for any hospital aiming at improving safety of intra-hospital transport.

The basic principles for intra-hospital and inter-hospital transport are the same, namely to ensure safety during this potentially dangerous transport. [18] We were specifically interested in intra-hospital transports because they occur frequently on the ICU and because the number of incidents during these transports is still very high. Our checklist is based on an earlier checklist by Jarden. [27] This is the only checklist that discerns three different transport phases. In other checklists the focus was only on the pre-transport phase namely to check the patient and equipment before transport. If the patient is checked before transport it lowers the risks of incidents during transport. However, patient transport is not limited to the pre-transport phase. It is essential that the entire transport process of critically ill patients is covered from start to end.

We wanted to adapt the checklist of Jarden [27] to our own situation. It is often necessary to customise a checklist because aspects of the checklist may not be suitable to a specific local situation. Also in our case, some of our hospital policies and procedures differed from the described checklist items. Therefore, ICUs need to customise the available checklists to their own situation taking into account the hospital procedures and circumstances in which a transport will be conducted.

A comprehensive method was used to develop the checklist. This included a review of the literature for available guidelines and checklists, an analysis of incidents related to transport in our hospital and an inventory of ICU physicians' and nurses' expert opinion over IHT. Due to this approach, we obtained different types of knowledge available on the subject and we were better able to build a comprehensive and practical checklist. This approach is supported by Hales *et al.* [30] who stated that peer-reviewed guidelines and evidence-based best practice should be considered to form the body of a checklist and that checklists should also reflect the local hospital and institution policies and procedures.

There are some differences between the Jarden's checklist [27] and ours. We added some items that are specifically related to our local situation and some that are a more generic addition for checklists on IHT. For example, in the pre-transport phase checking the availability of sufficient intravenous medication was added. While Jarden's checklist included a patient assessment and documentation section in the pre-transport phase, we eliminated many of these items because this information can be found in our Patient Data Management System. We added a few items to the checklist that were specific for our IHT policy. Examples of these are extending the length of intravenous tubing, hyper hydration for kidney protection and an MRI safety questionnaire for transport to MRI. In the post-transport phase the focus was on connecting the patient to the available equipment in the ICU and on checking the rate of administration of intravenous pumps with the Patient Data Management System. These items were important for our ICU due to frequently reported incidents that decreased the patient safety.

General guidelines and checklists provide guidance in developing a local checklist. The concept of local adaptation of the transport checklist developed by Jarden [27] was not previously described. In our opinion, customizing a checklist according to local policies and procedures improves the commitment of nurses and physicians to use this checklist.

A checklist can be seen as an important instrument to avoid incidents. It is of added value if it is introduced accompanied with education and training. Barriers to using checklists in healthcare are related to operational and cultural aspects. [13] Filling in a checklist adds to the nurse's workload. However, in our small feasibility study, it only took 4.5 minutes (range 3 to 10) per phase and it appeared that nurses were on the whole positive about using a transport checklist.

Our study has a few limitations. First, we have not yet investigated whether our checklist indeed decreases the number of IHT-related incidents and improves safety. This will be the subject of future research. Furthermore, the checklist is by definition most useful in our specific hospital because it is customized to the local hospital and ICU procedures and protocols. Third, while we implemented the pre- and post-transport phase checklist into the Patient Data Management System, the checklist items in the transport phase are still registered on paper (vital signs, medication and fluids). This may result in a potentially lower adherence during this phase.

A strong point of our study was the comprehensive way we developed the checklist. Particularly our inventory of what could go wrong during IHT and how to prevent it, which we achieved through interviews with ICU doctors and nurses, will have contributed to a clinically relevant checklist and to the applicability and acceptance of the checklist in daily practice by ICU doctors and nurses. We think that this checklist can contribute to the safety of ICU patients that need to be transported during their ICU stay. However, to confirm this, the next step to be taken is testing and evaluating the efficacy of the checklist: is patient safety increased with the checklist and are ICU nurses and ICU physicians satisfied using it in daily practice? Our checklist, though specifically adapted for one hospital, can be used in other hospitals as well. Each hospital should assess whether the items from the checklist are applicable to their specific situation. If necessary, local modifications can be made.

Conclusion

In conclusion, we applied a comprehensive approach to develop an intra-hospital checklist for safe transport of ICU patients to another department and back to the ICU. This checklist is not only based on available guidelines and checklists in the literature but also on reported incidents and expert opinions of ICU physicians and nurses. This resulted in a checklist that is a framework to guide ICU physicians and nurses through intra-hospital transports and provides a continuity of care to enhance patient safety.

Key messages

- A comprehensive method was applied to develop a checklist which can be used to increase the safety of intra-hospital transport of critically ill patients.
- The checklist covers the transport of critically ill patients from the start until the end of the process, including all three transport phases.
- Customizing the checklist according to local policies and procedures - using the comprehensive method suggested in this study - is important to improve the commitment of nurses and physicians.

List of abbreviations

CT Computed tomography
ICU Intensive Care Unit
IHT Intra-hospital transport
MRI Magnetic resonance imaging

Competing interests

The authors declare that they have no competing interests.

Authors'contributions

AB contributed to the development of the manuscript concept and design, carried out the study and performed primary writing and editing of all drafts of the manuscript. SA contributed to the development of the manuscript concept and design and performed editing of all drafts of the manuscript. SG contributed to the development of the manuscript concepts and design, performed the literature search, analysed incidents and interviewed ICU physicians and ICU nurses and performed editing of the manuscript. EdJ contributed to the development of the manuscript concept and design and performed editing of all drafts of the manuscript. All authors read and approved the final version of the manuscript.

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Appendix A. Questionnaire used for the structured interview of ICU physicians and ICU nurses for intra-hospital transport (translation from Dutch version)

Part A. Introduction and general questions

1. Profession
   - ☐ ICU Nurse
   - ☐ Student ICU Nurse
   - ☐ Resident
   - ☐ Fellow
   - ☐ ICU physician

2. Employment at ICU
   - ☐ < 1 year
   - ☐ 1 to 5 year
   - ☐ 5 to 10 year
   - ☐ > 10 year

3. How often do you transport patients to the radiology department per month?

4. Is there a protocol to transport patients?
   - ☐ Yes
   - ☐ No

   If 'Yes', do you know the contents of the protocol?
   - ☐ Yes
   - ☐ No
   - ☐ NA

   Do you examine the protocol before transport?
   - ☐ Never
   - ☐ Sometimes
   - ☐ Often
   - ☐ Always

   If you examine the protocol, what is the reason for examining the protocol?

5. How would you grade 'I am afraid to transport patient to the radiology department' on a scale from 0 "very scared" to 10 "not scared".

6. How would you grade 'I feel confident to transport the patient to the radiology department' on a scale from 0 "totally not confident" to 10 "very confident".

7. What is the most important factor as to why you feel afraid or not confident during transport?

Part B. Questions related to the pre-transport phase

8. Before transport is the destination clear?
   - ☐ Yes
   - ☐ No

   If 'Yes', do you know the best route through the hospital?
   - ☐ Yes
   - ☐ No

   If 'No', please specify ……..

9. How often is the room number at destination incorrect?

10. How many ICU staff members are sufficient to accompany the patient to the radiology department if:
    The patient is not intubated, please specify ……..
    The patient is intubated, please specify ……..

11. The following questions refer to which and how many ICU staff members, in your opinion, should accompany the patient during transport in the following situations.

    A. The patient is not intubated and who should accompany (nurse, resident, fellow or intensivist):
       - ☐ Number of inotropic drugs < 1
       - ☐ Number of inotropic drugs > 1
       - ☐ Agitated patient
       - ☐ Respiratory failure
       - ☐ Recent arrhythmia

    B. The patient is intubated and who should accompany (nurse, resident, fellow or intensivist):
       - ☐ Number of inotropic drugs < 1
       - ☐ Number of inotropic drugs > 1
       - ☐ Agitated patient
       - ☐ Recent arrhythmia
       - ☐ Haemodynamic failure
       - ☐ External equipment (e.g. ECMO or IABP)

12. Several devices are used during transport. Which of these devices are difficult to use?
    - ☐ Transport monitor
    - ☐ Transport ventilator
    - ☐ Suction device
    - ☐ Air tank
    - ☐ Oxygen tank

13. How would you grade 'the operating controls' of the following devices 'easy to use', 'difficult' or 'neutral'?
    - ☐ Transport monitor
    - ☐ Transport ventilator
    - ☐ Suction device
    - ☐ Air tank
    - ☐ Oxygen tank

14. Which problems are you dealing with in operating the devices?

15. What would you, at minimum, monitor during transport?
    - Monitor ECG
    - Invasive blood pressure
    - Respiratory rate
    - Pulse oximetry
    - Non-invasive blood pressure
    - Central venous pressure
    - Intra cranial blood pressure
    - Pressure arterial pulmonary
    - Electroencephalogram

16. Do you check the level of oxygen in the oxygen tank before transport?
    - Never
    - Sometimes
    - Often
    - Always

17. What is in your opinion the minimum level of oxygen in the oxygen tank before transport?

18. Do you take the transport bag with you during transport?
    - Yes
    - No

19. Did you ever use the transport bag (equipment and drugs for emergency use)?
    - Yes
    - No

20. Did you ever miss something in the transport bag?
    - Yes
    - No

    If 'Yes', please specify ……..

21. Do you always take the defibrillator with you?
    - Yes
    - No

    If 'Yes', please specify……..
    If 'No', please specify ……..

22. Do you check if there is a sufficient amount of drugs available during transport?
    - Never
    - Sometimes
    - Often
    - Always

23. Do you take extra intravenous medication during transport?
    - Yes
    - No

If 'Yes', please specify which medication:

- Inotropic
- Analgesia
- Sedative
- Muscle relaxant
- Not applicable
- Other, namely ……

24. When extra intravenous medication was taken, have you ever experienced that you don't have enough medication?

25. How would you grade how often 'there is insufficient medication' on a scale from 0 "never" to 10 "every transport"?

26. Do you take pre-prepared medication?
    If 'Yes' please specify which medication ……

27. Do you take extra intravenous fluids?
    In case of 'Yes' please specify which fluids and how many ……

28. In case of CT-Scan or MRI do you check the length of the intravenous tubes?
    - Never
    - Sometimes
    - Often
    - Always

29. Before transport, discussion takes place between physician and nurse regarding the situation of the patient?
    - Never
    - Sometimes
    - Often
    - Always
    - Not applicable

30. Who is notified that you are "on transport"?
    - Colleague
    - Head unit
    - None
    - Other, namely ……

31. Do you inform the radiology department?
    - Never
    - Sometimes
    - Often
    - Always

32. Which incidents occur frequently in the pre-transport phase?

33. Which improvement measures should be taken in this phase?

Part C. During transport questions

34. Do you record the following data during transport?
    - ☐ Vital signs
    - ☐ Given medication
    - ☐ Given intravenous fluids

    If more than 1 'Yes', how do you record this?

35. Do you discuss who is responsible to check the monitor in case of:
    a. During transport?
        - ☐ Yes
        - ☐ No

    b. During the procedure in the radiology department?
        - ☐ Yes
        - ☐ No

36. How is the visual on the transport monitor;
    a. During transport at from the ICU to the radiology department and vice versa
        - ☐ None
        - ☐ Insufficient
        - ☐ Sufficient
        - ☐ Good
        - ☐ Excellent

    b. During the procedure in the radiology department
        - ☐ None
        - ☐ Insufficient
        - ☐ Sufficient
        - ☐ Good
        - ☐ Excellent

37. Do you give extra sedation to the patient during transport?
    - ☐ Never
    - ☐ Sometimes
    - ☐ Often
    - ☐ Always

    Please specify the reason, ……

38. Do you give extra analgesia during transport?
    - ☐ Never
    - ☐ Sometimes
    - ☐ Often
    - ☐ Always

    Please specify the reason, ……

39. Do you give extra muscle relaxant to the patient during transport?
    - ☐ Never
    - ☐ Sometimes
    - ☐ Often
    - ☐ Always

    Please specify the reason, ……

40. The following questions refer to the cooperation with the radiology department.
    a. Is the radiology department ready when you arrive?
        - Never
        - Sometimes
        - Often
        - Always

    b. Personnel of the radiology department are helpful during the procedure?
        - Never
        - Sometimes
        - Often
        - Always
    c. Can you always plug in the oxygen and air?
        - Never
        - Sometimes
        - Often
        - Always
    d. How would you grade the technical skills of the personnel on a scale from 0 (poor) to 10 (excellent)?
    e. How would you grade the communication skills of the personnel on a scale from 0 (poor) to 10 (excellent)?

41. Which incidents occur frequently in the per-transport phase?

42. Which improvement measures should be taken in this phase?

Part D. Post-transport questions

43. In case of transport of the patient, do you report this in the medical chart?
        - Yes
        - No

    If 'Yes', what do you report (more answers possible)
        - Indication of transport
        - Duration of the transport
        - Patient status during transport
        - Action take in case of haemodynamic or respiratory failure
        - Incidents and complications
        - Extra intravenous medication given

    If 'No', please specify the reason ……

44. Which incidents occur frequently in the post-transport phase?

45. Which improvement measures should be taken in this phase?

Part E. General questions

46. Which transport related problems did you sometimes discover after transport of the patient?

47. In which circumstances would you refuse to transport the patient?

48. Would you refuse to transport the patient in the following situations?
    a. Positive End Expiratory Pressure
        - ☐ Yes
        - ☐ No

    If 'Yes', please specify at what level?

    b. Oxygen
        - ☐ Yes
        - ☐ No

    If 'Yes', please specify at what level?

    c. Inotropic
        - ☐ Yes
        - ☐ No

    If 'Yes', please specify at what level?

49. Do you think there is enough knowledge to ensure the safety during transport of patients if the transporter is an:
    a. ICU Physician
        - ☐ Yes
        - ☐ No

    b. ICU nurse
        - ☐ Yes
        - ☐ No

    If 'No', which improvement measures should be taken?

50. a. An examination is required before an ICU physician can accompany the patient?
        - ☐ Yes
        - ☐ No

    c. An examination is required before an ICU nurse can accompany the patient?
        - ☐ Yes
        - ☐ No

51. How would you grade your expertise in transport of critically ill patients on a scale from 0 (poor) to 10 (excellent)?

52. In your opinion which personnel (ICU nurse, ICU physician or both) is responsible for the following tasks;
    a. Preparation of the patient
    b. Coordination of the transport
    c. Completion of the transport bag
    d. Rechecking equipment and completion of the transport trolley

53. Several solutions can be introduced to enhance a safer transport. In your opinion, do the following solutions contribute to a safer transport?
        - ☐ Extending protocol
        - ☐ Checklist
        - ☐ More education
        - ☐ Transport nurse
        - ☐ Other, namely ……

Appendix B. Questionnaire used to assess feasibility and usability of current checklist LUMC (translation from Dutch version)

Part A. Content of the Checklist

1. Did you miss questions in the checklist?
   a. In the pre-transport checklist?
      - ☐ Yes
      - ☐ No

      If 'Yes', please specify ……..

   b. In the transport checklist?
      - ☐ Yes
      - ☐ No

      If 'Yes', please specify ……..

   c. In the post-transport checklist?
      - ☐ Yes
      - ☐ No

      If 'Yes', please specify ……..

2. Does the checklist contain unnecessary questions?
   - ☐ Yes
   - ☐ No

   If 'Yes', please specify ……..

3. Did you skip checklist items while you used the checklist?
   - ☐ Yes
   - ☐ No

   If 'Yes', please specify ……..

4. What is the reason for skipping these checklist items?

Part B. User friendliness

5. Was it easy to fill in the checklist?
   - ☐ Yes
   - ☐ No

6. Can you describe in your own words what you find useful or impractical for filling in the checklist?

7. When did you fill in the transport checklist?
   a. The pre-transport checklist?
      - ☐ Before transport
      - ☐ During transport
      - ☐ After transport

   b. The transport checklist?
      - ☐ Before transport
      - ☐ During transport
      - ☐ After transport

c. The post-transport checklist?
   - Before transport
   - During transport
   - After transport

8. Did you have sufficient time to fill in the checklist?
   a. The pre-transport checklist?
      - Yes
      - No
   b. The transport checklist?
      - Yes
      - No
   c. The post-transport checklist?
      - Yes
      - No

9. If 'No' for question 8, please specify ……..

10. What is your estimation of time you needed to fill in the checklist in the different phases? (in minutes)
    - Pre-transport
    - During transport
    - Post-transport

11. Did you check the checklist items by yourself?
    - Yes
    - No

12. Did you check the checklist items with a second person?
    - Yes
    - No

13. If the checklist items were checked with a second person, with whom did you check these items?

14. Why do you use the checklist – please specify in your own words?

15. In your opinion, will you recommend the checklist to a colleague?

16. If 'Yes' or 'No' for question 15, please specify……..

17. Any closing remarks?

Chapter 8

Incident and error reporting systems in Intensive Care – a systematic review of the literature

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International Journal for Quality in Health Care 2016, 28(1), 2-13

Abstract

Purpose: We performed a systematic review to assess (i) to what extent Incident Reporting Systems (IRS) on the adult intensive care unit (ICU) meet the criteria of the WHO Draft Guidelines for Adverse Event Reporting and Learning Systems, (ii) to what extent the IRSs comply with the four aspects of the iterative quality loop and (iii) whether IRSs have led to improvement measures in clinical practice.

Data sources: The authors searched multiple electronic databases from 1966 until June 26th 2014.

Study Selection: Studies were included if they reported incident reporting systems on the adult ICU.

Data Extraction: Data on study design, characteristics of the incident reporting system, implementation, feedback and improvement measures were collected using structured data extraction forms.

Results of data synthesis: A total of 2098 studies were identified and 36 studies reported IRSs on the adult ICU. Studies were divided into: ICU-specific IRSs and general IRSs. Items of the WHO checklist were assessed and categorized into the four phases of the iterative quality loop.

Conclusion: None of the IRSs completely fulfilled the WHO checklist criteria. With respect to the iterative loop, data input and data collection are well established but not much attention was given to analyzing incidents and to give feedback. This resulted in an administrative report system, rather than the much desired instrument for change of practice and increase of quality as an IRS can only effectively contribute to improve patient safety and quality of care if more attention is given to analyzing incidents and feedback.

Introduction

Quality of care and patient safety are important in all medical disciplines and in health-care systems all over the world. Particularly in the intensive care unit (ICU) patient safety may be jeopardized, since critically ill patients with multiple co-morbidities, undergoing invasive procedures in a high-risk environment, are at risk of experiencing errors and incidents.

Errors have become a serious problem in today's complex, high technology healthcare system. [1] Most errors result in little harm but may represent early warning signs of system failures with the potential to cause serious harm or death. [2] Moreover, some errors do cause serious harm. It was estimated in 1999 that 44,000 to 98,000 patients die each year in the USA as result of clinical errors. [2] Studies suggest that errors are common in the ICU, resulting in serious adverse events in 17% of patients. [3,4] Since Flanagan first described in 1954 the investigation of critical incidents to improve safety and performance among military pilots, healthcare organizations have been involved and have learned from error and incident analysis. [5,6] In 1999, the IOM reported that error and incident reporting systems are a key strategy for learning from incidents and preventing their recurrence. [2,4]

However, much attention is paid to the filling of incident reports, and not enough to making the most of the information the reports contain by meaningful analysis, formulation of lessons learned and improvement measures, feedback of these improvements and follow-up. [7] This undermines the very purpose of reporting. Successful translation of incident reporting to improvement measures depends upon four basic activities applied in an iterative quality loop. [7] These include (i) *data input*; there should be a non-punitive, independent learning culture, (ii) *data collection*; the way in which information is gathered and handled is extremely important in determining the quality of the report, (iii) *data analysis*; incident report data should be analysed to determine lessons learned, improvement measures and trends, (iv) *feedback*; feedback should address specific vulnerabilities and should disseminate the lessons learned and improvement measures to individuals and organisations. Furthermore, the effects of these measures should be monitored and can contribute to the change of attitude and knowledge of staff involved. [8] This will result in a continuous quality cycle in which the monitoring of the effect of the improvement measures on incidents will contribute to improvement of patient safety.

Guidelines on how to develop and apply an incident reporting system are scarce. The World Health Organization published the "WHO Draft Guidelines for Adverse Event Reporting and Learning Systems", with a checklist for incident reporting systems, which is the only guideline for developing an incident reporting system available to date. [7]

According to this guideline the most important goal and measure of success of a reporting system is the use of the results of incident analyses to formulate improvement measures and recommendations for healthcare system changes.

Besides the lack of guidelines for development of incident reporting systems, the barriers to learn and improve from incident reporting are that many incidents are simply not reported. Reasons for not reporting are unawareness, no recognition of the incident, lack of clear incident definition, time pressure, fear of punitive measures, lack of feedback and lack of belief that reporting results in future improvement. [9-11] In a previous study up to 62% of healthcare professionals stated that the lack of feedback was one of the greatest barriers to report incidents. [12,13] Therefore, to increase the usefulness of incident reporting systems, it is essential to improve feedback and focus on feedback of both information and preventive actions. The Framework for Safety Action and Information Feedback from Incident reporting (SAIFIR) describes five modes of feedback for IRSs and can support organizations to increase the usefulness of incident reporting and promote best practices. [10]

Over the last years, many IRSs have been developed and evaluated in the ICU setting. Unfortunately little is known on strengths and weaknesses of these systems, making it difficult for ICUs to choose an IRS to implement.

The aim of this review was to assess (1) to what extent *Incident Reporting Systems (IRSs)* on the adult ICU meet the criteria of the WHO Draft Guidelines for Adverse Event Reporting and Learning Systems, (2) to what extent the IRSs comply with the four aspects of the iterative quality loop namely data input, data collection, data analysis and feedback and (3) whether IRSs have led to improvement measures in clinical practice.

Methods

Search strategy

We systematically searched the following electronic databases from 1966 to 26 June 2014, PubMed/MEDLINE, COCHRANE, CINAHL, EMBASE, Web of science, Academic Search Premier and Science Direct, PiCARTA, INVERT, Dutch Artikelendatabank voor de Zorg, metaRegister of Controlled Trials, WHO International Clinical Trials Registry Platform, ClinicalTrials.gov, Current Controlled Trials, SpringerLink, Wiley Blackwell, Lippincott-Williams&Wilkings, HighWire, InformaHealth and Google Scholar.

The databases were searched for peer-reviewed literature with the following terms: “Incident and error report”, “ICU”, “data collection” and “reporting systems”. In addition, we hand searched reference lists of included articles and used citation tracking of all relevant studies.

The language of the articles was restricted to English. We were assisted by a librarian and the complete electronic search strategy can be found on the internet; http://intqhc.oxfordjournals.org/content/suppl/2015/12/10/mzv100.DC1.

Study Selection

Two investigators (AB and SA) assessed the titles and abstracts for prospective studies. Inclusion criteria were (1) studies concerned with the systematic collection of incidents, adverse events and/or errors, (2) in adult or mixed adult ICU patients, (3) with a clear description of the incident reporting system, in terms of the content and mode of application. Excluded were studies in pediatric patients, case-reports, letters to the editor, expert opinions and abstracts from scientific meetings. In case of duplicate publication only the first or the one with the description of the incident reporting system was included. All studies that on full text examination failed to meet the inclusion criteria, were excluded (Figure 1). Any disagreement between the authors was solved by a third investigator (EJ).

Data extraction

The authors independently extracted data from each study in a predefined data extraction form based on the systematic review by Snijders et al. and the World Health Organization guideline "WHO Draft Guidelines for Adverse Event Reporting and Learning systems". [14,15]

A two-step protocolized process of data extraction was undertaken. We categorized Incident reporting systems in: IRSs specifically developed for the ICU (ICU-specific IRS) and general IRSs applied in the ICU (general IRS). Secondly, we assessed whether the investigators analyzed the incidents to discover contributing and etiologic factors and whether they applied a system approach. A system approach is defined as an approach which concentrates on the care system and on the conditions under which individuals work and which tries to build defenses on a system level to avert errors or mitigate their effects. [16] The options in assessing the IRSs for applying a system approach were threefold: Firstly, an explicit system approach was employed and the focus was on underlying (system) factors contributing to errors and incidents. Secondly, a system approach was not explicitly mentioned, but contributing or etiologic factors were reported. Thirdly, no system approach or contributing or etiologic factors were reported.

We also assessed to what extent the four phases of the iterative loop were covered by the IRS. These were (I) data input (II) data collection, (III) data analysis and (IV) feedback. [7]

Within these four phases of the iterative loop, we assessed which items of the WHO checklist were covered (Table 1). In addition to the WHO Draft Guidelines for Adverse Event Reporting and Learning Systems we specifically analyzed the way implementation was described in the different studies. After developing the data input and data collection it is important that the IRS will be incorporated in daily practice. Encouraging healthcare professionals to report critical incidents in daily practice can be accomplished by a comprehensive approach: a solid and extensive implementation phase of the IRS including continuous education with respect to the recognition and reporting of incidents.

Study Quality

To rate the quality of the included studies we used a modified 11 point checklist for cohort and qualitative studies available by the Cochrane Collaboration. [17] Scores can range from zero to 11. Higher scores refer to better quality. Description of the used parameters can be found in Appendix A.

Table 1. Data extraction tool

Phases iterative loop	Description	WHO checklist items
Data input	This refers to the information which is needed to enhance a learning culture.	Voluntary or mandatory reporting Non-punitive Confidential Independent
Data collection	This refers to the process of reporting: who files the reports and how physicians, nurses or other healthcare professionals can report incidents.	What is reported Who can report How can one report
Implementation	This refers to the process of implementation of an IRS in daily practice.	-
Data analysis	This refers to the classification and analysis of incidents to understand the underlying clinical circumstances and system causes	Approach to classification Approach to analysis System oriented Expert Analysis Timely
Feedback	Feedback is to learn from mistakes and to improve patient safety in the future.	Feedback Follow-up

Data extraction tool. In addition to the criteria given in the WHO Draft Guidelines for Adverse Reporting and Learning Systems, we added one item 'implementation'. To incorporate and IRS in daily practice it is important the implementation process is described.

Results

The electronic search strategy generated 2098 citations. Based on title and abstract, the authors reviewed 58 articles. Twenty-three studies did not meet the inclusion criteria [4,18-39] (Figure 1). After checking reference lists of the included studies, one additional article was included. [40] Thirty six articles were included in the final analysis. [40-72]

The 36 studies described 23 different instruments for collecting and analyzing incidents.

Fourteen IRSs were specifically developed for the ICU [41-43,46-51,53,55,56,58,61-64,66,67,69,71-75] the other nine were general IRS developed for any hospital ward and were applied on the ICU. [18,40,44,45,52,54,57,59,60,65,68,76] While most studies were single center studies, nine represented large national or international projects to standardize incident reporting: the University of Missouri Health Care Patient Safety Network System (MUHC PSN) [59], Medication errors reporting program (MEDMARX) [57], Australian Patient Safety Foundation (APSF) [52], National Patient Safety Agency (NPSA) [65,68,76], European Society of Intensive Care Medicine – Sentinel Events Evaluation (ESICM-SEE) [69,71], Australian Incident Monitoring Study in the Intensive Care Unit (AIMS-ICU) [41-43,47], Safety Action Focus Everyone – reporting form (SAFE-reporting form) [53,56,61,64,66], ICU Safety Reporting System (ICUSRS) [55,62,63,67] and Safety and Risk in Critical Patient (SYREC). [74] (Table 1 and 2, Appendix B and C).

The median study quality score was 8.5 (IQR 7-9.5) for studies based on general IRSs and 9 (IQR 7 – 9.5) for ICU-specific IRSs is presented in Appendix A.

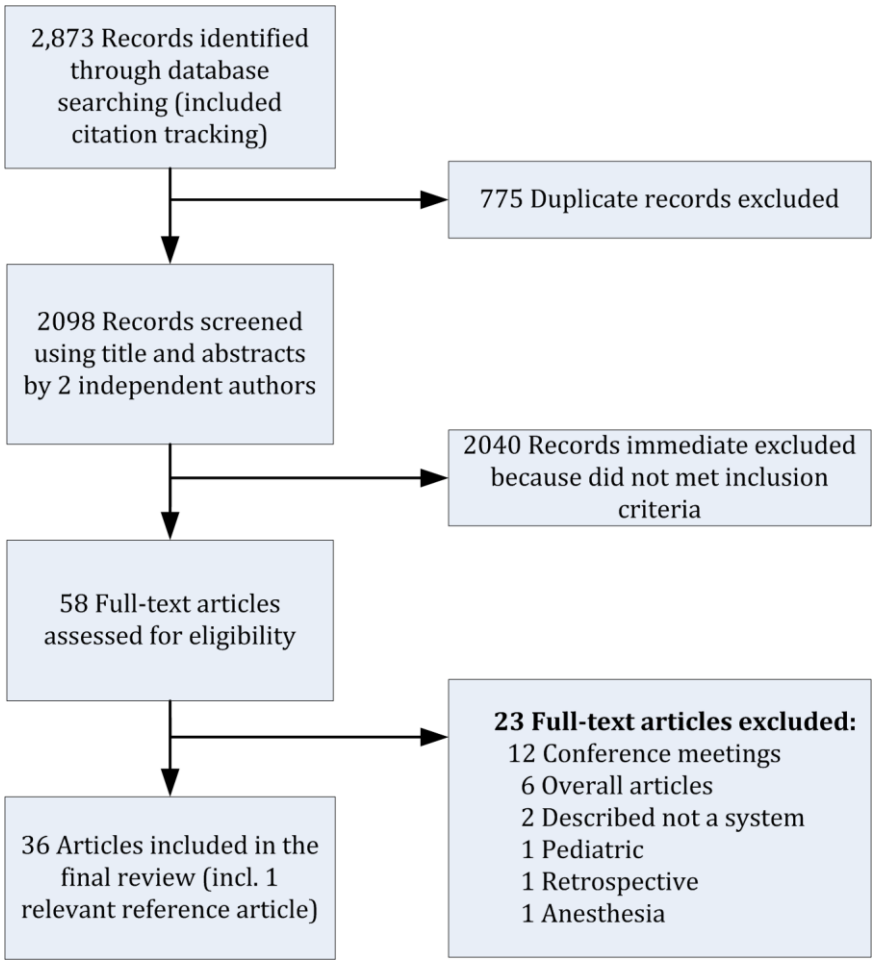

Figure 1. Study selection flow diagram

Comparing different incident reporting systems using the WHO checklist criteria

IRSs included different aspects of the criteria described in the WHO checklist (i.e. data input, data collection, data analysis and feedback) but none of the IRSs completely fulfilled all the criteria. Aspects such as approach to analysis, improvement measures and confidentiality regarding patient or reporter were described in 16 of the included articles. (Table 2 and 3) With respect to the four phases it was apparent that the fourth, and most important phase, the feedback phase, i.e. feedback of the safety information, formulation of improvement measures, and feedback and dissemination of the lessons learned and improvement measures, was described in only 14 articles.

Data input

Description of the way data input is organized in the different reporting systems is given in table 2 and 3. The following aspects are important in this phase: Is reporting *voluntary*, *non-punitive*, *set up to learn* or *imposed by an independent external regulatory authority*? According to the WHO guideline the purpose of an incident reporting system spans a spectrum of specific aims. At one end of the spectrum the focus is on learning within the own organization. At the other end is the IRS imposed by external regulatory agencies to ensure public accountability. Interestingly, all studies reported that the IRS was independent of an external authority (such as the health ministry). Furthermore, all studies reported that they were non-punitive and that physicians and nurses could report on a voluntary basis. The majority of the ICU-specific IRSs (23/25) [41-43,46-49,51,53,55,56,58,61-64,66,69,71-75] guaranteed anonymity with respect to the reporter compared to 7/11 [40,45,52,54,57,59,65] of the general IRSs. Anonymity with respect to patients was guaranteed in 15/25 [24,42,43,46,47,51,55,58,62,63,69,71,73-75] ICU-specific IRSs compared to 4/11 [40,52,57,65] general IRSs. None of the IRSs revealed identities of patients or reporters to external organizations.

Data collection

All studies differed with respect to the definition of incident, error or complication, and large variation was observed in the use of these terms. Most often, incidents rather than errors were studied (30/36). Only for medication related problems the focus was on errors. [44,45,57,60,71,73] Incidents collected by independent observers were mostly incidents related to airway management, mechanical ventilation and patient management (e.g. lack of documentation, incorrect patient position). Self-reported incidents by medical staff were mostly related to catheter, drain, tube and medication. Incidents found by checking medical charts by an independent physician and nurse were mainly events with substantial patient harm (e.g. sepsis, postoperative pneumonia, premature discharge). [43]

Table 2. Assessment of the WHO checklist criteria of the General IRSs

		Data input[‡]	**Data Collection**				**Implementation**	**Data Analysis**					**Feedback**	
Acronym[1]	Author Year (ref)	Confidentiality guaranteed for[2]:	Process of reporting				Formal implementation plan	Approach classification	Approach to analysis [4]	System oriented[5]	Expert Analysis	Timely	Feedback given to reporters	Follow-up
			What is reported	Who can report[3]	Structured form (S), open questions (O)	Electronic or paper		Classification by event type or causation		Recommendations focuses on changes in systems, process, products	Reports are evaluated by experts	Reports are analyzed promptly		Agency that receives reports is capable of disseminating recommendations
MUHC PSN	Kivlahan 2002 [59]	R,O	Incident	P,N OH	S,O	Electronic	+	Event	1,3 (-)	+/-	+	+	Monthly	-
MEDMARX	Kane-Gill 2010 [57]	P,R,O	Error	P,N Ph	S,O	Electronic	-	Event Causation	1,2,3 (A)	+/-	+	-	-	+
APSF	Graf 2005 [52]	P,R,O	Incident & Error	P,N OH	S,O	Paper	+	Event Causation	1,2,3 (A)	+/-	+	weekly	-	+
NPSA	Parke 2003 [65]	P,R,O	Incident	P,N	S,O	Paper	+	Event	1,3 (-)	+	+	-	Monthly news-letter	+
	Thomas 2008 [70]	O	Incident	P	S,O	Electronic	-	Event Causation	1,2,3 (A)	+/-	+	-	-	+
	Thomas 2009 [68]	O	Incident	P	S,O	Electronic Paper	-	Event	1,3 (-)	-	+	-	-	+
-	Wright 1991 [40]	P,R,O	Incident	P	S,O	Paper	-	Event Causation	1,2,3 (CF)	+	+	-	Monthly	-
-	Hart 1994 [54]	R,O	Incident	P,N	S,O	Paper	+	Event Causation	1,2,3 (CF)	+/-	+	-	Monthly	+
-	Kopp 2006 [60]	O	Incident & Error	Ph	S	Paper	+	Event Causation	1,2,3 (A)	+	+	-	-	+
-	Benkirane 2009 [44]	O	Incident & Error	P,Ph OH	S,O	Paper	-	Event Causation	1,2,3 (CF/A)	+	+	-	Every 2 weeks	+
-	Bohomol 2009 [45]	R,O	Incident	P,N Ph	NR	Paper	+	Event Causation	1,2,3 (A)	+/-	+	-	-	-

[‡] All general IRSs were voluntary, non-punitive and were set up to promote learning from incidents and were assessed independent of any authority with the power to punish the reporter or hospital.

[1] Acronym: MUHC PSN = University of Missouri Health Care Patient Safety Network System, MEDMARX = Medication errors reporting program, APSF = Australian Patient Safety Foundation, NPSA = National Patient Safety Agency [2] P =patient, R=reporter, O=organization, [3] P= Physician, N = Nurse, Ph=Pharmacist, OH=Other health professional [4] Approach to analysis; 1. Summaries and descriptions, 2. Causal analysis, 3. Systems analysis, A= Aetologic factors, CF= Contributing factors, [5] System oriented; + = Yes, explicitly, +/- = Yes, inexplicitly, - = No.

ICU-specific IRSs detect and report more ICU-specific incidents (e.g. airway-, dialysis-, IABP-, ICP monitoring-related incidents). [41-43,46,48-50,58,62,67]

In the majority of studies (28 of 36) both physicians and nurses could report. Reporting by physicians varied from 4 to 83% in different studies and by nurses from 6 to 80%. In 12 studies nurses [41,42,50,53,56,59,61-63,66,67,75] were more likely to report incidents while in three studies most incidents were reported by physicians. [47,48,52] Furthermore, nurses most often reported errors and risky situations, whereas physicians mostly reported incidents that actually harmed patients. [66] The number of reported incidents by physicians increased when reporting was made easy, clear, and safe. [43,48,53,56,66] Various methods were used for submitting incident reports. A form with both structured and non-structured questions was most commonly used (28/36 studies). [40-44,47-59,61-66,68,70,72,75] Five studies used a structured form with predefined incidents. [46,60,69,71,73] Registration of incidents was done electronically in nine of 36 studies [55,57,59,62,63,67,68,70,72], as opposed to paper-based registration in 27 of 36. [40-54,56,58,60,61,64-66,69,71,73-75] Electronic registration was often part of nation-wide or international initiatives (Table 2 and 3). [43,62]

Implementation

Implementation was described in 6 of 11 [45,52,54,59,60,65] general IRSs and in 21 of 25 ICU-specific IRSs. [24,42,43,47-51,55,56,61-64,66,67,69,71,72,74,75] The intensity of the implementation measures differed largely, ranging from a single introductory meeting to multiple training sessions and multidisciplinary meetings. For example the organization that used the AIMS-ICU IRS applied an extensive implementation with a multidisciplinary team approach, tutorial sessions, and regular group discussions to debate the incidents and possible preventive strategies (Table 2 and 3, Appendix D and E).

Data analysis

Nine studies described how soon incidents were analyzed after they were reported. [46,47,52,55,56,59,64,67,75] The time in these studies varied from within 24 hours for urgent incidents to within one month. In all studies, classification of incidents was used to present the data. The approach to classification was by event type in 15 studies [48-51,53,56,58,59,64-66,68,69,73,74] and by event type and causation in 21 studies. [40-47,52,54,55,57,60-63,67,70-72,75]

Contributing or etiologic factors were determined in 22 studies (58%). [40-47,50,52,54,55,57,60-63,67-69,71,75] In 20 studies incidents were analyzed with a system approach. [40-47,52,54,55,57,60-63,67,68,71,75]

Table 3. Assessment of the WHO checklist criteria of the ICU-specific IRSs

		Data input[‡]	**Data collection**				**Implementation**	**Data Analysis**					**Feedback**	
Acronym[1]	Author Year (ref)	Confidentiallity guaranteed for[2]:	Proces of reporting				Formal implementation plan	Approach classification	Approach to analysis [4]	System oriented[5]	Expert Analysis	Timely	Feedback given to reporters	Follow-up
			What is reported	Who can report[3]	Structured form (S), open questions (O)	Electronic or paper		Classification by event type or causation		Recommendations focuses on changes in systems, process, products	Reports are evaluated by experts	Reports are analyzed promptly		Agency that receives reports is capable of disseminating recommendations
ESICM SEE	Valentin 2006 [69]	P,R,O	Incident	P,N	S	Paper	+	Event	1,2,3 (A)	-	-	-	-	-
	Valentin 2009 [71]	P,R,O	Error	P,N	S	Paper	+	Event Causation	1,2,3 (CF)	+/-	+	-	-	-
AIMS-ICU	Beckmann 1996 [42]	P,R,O	Incident	P,N OH	S,O	Paper	+	Event Causation	1,2,3 (CF)	+	+	-	Discus-sion of incidents	-
	Beckmann 1996 [41]	P,R,O	Incident	P,N OH	S,O	Paper	+	Event Causation	1,2,3 (CF/A)	+/-	+	-	Regular staff meeting	-
	Buckley 1997 [47]	P,R,O	Incident	P,N	S,O	Paper	+	Event Causation	1,2,3 (CF/A)	+/-	-	+/-	3 montlhy meetings	+
	Beckmann 2003 [43]	P,R,O	Incident	P,N	S,O	Paper	+	Event Causation	1,2,3 (CF/A)	+	+	-	-	-
SAFE-repor-ting form	Osmon 2004 [64]	R:optional,O	Incident	P,N Ph,OH	S,O	Paper	+	Event	1,3 (-)	-	+	Monthly	-	-
	Nast 2005 [61]	R:optional,O	Incident	P,N OH	S,O	Paper	+	Event Causation	1,2,3 (A)	+/-	+	-	-	-
	Schuerer 2006 [66]	R:optional,O	Incident	P,N Ph,OH	S,O	Paper	+	Event	1,3 (-)	-	+	-	-	+
	Harris 2007 [53]	R:optional,O	Incident	P,N OH	S,O	Paper	-	Event	1,3 (-)	-	+	-	-	-
	Ilan 2011 [56]	R:optional,O	Incident	P,N Ph,OH	S,O	Paper	+	Event	1,3 (-)	-	-	- (only urgent)	Monthly meetings Bimonthly news-letter	+
ICUSRS	Needham 2004 [62]	P,R,O	Incident	P,N	S,O	Electronic	+	Event Causation	1,2,3 (CF)	+	+	-	-	-
	Needham 2005 [63]	P,R,O	Incident	P,N	S,O	Electronic	+	Event Causation	1,2,3 (A)	+	+	-	-	-
	Holz-mueller 2005 [55]	P,R,O	Incident	P,N Ph,OH	S,O	Electronic	+	Event Causation	1,2,3 (CF)	+	+	Monthly	Monthly report Quarterly news-letter	+

Table 3. (cont.)

		Data input[ǂ]	Data collection				Implementation	Data Analysis					Feedback	
Acronym[1]	Author Year (ref)	Confidentiality guaranteed for[2]:	Proces of reporting				Formal implementation plan	Approach classification	Approach to analysis [4]	System oriented[5]	Expert Analysis	Timely	Feedback given to reporters	Follow-up
			What is reported	Who can report[3]	Structured form (S), open questions (O)	Electronic or paper		Classification by event type or causation		Recommendations focuses on changes in systems, process, products	Reports are evaluated by experts	Reports are analyzed promptly		Agency that receives reports is capable of disseminating recommendations
	Sinopoli 2007 [67]	O	Incident	P,N OH	NR	Electronic	+	Event Causation	1,2,3 (CF)	+	+	+		-
SYREC	Merino 2012 [74]	P,R,O	Incident	P,N	NR	Paper	+	Event	1,2 (-)	-	+	-	-	-
-	Flaatten 1999 [51]	P,R,O	Error	P,N OH	S,O	Paper	+	Event	1,3 (-)	-	+	-	-	-
-	Bracco 2001 [46]	P,R,O	Incident	P	S	Paper	ND	Event Causation	1,2,3 (A)	+/-	+	< 24h	-	-
-	Donchin 2003 [50]	O	Error	P,N	S,O	Paper	+	Event	1,2,3 (A)	-	+	-	-	-
-	Capuzzo 2005 [48]	R:optional,O	Incident	P,N	S,O	Paper	+	Event	1,3 (-)	-	-	-	Weekly discussion	-
-	v.d. Veer 2006 [72]	R,O	Incident	P,N	S,O	Electronic	+	Event Causation	1,2,3 (-)	+	-	-	Monthly feedback	-
-	Chacko 2007 [49]	R,O	Incident	P,N	S,O	Paper	+	Event	1,3 (-)	+	+	-	Monthly discussions	+
-	Kaur 2008 [58]	P,R,O	Incident	P	S,O	Paper	-	Event	1,3 (-)	-	+	-	-	-
-	Agalu 2012 [73]	P,R,O	Error	N,Ph	S	Paper	-	Event	1,3 (-)	-	+	-	-	-
-	Pagnamento 2012 [75]	P,R,O	Incident	P, N, OH	S,O	Paper	+	Event Causation	1,2,3 (CF)	+	+	-	Structural meeting with staff	+

[ǂ] All ICU specific IRSs were voluntary, non-punitive and were set up to promote learning from incidents and were assessed independent of any authority with the power to punish the reporter or hospital.

[1] Acronym: MUHC PSN = University of Missouri Health Care Patient Safety Network System, MEDMARX = Medication errors reporting program, APSF = Australian Patient Safety Foundation, NPSA = National Patient Safety Agency [2] P =patient, R=reporter, O=organization, [3] P= Physician, N = Nurse, Ph=Pharmacist, OH=Other health professional [4] Approach to analysis; 1. Summaries and descriptions, 2. Causal analysis, 3. Systems analysis, A= Aetologic factors, CF= Contributing factors, [5] System oriented; + = Yes, explicitly, +/- = Yes, inexplicitly, - = No.

Recommendations derived from analyzing incidents should focus on changes in the care system, clinical processes or outcomes rather than being targeted at individual performances. Eight of the 11 general IRSs studies [40,44,45,52,54,57,60,70] reported a system approach by uncovering contributing or etiologic factors compared to 12/25 ICU-specific IRSs studies. [41-43,46,47,55,61-63,67,71,75] The most frequently reported contributing factors were lack of communication, neglect of protocol or procedure, and lack of (medication) knowledge (Table 2 and 3).

Feedback

Twenty two studies (58%) did not report feedback. For the studies that did, large variation existed in the intensity of feedback after analysis of incidents. [40-42,44,47-49,54-56,59,65,72,75] It varied from daily feedback to once per month (10/14). [40,47-49,54-56,59,65,72] Written summaries [47], newsletters [55,56,65] and discussion of incidents [24,42,48,49,75] were used as feedback in 5/14 studies. Only fourteen of the 36 studies described which improvement measures and recommendations were made. [44,47,49,52,54-57,60,65,66,68,70,75]

It was impossible to establish a quantitative relationship between the intensity of the implementation process or feedback process and the number of reported incidents or formulation of improvement measures. The only signal that can be distinguished is that in the studies that formulated and reported improvement measures, a multidisciplinary implementation process and/or regular feedback meetings and report sessions had been part of the incident registration process (Table 2 and 3).

Which improvement measures were taken?

According to the WHO guideline the most important aim of an IRS is to formulate improvement measures and recommendation for system changes. The improvement measures and recommendations described by the 14 studies can be categorised in four categories: Technology, Organization, Communication and Medication. To prevent incidents in the category Technology recommendations were for example to use barcoding for perfusor pumps [57,60], electronic prescribing of medication [70,75] and formal introduction of new equipment such as monitors with more reliable oximetry, new models of perfusor and infusion pumps and assist devices. [47,49] Recommendations to reduce incidents related to Organization mainly pertained to adjustments to and introduction of (new) protocols. [44,47,49,52,54,60] Recommendations to enhance Communication were for example: face-to-face handover between departments [70], and regular meetings with the pharmacist [44,60,75], radiologist and microbiologist on the ICU. [47] To prevent Medication errors the use of colour-coded labels [49,75], use of simple prescribing orders, and education and feedback to physicians were introduced (Table 4). [44,70]

Table 4. Improvement measures and recommendations

	Category	Examples of improvement
Technology	Perfusion or infusion pump	CPOE [57,60] Advanced infusion pumps [57,70,60] Bar coding [57,60] Electronic prescribing [70,74]
	Monitoring	Introduction new monitor with more reliable oximetry [49] Identical models of perfusor & infusion pumps [74]
	Faulty/unsuitable equipment	Laryngoscopes [47] IABP [47]
Organization	Protocol	Compiled in binders: Venous thromboembolism prophylaxis [52] Stress ulcer prophylaxis [52] Insulin algorithm [52] Lung protective ventilation [52] Early goal directed therapy [52] Sedation scale [52] Protocol changes [54] Standardizing therapeutic protocols [44] Checking ventilation setting and tracheal tube care [44] Memory cards contain abbreviated forms of standards, guidelines & algorithms [52] Sedation policy protocolised [49] Capnography was mandatory for all tracheostomies and intubations [49] Inspection of airway devices for position, patency and cuff pressure was adopted as a new nursing policy [49]
	Protocol development	Sedative/analgesics in mechanically ventilated patients [60] Pain control policies [60] Administration practices of medications with tube feedings [60] Required at least four staff members for moving and repositioning of patients [49]
	Communication	Communication skills was highlighted during regular meetings. Poor communication discussed daily with affected team members [52] Using good face-to-face handover with written information and correct labelling of infusions [70] Transfer of care form was designed to aid in communication between operation theatre and SICU [66]
	Incident reporting system	More detailed analysis of human error (for example subdivided into planning, execution and surveillance [65] Provide better classification and identification of the areas in which improvements in patient care could be made [68] Web based reporting system designed and access from any computer (even from home) [55]
	Personnel	Pharmacist in ICU [60,44,74] Reducing medical junior's work hours [44] Senior nursing numbers were expanded and their role redefined with increased responsibility for bedside teaching and care of patients [47] Clinical nurse specialist was appointed to provide an educational programme for nursing staff at three levels a. introductory course for newcomers b. intermediate course for experienced ICU nurses c. advanced diploma course for experienced nurses [47]
	Management	Patient regular meetings with radiologist and microbiologist were introduced [47] System level changes [56]
	Education	Bedside teaching tutorials [47] Academic meetings [47]

Table 4. (cont.)

	Category	Examples of improvement
Medication	Perfusion or infusion pump	Clear and appropriate colour coded labelling of syringes and lines with labels that are already commercially available [70,74] Standardised colour coding of syringes [49]
	Prescribing	As simple as possible [70] Prescribers should be given educations and feedback [70] Access to drug information and advice from clinical pharmacist [70] Systematic checking of the junior's prescription [44]

Discussion

In this review, we systematically studied peer-reviewed incident reporting systems applied in the adult ICU. The goal was to assess to what extent the different incident reporting systems complied with the WHO checklist and to describe to what extent the IRSs executed the four aspects of the iterative loop of quality improvement strategies. Furthermore, we studied which improvement measures were actually achieved using the different IRSs.

A total of 23 different IRSs have been used so far. All IRSs used different definitions for incidents, errors and complications and were applied in different settings making direct comparisons difficult. Thus it is not possible to establish an 'optimal' IRS to choose for use in daily practice. We found that the two first phases of the iterative loop, data input and data collection are well established. Not much attention is given to the third phase (e.g. analysis of incidents and eliciting contributing factors and causes) and the fourth phase (e.g. feedback to the workplace).

We included only peer-reviewed IRSs but we are aware of the fact that there are more incident reporting systems commercially available. We focused on peer-reviewed studies of IRSs because a full description of the used IRSs was available, different aspects of the IRS were critically evaluated and we were able to check the consistency of items with the WHO Draft Guidelines for Adverse Event Reporting and Learning Systems. A complete list of commercially available incident reporting systems would be helpful, but we were not able to find such an overview on the internet.

Some IRSs were specifically developed for ICU patients while others were used in all in-hospital settings. It seems logical to assume that ICU-specific IRSs are best suited for incident reporting in ICU patients. We found indeed that ICU-specific IRSs detect and report more ICU-specific incidents. However, since the ICU period is often a small circumscribed period during hospital stay, incidents may be closely related to events occurring before and after ICU stay. Therefore, to obtain maximum information on incidents and contributing factors, we prefer a general IRS which pays attention to incidents occurring in all phases of the hospital stay of a patient. An integrated approach

is necessary to establish the chronology and the details of the events leading to the incident. [7] The three factors that might be most important to promote incident reporting by health care professionals, e.g. voluntary and non-punitive reporting and confidentiality, were guaranteed in nearly all studies. [9] It is a challenging aspect for risk management systems to ensure confidentiality on the one hand, while on the other hand maintaining a dialogue between the risk management team and local staff to ensure the opportunity to obtain additional information on the incident. [10] Voluntary reporting may lead to some underreporting of incidents, but as the aim of incident reporting is to learn from errors and incidents rather than to estimate the absolute number of incidents happening, the risk of underreporting in a voluntary system is a minor issue.

The main goal of incident reporting is to analyze incidents and to formulate and disseminate recommendations for a system change. [15,77] The analysis of incidents offers the opportunity to uncover process- and structure- related factors. [78] Underlying factors should be analyzed with a standardized terminology and classification taxonomy. This makes it easier to file patient safety reports and to conduct root cause analysis in a consistent way. [79] We believe that insight in these factors, e.g. understanding why incidents happened, increases the chance of finding successful measures to improve patient safety and quality of care. [80]

Effective feedback from incident reporting systems is essential for organizations to learn from failure in the delivery of care and to promote future reporting. Safety feedback must share to the medical staff specific vulnerabilities in the health care system to raise awareness and must include timely corrective actions to improve safety. [10] According to Benn et al. five modes of feedback for incident reporting systems can be established namely: (1) bounce back (information to the reporter), (2) rapid response (action within local work system), (3) raise risk awareness (information to all front-line personnel), (4) inform staff of actions taken (information to reporter and wider reporting community), and (5) improve work systems safety (action within local work systems).

In our review we established that for IRSs used on the ICU the safety-feedback loop is not closed as little is reported about feedback and large variation exists in the manner and intensity of feedback. If feedback was described in the IRSs most of the time this was related to giving cyclic aggregated information on incidents to front-line personnel in meetings or newsletters, where incidents and sometimes possible preventive measures were discussed. Incidentally feedback consisted of improvement measures that were formulated or taken. None of the systems gave direct and timely information to the reporter which can be easily explained by the fact that most of the incident registration systems were paper-based instead of electronic reporting. To improve incident reporting one must be aware that the safety loop is an ongoing cyclical process of

functional stages involving (a) report, receipt, screening and archiving of incidents, (b) analysis of trends in aggregated incidents and root cause analysis of specific incidents and, (c) dissemination of information on vulnerabilities and development and implementation of preventive measures and system improvements. It is important for healthcare organizations to realize that all modes of feedback as described by Benn et al should be continuously applied. Although feedback is in the strict sense not a direct feature of an IRS itself, it is a very essential component of its successful implementation. After the feedback phase it is important that success of the installed improvement measures will be monitored. The IRS can be used to monitor the reported incidents related to the improvement measures. However, none of the studies studied the effectiveness of the improvement measures on the quality of care and reduction of the occurrence of incidents.

If healthcare professionals perceive that their leaders do not take action based upon submitted incidents, this will lead to apathy among physician and nurses and reluctance to report incidents. [10] Furthermore, healthcare workers can only learn from incidents, if feedback about these incidents with contributing factors is offered to them.

Nurses generally reported more incidents related to risky situations, compared to physicians who reported more incidents related to actual harm. The reasons for this are not clear but it has been suggested that factors such as shame, fear of being branded incompetent and of legal reprisal that may be attached to incidents that actually harmed a patient are important. [81] We found that the number of reported incidents by physicians increased when reporting was made easy, clear, and especially safe. Attention should be paid to develop a reporting form that takes little time to complete. From the literature it was not possible to provide an overview of the fill in time of the reporting form.

Large variations existed in the use and definition of terms such as incidents, errors, and events. This may lead to interpretation bias on the reporter level and it also makes studies difficult to compare. To optimize and facilitate incident reporting it is essential to provide the reporters with a clear definition. The definition by Beckmann [42] is most often advocated: “an incident is any event or outcome which could have reduced, or did reduce the safety margin for the patient. It may or may not have been preventable and may or may not have involved an error on the part of the health care team”.

The reporting of critical incidents in daily practice can be accomplished by a comprehensive approach: a solid and extensive implementation phase of the IRS, continuous education with respect to the recognition and report of incidents. The latter has to be made clear and easy. Regular adjustments of the IRS based on the experiences of the reporters and reviewers, structural feedback on reported incidents and lessons learned (preferably in multidisciplinary meetings), and specific attention for quality improvement programs based on the lessons learned. [82] And first and foremost, a

successful IRS demands a safe reporting climate, awareness of the hazards to patient safety, and local leadership. [43,48,53,56,66]

In our review some limitations should be mentioned. 1) Data of the included studies are of qualitative nature and it was not possible to quantify the data. Due to this, it was not possible to assess quantitative relationships between the different characteristics of the IRSs and the outcomes of the IRSs. 2) The used definitions and terms such as incident and error of the study varied largely between the studies. Therefore, it is difficult to compare the studies and give a definitive judgment which definition should be used in practice. 3) Studies included in this review differed in their methodological quality. 4) There is no objective evidence whether reporting systems lead to improvement quality of care and improved outcome. Finally, few studies directly compared two different IRSs. Future research should focus on whether IRSs, through feedback and formulation of improvement measures, actually lead to improved quality of care and better patient outcome. Secondly, future research should focus on the direct comparison of two different incident reporting methods to obtain valuable information of success factors and to facilitate the choice between different IRSs.

Conclusion

Nearly all IRSs used different definitions for incident, error or complications thus no single definition could be extracted. None of the IRSs completely fulfilled the WHO checklist criteria. With respect to the iterative loop, data input and data collection is well established but much less attention is given to the analysis of incidents and to feedback of information and corrective actions. This resulted in an administrative reporting system, rather than the much desired instrument to change clinical practice. The phases of data analysis, formulation of improvement measures and feedback needs to be given more attention before an IRS can effectively contribute to improve patient safety and quality of care. Healthcare organizations need to focus on trained experts who particularly can support feedback of information and improvement measures and assist in the implementation of improvement measures and the follow-up of the effects of the measures.

Acknowledgements

The authors acknowledge Jan Schoones, librarian, of the Walaeus library of Leiden University Medical Center for his assistance.

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Appendix A. Methodological Assessment

We established the following parameters of quality:
(1) Are the relevance and goal of the study clearly described?
(2) Is the study group defined?
(3) Is the number of incidents reported?
(4) Is an incidence/error defined in advance?
(5) Are the data adequately collected?
(6) Is a system approach applied to categorize collected incidents?
(7) Are circumscribed methods used to establish contributing and etiologic factors?
(8) Are the outcome and conclusions of the study clearly described?
(9) Is the implementation clearly described?
(10) Is the method (electronic vs. paper) clearly described?
(11) Are the etiologic factors determined?

Appendix A. Methodological Assessment

Acronym	Author Year (ref)	Relevance & goal	Popula-tion	n. of incidents	Data adequately collected	System Approach	Method establish Etiology	Outcome, conclusion	Definition incident	Implemen-tation	Method collection incidents	Etiology factors	Total score
General IRS													
MUHC PSN	Kivlahan 2002 [59]	1	1	1	1	0,5	0	0	1	1	1	0	7,5
Medmarx	Kane-Gill 2010 [57]	1	1	1	1	0,5	0	1	1	0	1	1	8,5
APSF	Graf 2005 [52]	1	1	1	1	0,5	0	1	1	1	1	1	9,5
NPSA	Parke 2003 [65]	0	0	1	1	1	0	0	1	1	1	0	6
	Thomas 2008 [70]	1	0	1	1	0	0	1	1	0	1	1	7
	Thomas 2009 [68]	1	0	1	1	0	0	1	1	0	1	0	6
-	Wright 1991 [40]	1	0	1	1	1	1	0	1	0	1	1	8
	Hart 1994 [54]	1	1	1	1	0,5	0	1	1	1	1	1	9,5
	Kopp 2006 [60]	1	1	1	1	1	0	1	1	1	1	1	10
	Benkirane 2009 [44]	1	1	1	1	1	1	1	1	0	1	1	10
	Bohomol 2009 [45]	1	1	1	1	0,5	0	1	1	1	1	1	9,5
ICU-Specific IRS													
ESICM SEE	Valentin 2006 [69]	1	1	1	1	0	0	1	1	1	1	1	9
	Valentin 2009 [71]	1	1	1	1	0,5	0	1	1	1	1	1	9,5
AIMS-ICU	Beckmann 1996 [42]	1	1	1	1	0,5	0	1	1	1	1	1	9,5
	Beckmann 1996 [41]	1	1	1	1	0,5	0	1	1	1	1	1	9,5
	Buckley 1997 [47]	1	1	1	1	0,5	0	1	1	1	1	1	9,5
	Beckmann 2003 [43]	1	1	1	1	1	0	1	1	0	1	1	9
SAFE	Osmon 2004 [64]	1	1	1	1	0	0	1	0	1	1	0	7
reporting	Nast 2005 [61]	1	1	1	1	0,5	1	1	1	1	1	1	10,5
form	Schuerer 2006 [66]	1	1	1	1	0	0	1	0	1	1	0	7
	Harris 2007 [53]	1	1	1	1	0	0	1	0	1	1	0	7
	Ilan 2011 [56]	1	1	1	1	0	0	1	0	1	1	0	7
ICUSRS	Needham 2004 [62]	1	0	1	1	1	0	1	1	1	1	1	9
	Needham 2005 [63]	1	0	1	1	1	0	1	1	1	1	1	9
	Holzmueller 2005 [55]	1	1	1	1	1	0	0	1	1	1	1	10
	Sinopoli 2007 [67]	1	1	1	1	1	0	1	1	1	1	1	10
Syrrec	Merino 2012 [74]	1	1	1	1	0	0	1	1	1	1	0	8
-	Flaatten 1999 [51]	1	1	1	1	0	0	1	1	1	1	0	8
	Bracco 2001 [46]	1	1	1	1	0,5	0	1	0	0	1	1	7,5
	Donchin 2003 [50]	1	1	1	1	0	0	0	1	1	1	1	8
	Capuzzo 2005 [48]	1	1	1	1	0	0	1	1	1	1	0	8
	v.d. Veer 2006 [72]	1	0	1	1	1	0	0	1	1	1	0	7
	Chacko 2007 [49]	1	1	1	1	1	0	1	1	1	1	0	9
	Kaur 2008 [58]	1	1	1	1	0	0	1	1	0	1	0	7
	Agalu 2012 [73]	1	1	1	1	0	0	1	0	0	1	0	6
	Pagnamenta 2012 [75]	1	1	1	1	1	0	1	1	1	1	1	10

Acronym: MUHC PSN = University of Missouri Health Care Patient Safety Network System, MEDMARX = Medication errors reporting program, APSF = Australian Patient Safety Foundation, NPSA = National Patient Safety Agency. ESICM-SEE = European Society of Intensive Care Medicine – Sentinel Events Evaluation, AIMS-ICU = Australian Incident Monitoring Study in the Intensive Care Unit, SAFE-reporting form = Safety Action Focus Everyone – reporting form, ICUSRS = ICU Safety Reporting System, UHC PSN = University of Missouri Health Care Patient Safety Network System, MEDMARX = Medication errors reporting program, APSF = Australian Patient Safety Foundation, NPSA = National Patient Safety Agency.

Appendix B. Study design - General Incident Reporting System

Acronym[1]	Author Year (ref)	Study period Year start (months)	Hospitals [2]	Adult	ICUpopulation[3]	Multicenter (n)	Aim of the study
MUHC PSN	Kivlahan 2002 [59]	2001(4) 2002 (3)	Teaching	Yes	C	No	To create and implement a comprehensive registry of adverse events.
MEDMARX	Kane-Gill 2010 [57]	2001(54)	Teaching	Yes	C	No	Determine if there was a need for Intensive Care Unit (ICU) -specific surveillance systems based on difference in Medical Errors between Intensive Care Units (ICUs) and General Care Units (GCUs). Compare voluntarily reported Medical error data including type, cause, outcomes for Medical Errors occurring in the Intensive Care Unit with Medical Errors occurring in General Care Units.
APSF	Graf 2005 [52]	2002 (3)	Teaching	Yes	M	No	To reveal the frequency, type, consequences, and associations of errors and incidents in a medical Intensive Care Unit (ICU).
NPSA	Parke 2003 [65]	2001 (24)	Non-teaching	Yes	ND	No	Not described
	Thomas 2008 [70]	2006 (7)	NHS Hospital	Yes	ND	Yes (141)	To identify and classify incidents associated with medication use in intensive care units and high dependency units and to suggest changes that could be made to improve medication safety
	Thomas 2009 [68]	2008 (3)	NHS Foundation	Yes	ND	Yes (141)	To review and re-classify incidents submitted to the NPSA from the location 'Intensive Care/High Dependency'. To develop a specialty specific reporting system for critical care that would be consistent with the NPSA reporting system, a better understanding of incidents submitted from critical care. To use the classification of submitted incidents to define areas of practice where efforts should be focused to improve patient care.
-	Wright 1991 [40]	ND (12)	Non-teaching	Yes	ND	No	We wondered whether the critical incident technique could be helpful in investigating mishaps in an intensive therapy unit.
-	Hart 1994 [54]	1991 (24)	Teaching	Yes	C	No	To delineate the nature and precipitating factors of incidents which had the potential to cause harm to our patients.
-	Kopp 2006 [60]	2003 (1/2) 16,5 days observation	Teaching	Yes	C	No	To determine the incident of medication errors, potential Adverse Drug Events, and actual Adverse Drug Events. To determine the preventability of these events. To evaluate system failures leading to their occurrence
-	Benkirane 2009 [44]	2007 (3)	Teaching	Yes and paediatric	C	Yes (2)	To assess the prevalence rate of Adverse Drug Events to determine those related to Medical Errors to develop prevention strategies
-	Bohomol 2009 [45]	2006 (1)	Teaching	Yes	C	No	To investigate the incidence types and causes of Medical Errors and the consequences for patients.

[1] Acronym: MUHC PSN = University of Missouri Health Care Patient Safety Network System, MEDMARX = Medication errors reporting program, APSF = Australian Patient Safety Foundation, NPSA = National Patient Safety Agency.

[2] Hospitals: Teaching=Academic/university/teaching/tertiary, Non-teaching=general and community .

[3] ICU-population: S=surgical, M=Medical, C= Combination, ND=Not described.

Appendix C. Study design - ICU-specific Incident reporting system

Acronym[1]	Author Year (ref)	Study period Year start (months)	Hospitals [2]	Adult	ICUpopulation [3]	Multicenter (n)	Aim of the study
ESICM SEE	Valentin 2006 [69]	2004 24 hours observation	280 ICU's aangesloten bij ESICM, 29 countries	Yes	C	Yes (205)	To study the prevalence of selected unintended events and to assess the impact of several Intensive Care Unit (ICU) - and patient-related factors, such as workload of medical personnel and severity of illness, on the frequency and types of selected unintended events.
	Valentin 2009 [71]	2007 (1 day)	ND	Yes	C	Yes (113)	We assessed the impact of parenteral medication errors and the outcome of patients exposed to such errors.
AIMS-ICU	Beckmann 1996 [42]	1993 (2) (Pilot)	Teaching Non-teaching	Yes	C	Yes (3)	To develop and evaluate a tool to systematically identify and analyze adverse events in the intensive care environment.
	Beckmann 1996 [41]	1993 (11)	Teaching Non-teaching	Yes	C	Yes (7)	Develop and evaluate a tool suitable for use at national level to systematically identify and analyze incidents in the intensive care environment.
	Buckley 1997 [47]	Unknown (36)	Teaching	Yes	C	No	To document the frequency of critical incidents in the Intensive Care Unit (ICU), to identify the causes of incidents and to develop preventative strategies so as to prevent recurrence of incidents thus decreasing possible morbidity and mortality.
	Beckmann 2003 [43]	1999 (2)	Teaching	Yes and pediatric	C	No	Examine and compare facilitated incident monitoring (FIM) and MCR (medical chart review) as methods to identify quality problems in intensive care that are amenable to quality improvement interventions.
SAFE reporting form	Osmon 2004 [64]	2002 (5)	Teaching	Yes	M	No	First, to describe the frequency and types of reported medical evens occurring in an intensive care unit setting. Second, to determine the impact of the reported medical events on patient outcomes.
	Nast 2005 [61]	ICU 2003 (12) PACU 2003 (7)	Teaching	Yes	S	No	To provide a mechanism for physicians to report medical errors, near misses, and risky situations. To provide new knowledge that would lead to improvements in patient safety.
	Schuerer 2006 [66]	2003 (9)	Teaching	Yes	S	No	Currently, It is unknown if different groups of health-care workers would have differential reporting rates using a written reporting system, and whether the simpler paper-based system might be used more than the electronic systems that have recently proliferated.
	Harris 2007 [53]	MICU 2002 (14) CTICU 2003 (12) SICU 2003 (10)	Teaching	Yes	C	No	Evaluates healthcare worker reporting for medical errors and patient safety events by two different methods (paper-based and computer-based) with three Intensive Care Unit environment.
	Ilan 2011 [56]	2008 (12)	Teaching	Yes	C	No	To increase reporting rates, enhance report analysis, and provide timely feedback and responsive action.
ICUSRS	Needham 2004 [62]	2002 (12)	Teaching	Yes and pediatric	M	Yes (18)	To describe the characteristics and patient harm of airway incidents To compare the contributing and limiting factors associated with airway incidents compared with all other non airway report within the ICUSRS.
	Needham 2005 [63]	2002 (12)	Teaching	Yes and pediatric	M	Yes (18)	To describe the characteristics of and patient harm associated with Line Tube Drain (LTD) incidents and to compare the contributing, limiting and preventive factors associated with LTD incidents with those of all other non-LTD incidents within the ICUSRS.

Appendix C. (cont.)

Acronym[1]	Author Year (ref)	Study period Year start (months)	Hospirals [2]	Adult	ICU population[3]	Multicenter (n)	Aim of the study
	Holzmueller 2005 [55]	2002 (12)	ND	Yes and pediatric	C	Yes (18)	To build a system staff would use, the ICUSRS study was also designed to collect as much information as possible about harmful or potentially harmful incidents in Intensive Care Units (ICUs) and to apply these data to improvement efforts in patient safety. To better understand contributions of structured versus text data for improving patient safety.
	Sinopoli 2007 [67]	2002 (24)	Teaching	Yes	C	Yes (19)	To compare these contributing, limiting, and preventive system factor associated with safety incidents for medical versus surgical patients in Intensive Care Units (ICUs) and to compare the characteristics and type of patient harm associated with these incidents.
SYREC	Merino 2012 [74]	2007 (24 hour observation)	Teaching Non-Teaching	Yes	C	Yes (76)	To estimate the incidence and characteristics of adverse events (AEs) and no-harm events (NHEs) in critically ill patients.
-	Flaatten 1999 [51]	1995 (13)	Teaching	Yes	C	No	To learn more about occurrence of errors in our unit in general. To investigate the relationship between the severity of the error and the consequences.
-	Bracco 2001 [46]	1995 (13)	Teaching	Yes	C	No	To evaluate the occurrence of critical incidents in an Intensive Care Unit (ICU) prospectively, focusing on incident due to human factors. To identify patients or situations at risk and to try to determine clinical and financial consequences of human related incidents.
-	Donchin 2003 [50]	1989 (4)	Teaching	Yes	C	No	To investigate the nature and causes of human errors in an active Intensive Care Unit (ICU) in an effort to develop a methodology to avoid or reduce error frequency and impact.
-	Capuzzo 2005 [48]	2003 (28 days)	Teaching	Yes	C	No	To compare the incidence and type of unintended events reported by facilitated Intensive Care Unit (ICU) staff with those recorded concurrently by an observer.
-	v.d. Veer 2006 [72]	2004-(17)	Teaching	Yes	ND	No	To design and implement an Intensive Care Unit (ICU) incident registry. Increase awareness, change clinician behavior and improve patient safety.
-	Chacko 2007 [49]	2002 (33)	Teaching	Yes	C	No	Analyzing the type, frequency and outcomes of critical incidents in our multidisciplinary Intensive Care Unit (ICU) and to look at ways to devise system-based strategies to prevent such incidents.
-	Kaur 2008 [58]	2006 (6)	Non-teaching	Yes	C	No	To do an audit of reported critical events during intensive care stay. To develop a critical event reporting system in the Intensive Care Unit (ICU) of our hospital.
-	Agalu 2012 [73]	2012 (2)	Teaching	Yes	C	No	To assess medication administration errors in the intensive care unit of Jimma University Specialized Hospital.
-	Pagnamento 2012 [75]	2012 (24)	Non-Teaching	Yes	C	Yes (4)	Exploited a self-reporting strategy during gthe hospital stay and tested the hypothesis that a multifaceted intervention focuses on medication errors decreased the risk-index scores for drug related AEs.

[1]Acronym: ESICM-SEE = European Society of Intensive Care Medicine – Sentinel Events Evaluation, AIMS-ICU = Australian Incident Monitoring Study in the Intensive Care Unit, SAFE-reporting form = Safety Action Focus Everyone – reporting form, ICUSRS = ICU Safety Reporting System, SYREC study = Safety and Risk in Critical Patients.
[2] Hospitals: Teaching=Academic/university/teaching/tertiary, Non-teaching=general and community. [3] ICU-population: S=surgical, M=Medical, C= Combination, ND=Not described.

Appendix D. Implementation of the General Incident Reporting System

Acronym[1]	Author, Year (ref)	Implementation process
MUHC PSN	Kivlahan 2002 [59]	Training staff members, training database and pre-implementation survey was given.
MEDMARX	Kane-Gill 2010 [57]	No
APSF	Graf 2005 [52]	During run-in period of 4 weeks, prior to the data collection process all staff members were repeatedly encouraged to make use of the IRF and examples of how, why and when to use the IRF were provided.
NPSA	Parke 2003 [65]	Multidisciplinary meetings
	Thomas 2008 [70]	No
	Thomas 2009 [68]	No
-	Wright 1991 [40]	No
-	Hart 1994 [54]	All staff were introduced to the concept of incident reporting and encouraged to participate
-	Kopp 2006 [60]	Nurses were informed about the purpose study. Observers would intervene only in the event that the medication error would cause substantial patient harm or discomfort. Nurses were invited to voluntarily participate in the study, informed consent was obtained
-	Benkirane 2009 [44]	No
-	Bohomol 2009 [45]	Informed of every step of the investigation and the nature of the research and asked to sign an informed consent form.

[1]Acronym: MUHC PSN = University of Missouri Health Care Patient Safety Network System, MEDMARX = Medication errors reporting program, APSF = Australian Patient Safety Foundation, NPSA = National Patient Safety Agency.

Appendix E. Implementation of the Intensive care unit Specific Incident Reporting System

Acronym[1]	Author, Year (Ref)	Implementation process
ESICM SEE	Valentin 2006 [69]	ICU coordinator responsible for briefing of the ICU team.
	Valentin 2009 [71]	ICU coordinator responsible for briefing of the ICU team.
AIMS-ICU	Beckmann 1996 [42]	Multidisciplinary team approach, tutorial/interview sessions
	Beckmann 1996 [41]	Starters pack, tutorial sessions, group discussions and during ward rounds.
	Buckley 1997 [47]	Small group discussions for nurses. Examples of critical incident were presented and discussed.
	Beckmann 2003 [43]	Part of orientation on ICU. Discussing incident monitoring at ward round and clinical session (bedside discussions, consultations or grand round presentation
SAFE reporting form	Osmon 2004 [64]	Series of in-services for all patient care providers and support staff
	Nast 2005 [61]	Group and individual in-services.
	Schuerer 2006 [66]	Group and individual in-services.
	Harris 2007 [53]	No
	Ilan 2011 [56]	Multifaceted approach, education, reminders, regular updates, personal and group feedback, weekly leadership rounds.
ICUSRS	Needham 2004 [62]	ICU staff members received training using the web-based data entry system.
	Needham 2005 [63]	ICU staff members received training using the web-based data entry system.
	Holzmueller 2005 [55]	Two day training visit.
	Sinopoli 2007 [67]	Training to staff at participating ICUs.
SYREC	Merino 2012 [74]	Two coordinators (physician and nurse) were designated for each participating center. Materials for training were distributed to all professionals.
-	Flaatten 1999 [51]	ICU staff informed during staff meeting and periodic internal ICU newsletter.
-	Bracco 2001 [46]	ND
-	Donchin 2003 [50]	Several meetings.
-	Capuzzo 2005 [48]	Several meetings research team. During study enhanced reporting by director during ward rounds. Poster with guidelines on the wall next to the forms.
-	v.d. Veer 2006 [72]	Short introduction on the background of the registry and some of the specific items.
-	Chacko 2007 [49]	Preliminary team meetings.
-	Kaur 2008 [58]	No
-	Agalu 2012 [73]	No
-	Pagnamento 2012 [75]	Structured meetings with the care staff during the study period.

[1]Acronym: ESICM-SEE = European Society of Intensive Care Medicine – Sentinel Events Evaluation, AIMS-ICU = Australian Incident Monitoring Study in the Intensive Care Unit, SAFE-reporting form = Safety Action Focus Everyone – reporting form, ICUSRS = ICU Safety Reporting System, SYREC study = Safety and Risk in Critical Patients.

Chapter 9

Questionnaires on family satisfaction in the adult ICU; a systematic review including psychometric properties

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Critical Care Medicine 2015 Aug;43(8):1731-44

Abstract

Objectives: To perform a systematic review of the literature to determine which questionnaires are currently available to measure family satisfaction with care on the ICU and to provide an overview of their quality by evaluating their psychometric properties.

Data Sources: We searched PubMed, Embase, The Cochrane Library, Web of Science, PsycINFO and CINAHL from inception until October 30, 2013.

Study Selection: Experimental and observational research articles reporting on questionnaires on family satisfaction and/or needs in the ICU were included. Two reviewers determined eligibility.

Data Extraction: Design, application mode, language and the number of studies of the tools were registered. With this information, the tools were globally categorized according to validity and reliability: level I (well-established quality), II (approaching well-established quality), III (promising quality) or IV (unconfirmed quality). The quality of the highest level (I) tools was assessed by further examination of the psychometric properties and sample size of the studies.

Data Synthesis: The search detected 3,655 references, from which 135 articles were included. We found 27 different tools that assessed overall or circumscribed aspects of family satisfaction with ICU care. Only four questionnaires were categorized as level I: the Critical Care Family Needs Inventory, the Society of Critical Care Medicine Family Needs Assessment, the Critical Care Family Satisfaction Survey and the Family Satisfaction in the Intensive Care Unit. Studies on these questionnaires were of good sample size ($n \geq 100$) and showed adequate data on face/content validity and internal consistency. Studies on the Critical Care Family Needs Inventory, the Family Satisfaction in the Intensive Care Unit also contained sufficient data on inter-rater/test-retest reliability, responsiveness and feasibility. In general, data on measures of central tendency and sensitivity to change were scarce.

Conclusions: Of all the questionnaires found, the CCFNI and the FS-ICU were the most reliable and valid in relation to their psychometric properties. However, a universal "best questionnaire" is indefinable because it depends on the specific goal, context and population used in the inquiry.

Introduction

In recent years, quality of care has become a central issue in healthcare systems worldwide. Particularly, the quality as perceived by patients and their family is a current focus of interest. It is generally accepted that improvement in the quality of care involves a wide range of strategies including the use of evidence-based health care, guidelines and protocols, quality improvement cycles and changes in safety and risk management. [1] Essential in each of these strategies is the monitoring and evaluation of delivered care. In the ICU, satisfaction with the care provided is considered just one of the many quality of care indicators and an important tool for improving care. [2-4] Since most ICU patients cannot make decisions themselves, family members are actively involved in the care process as surrogate decision-makers and are, therefore, judges of care quality. However, family satisfaction with care is complex and not clearly defined.

In the current body of literature, different aspects of family satisfaction are considered important for family members but no gold standard currently exists to assess this concept. One line of reasoning is that satisfaction is the fulfillment of family needs or requirements which, if fulfilled, relieve or diminish the distress of the family members or improve their sense of well-being. [5] However, Heyland et al [6] remark that although satisfaction reflects the amount of fulfillment of needs and expectations, meeting needs does not guarantee satisfaction. In general, expectations of care, information provided, communication, hospital infrastructure, and patient- and family related factors all play a role in family satisfaction with ICU care. [1] Family satisfaction is also related to the family being provided with clear information because this enables them to actively participate in the decision-making process. [6-8]

At present there are several tools available, mostly questionnaires, that measure family satisfaction with ICU care. Because family satisfaction can be influenced by multiple factors, and the acquired data must be accurate, good validation is obligatory for the adequate use of the questionnaires. Psychometric properties, such as reliability and validity, are essential elements of questionnaires because these describe the quality of the measurement. Questionnaires lacking good psychometric values may not measure the construct they intend to assess, or the values that arise from the questionnaire may not represent the “true” value. This may not only hamper research but also misguide the clinician working with the tool. Thus, the quality of a questionnaire is determined by its psychometric properties.

Therefore, the aim of this review is to determine which questionnaires assessing family satisfaction with ICU care are currently available and to provide an overview of their quality by determining their psychometric properties.

Methods

Search Strategy and Selection Criteria

We searched PubMed, Embase, The Cochrane Library, Web of Science, PsycINFO, and CINAHL from inception to October 30, 2013. The databases were searched for medical literature with the following terms: "questionnaires", "family satisfaction", "family needs" and "intensive care". The complete electronic search strategy can be found on the internet: http://links.lww.com/CCM/B257.

Reference lists of review articles and eligible primary studies were checked to identify cited articles not captured by electronic searches.

Study selection

Included were studies that specifically used a questionnaire to measure family satisfaction and/or family needs in the adult (>18 years) ICU, published in peer-reviewed journals. The language of the articles was restricted to English.

Excluded were studies that did not use a questionnaire to measure family satisfaction. Also excluded were reviews, editorials, and letters to the editor. Furthermore, studies on instruments for *medical staff* satisfaction and *patient* satisfaction were excluded as were studies on parent satisfaction in pediatric or neonatal ICU. The latter was done because the specific parent-patient relationship in children less than 18 years old differs from the family-patient relationship in adults. [9] Family was defined as next of kin or other persons with a close relationship to an ICU patient.

Two reviewers (J.B. and A.B.) scrutinized the titles and abstracts of all references on possible inclusion. Second, final inclusion/exclusion decisions were made after independent examination of the full manuscripts. All studies that on full text examination failed to meet the inclusion criteria were excluded. Disagreement between reviewers was resolved by consensus, and if necessary, judgment of a third author was decisive. Reference manager 12.0 (Thomson ISI ResearchSoft, Philadelphia, PA) was used to manage all search results.

Extracted data

The following data were systematically extracted from the studies: author/research group, year of publication, timeframe and means of collecting information, name and version of the tool used, language of the tool, number of questions and domains (subscales) in the tool. And furthermore, information on sample size and psychometric properties was extracted (see below).

Quality assessment

A two-step model was used to assess the quality of the tools and the psychometric properties.

Assessment of general quality and global psychometric properties

To establish the general quality and global psychometric properties (i.e. validity and reliability) of the tool, first all available data for each tool were grouped. Subsequently, the classification model adapted from Cohen et al [10] was applied. This model is an analogue to the well-accepted criteria used to establish effectiveness of treatment in systematic reviews. [11] At the highest quality level (level 1), what is taken into account is whether (A) a tool is presented by different research groups in different peer-reviewed articles, (B) sufficient detail of the tool is available to allow evaluation and replication (e.g. complete item list and means must be published) and (C) substantial data is available regarding validity and reliability (Table 1).

A tool had to fulfill all the criteria of a specific level to be assigned the quality of that level. When the combined research of a tool met all three criteria defined above (A, B, and C) for level I, it was considered "well-established quality" (++). When one of these criteria was not met, but a tool did meet the standards for level II quality described in Table 1, it was classified as "approaching well-established quality" (+). When one or more of these level II standards were not met, the tool was evaluated with respect to the criteria of level III, "promising quality" (+/-). Finally, when the tool did not meet one or more of the criteria of level III, it was considered level IV, of "unconfirmed quality" (-).

In category C**,** "++" was scored when validity and reliability were named precisely and when values presented showed good validity (ie, the values were proven to assess the intended construct, or Cronbach α was > 0.70 for all factors) and good reliability (Spearman Brown or Split half > 0.8 of scale and subscales both, or Κ < 0.061 or Pearson's r > 0.8). In category C, a "+" was scored when both validity (either face validity, content validity, or construct validity) and reliability (either internal consistency, inter-rater reliability, test-retest reliability) were named but not precisely defined, or when values presented showed moderate validity (Table 1).

In category C, a "+/-" was scored when either validity or reliability were named, but not precisely defined, or when no values were presented or when low values were presented. Lastly, in category C, a "-" was scored when validity and reliability were not mentioned or when no data on validity or reliability were reported.

Assessment of psychometric properties

All studies describing tools that were considered to be of "well-established quality" were entered in the second step of the analysis. The sample size of the studies and the

following psychometric properties of the tools were systematically assessed: face-, content-, and construct-validity, reliability, measures of central tendency, sensitivity, responsiveness and feasibility. [12] This was achieved by grouping the data for each version of the tools (e.g. language, reduced, or extended version) and coding each psychometric property as (1) good, (2) mediocre, (3) poor, or (4) having insufficient data to judge the quality of the psychometric properties.

Psychometric properties were defined as follows.

Sample size

An adequate sample size is needed to detect reliable psychometric data, we used an arbitrary $n > 100$ per (sub)group cutoff as published by Friberg et al. [13]

Validity

Validity refers to the extent to which a tool actually measures family satisfaction. Three types of validity were distinguished: face validity, content validity, and construct validity.

Face validity refers to the extent to which a tool is subjectively viewed as covering the concept it purports to assess. Interviews with experts and focus groups are often used to determine this. Furthermore, to fulfill this criterion, the purpose of the tool must be explicitly stated because omission might lead to a discrepancy between an intended and actually assessed target. [13]

Content validity differs from face validity in that it does not refer to what is subjectively measured but to whether the items of a tool indeed include the appropriate information and content. [12] Open-ended questions in a tool can increase its content validity by exploring not mentioned information. As the literature on content validity in family satisfaction is still scarce and both face validity and content validity involve the relationship of questions and their intended content, they were grouped together.

Construct validity is determined by the validity of abstract variables that cannot be directly observed (latent variables). These constructs are assessed by their relationships with other variables. [12,14] Factor analysis or comparisons with other scales that are supposed to assess the same construct are used to investigate the internal structure and validity of domains. Without good construct validity, it is hard to determine what the tool exactly measures. In the area of family satisfaction, this could involve questions regarding the atmosphere of the waiting room, which does not necessarily reflect satisfaction with ICU care. Tools were considered adequate in this domain when they either exhibited clear, defined factors that in turn showed good internal consistency

(Cronbach α >0.70) or when their concurrent validity was high. The latter means that a questionnaire shows a high correspondence with another questionnaire when assessing the same construct (Pearson's $r > 0.70$ or high Cronbach α). [13] Construct validity also covers the aspect of correct questionnaire translation into a different language [1]. Adequate translation of a questionnaire is an important and time-consuming procedure that aims for "equivalence" with the original. [12] Because research of family satisfaction is performed in many different countries, results of the data obtained need to be comparable.

Reliability

Reliability refers to the overall consistency of a tool's data across time, settings, and people. This is important because without sufficient reliability the scores obtained may not reflect the "true" scores. For example, the questions may refer to interpersonal conduct of the nurses at a given moment. This may be different from nurse to nurse and subsequently from shift to shift. Therefore, this question score may change daily and is dependent on family members' personal preferences. The following aspects of reliability were investigated: internal consistency, inter-rater reliability, and test-retest reliability. Internal consistency is the extent to which all items of a tool measure the same content. Cronbach α, which is a measure of the average correlation of scores from a measure with the scores of all of its items, is the most commonly used unit of internal consistency. [12] In general, acceptable Cronbach coefficients for research and clinical purposes are 0.70 and 0.90, respectively. [12,15] Other internal consistency units include Spearman-Brown and split-half reliability. In this study we predetermined a degree of greater than 0.80 for both units to represent adequate internal consistency.

Inter-rater (interobserver) and test-retest reliability are both concerned with the robustness of the outcomes of a tool when applied by another person (inter-rater) or at another moment (test-retest). A good agreement of a measure between different raters/observers or by the same raters at different moments is typically represented by K statistics (> 0.60) [12] or by a high correlation between the two outcomes (Pearson's $r >$ 0.80).

Measures of central tendency such as the mean and standard deviation (SD) of the scale and subscales need to be known as they form the basis for comparison [13] and interpretation of scores. Information about the presence or absence of floor and ceiling effects is needed too in this regard. When these effects are present, non-parametric test should be applied. In these cases, the interpretability of high or low scores is limited substantially.

Table 1. Categories for classification of instruments based on Cohen and modified by authors

Level of Quality	Criteria for Categories	Quality indication
I	A. The measure must have been presented in at least two peer-reviewed articles by different investigators or investigatory teams (++) B. Sufficient detail about the measure to allow critical evaluation and replication, e.g., complete description of the items and scoring of the tool (++) C. Detailed information indicating good validity and reliability in at least one peer-reviewed article (++)	Well-established quality
II	A. The measure must have been presented in at least two peer-reviewed articles, which might be by the same investigator or investigatory team (+) B. Sufficient detail about the measure to allow critical evaluation and replication, e.g., the domains and subscales of the tool have been described (+) C. Validity and reliability information either presented in vague terms or only moderate values presented (+)	Approaching well-established quality
III	A. The measure must have been presented in at least one peer-reviewed article (+/-) B. Sufficient detail about the measure to allow evaluation, e.g., the questionnaire and its purpose have been described, or the questionnaire was presented in another article (+/-) C. Validity and reliability information presented in vague terms (e.g., no statistics) or low values presented (+/-)	Promising quality
IV	Negative sore in A, B, and/or C (-)	Unconfirmed quality

Validity and reliability were assessed and scored as follows:

"++" in category C was scored when both validity (either face-, content- or construct -) and reliability (either internal consistency, inter-rater reliability, test-retest reliability) were named precisely and when values presented showed good validity (ie, the values were proven to assess the intended construct, or Cronbach α was >0.70 for all factors), and good reliability (Spearman Brown or Split half > 0.8 of scale and subscales both, or K < 0.061 or Pearson's r > 0.8).

"+" in category C was scored when both validity (either face-, content- or construct-) and reliability (either internal consistency, inter-rater reliability, test-retest reliability) were named but not precisely defined or when values presented showed moderate validity (authors suggested that the tool assesses the intended construct, or Cronbach α > 0.70 but not for all factors), and reliability (Spearman Brown > 0.8 for either the scale or the subscales, but not both).

"+/-" in category C was scored when either validity (either face-, content- or construct-) or reliability (either internal consistency, inter-rater reliability, test-retest reliability) were named but not precisely defined, or when no values were presented, or when low values were presented (Cronbach α < 0.70 for all factors), or reliability (Spearman Brown < 0.8).

"--" in category C was scored when validity or reliability were not mentioned or when no data on validity or reliability was reported.

Sensitivity is a related concept. It is the ability of a tool to detect a "true problem case" (resulting in the percentage of dissatisfied family members who are correctly identified as feeling dissatisfied). *Specificity*, on the other hand, measures the proportion of negatives that are correctly classified as such (satisfied family members correctly identified as such). Floor and ceiling effects greatly compromise sensitivity and specificity because the scores of true problem cases and true negatives then tend to lie close to each other or are even indistinguishable. True sensitivity cannot be determined in the field of family satisfaction because a gold standard is unobtainable.

Responsiveness is the ability of a scale to detect (meaningful) changes over time. [16,17] This is a particularly important asset when a tool is used to measure the effect of an intervention, for example, a hospitality workshop for healthcare workers. To demonstrate this ability, the tool must first have good test-retest reliability because otherwise the changes could be attributed to mere chance. Also in this psychometric domain, ceiling and floor- effects have detrimental influences.

Feasibility relates to the ease and timeframe needed to administer and process an instrument. [14,18] In other words, whether it is acceptable and practical in clinical use and scientific practice. In this study, we focused on the mode of administration (e.g., interview, and questionnaire) and the amount of time needed to apply the tool.

Results

Selected studies

The search detected 3,655 references of which 2,354 references were excluded because they were duplicates. Thus, 1,301 records were screened based on title and abstract. Of these 1,301 records, 1,153 articles did not meet the inclusion criteria (i.e., the abstract originated from a poster, it was not a peer reviewed article, the article did not study adult patients or did not report on family satisfaction). Subsequently, 148 full-text articles were assessed for eligibility and 13 more articles were excluded. [19-31] Reasons for article exclusion were as follows: studies in which family satisfaction was combined with patient satisfaction [19,28,31], studies that measured hospital staff satisfaction [22-27,29,30], studies in which satisfaction or needs were not measured [20], and a study on the implementation of a quality indicator bundle. [21] In total, we selected 135 studies for this review. [4-8,32-170] A flow diagram of the study is depicted in Figure 1.

Definition

No uniformly used definition of family satisfaction was found. Two main domains were identified; these were 'needs met' and 'satisfaction with care'. Within these domains, several subdomains were studied.

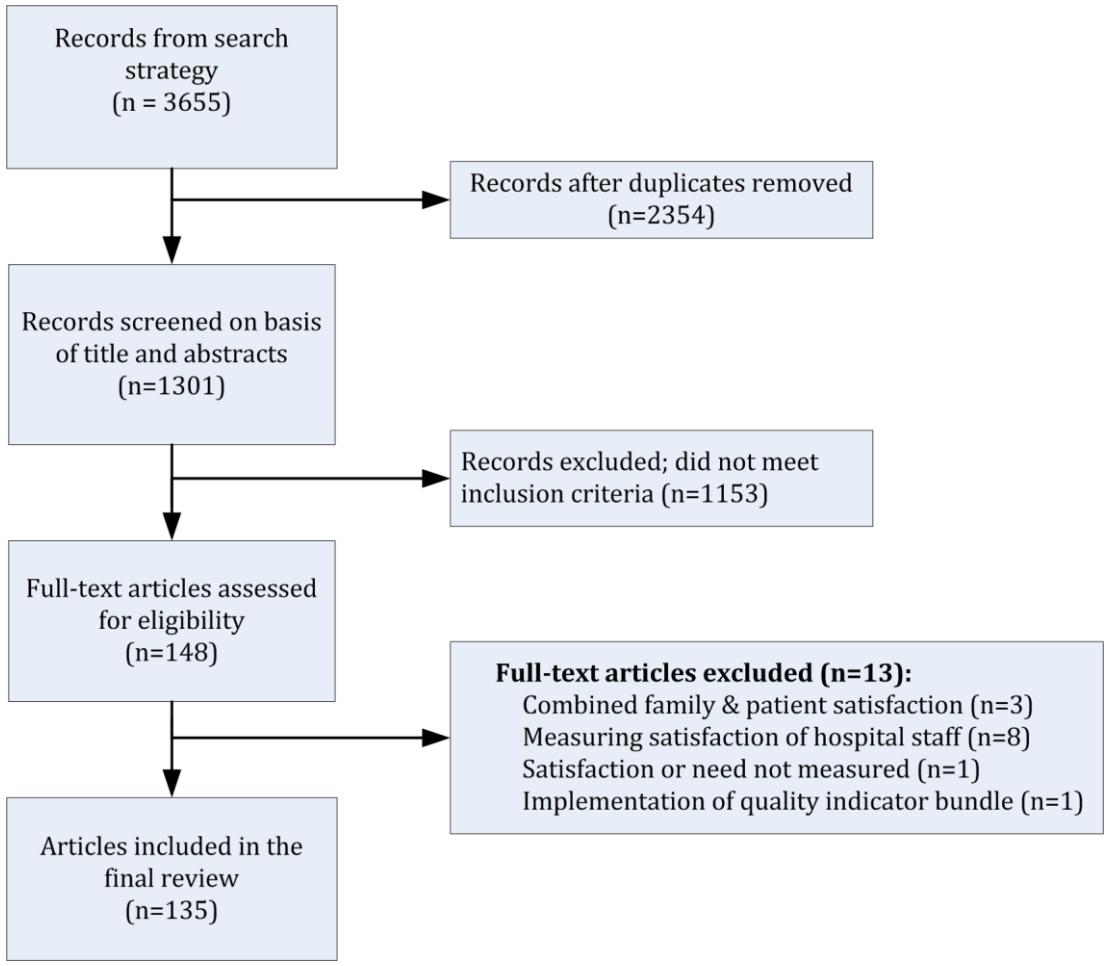

Figure 1. Study selection flow diagram

Description of the tools

In these 135 studies, 27 different questionnaires were described. Twenty-one were self-reported questionnaires, six were applied by structured interview (Table 2). Nineteen tools were classified as level IV, "unconfirmed quality", three as level III, "promising quality", and one as level II, "approaching well-established quality". [10] Four questionnaires were classified as level I, "well-established quality": the Critical Care Family Needs Inventory (CCFNI), the Society of Critical Care Medicine Family Needs Assessment (SCCMFNA), the Critical Care Family Satisfaction Survey (CCFSS) and the Family Satisfaction in the Intensive Care Unit (FS-ICU). A detailed overview of the quality of each study can be found in Appendix A.

Table 2. Level of Evidence

Instrument	Year	Level of Evidence				Mode of assessment
		A. Literature	B. Sufficient Details	C. Validity/ Reliability	Overall quality (I,II,III,IV)	
Critical care Family Needs Inventory [5,32-82, 90,92,109,114,116,119,124,125]	1979-2013	++	++	++	I	Questionnaire
Society of Critical Care Medicine Family Needs Assessment [7,133,137,140,143,157]	1998-2012	++	++	++	I	Questionnaire
Critical Care Family Satisfaction Survey [8,83,85,86,95,97,98,111,115,120]	2001-2013	++	++	++	I	Questionnaire
Family Satisfaction in the Intensive Care Unit [4,6,51,84,87,91,93,94,96,99,100,102,104-106,110,113,121,127,130,131,141,146-150,153,158-161]	2001-2013	++	++	++	I	Questionnaire
Quality Of Death and Dying communication [103,122]	2004-2007	+	+	+	II	Questionnaire
Myhren[129,136]	2004-2011	++	+/-	++	III	Questionnaire
Family members perception of nurses roles [117]	2005	+/-	+	+	III	Questionnaire
Quality Of Communication [101]	2006	+/-	+	+/-	III	Questionnaire
Liddle et al [158]	1988	-	-	-	IV	Questionnaire
Dockter et al [108]	1988	+/-	-	-	IV	Questionnaire
Dixon et al [112]	1997	+/-	+	-	IV	Questionnaire
Malacrida et al [140]	1998	+/-	+	-	IV	Questionnaire
Keenan et al [139]	2000	+/-	-	-	IV	Questionnaire
Roland et al [151]	2001	+/-	-	-	IV	Questionnaire
Deitrick et al[118]	2005	+/-	+	-	IV	Questionnaire
Kjerulf et al [134]	2005	+/-	-	-	IV	Questionnaire
Humble et al [144]	2009	+/-	+	-	IV	Questionnaire
Whitcomb et al [156]	2010	+/-	+	-	IV	Questionnaire
Cheung et al [89]	2010	-	-	-	IV	Questionnaire
Family Needs Questionnaire [123]	2010	+/-	-	-	IV	Questionnaire
Sundararajan et al [126]	2012	+/-	+	-	IV	Questionnaire
Cuthbertson et al [88-107]	2000-2010	++	+	-	IV	Interview [a]
Kirchhoff et al [137]	2002	-	-	-	IV	Interview [a]
Kutash et al [149]	2007	-	+	-	IV	Interview [a]
Sacco et al [164]	2009	+/-	-	++	IV	Interview [a]
Nelson et al [132]	2010	+/-	++	-	IV	Interview [a]
Siddiqui et al [128]	2011	+/-	+	-	IV	Interview [a]

Mode of assessment: [a] Assessed by structured interview other questionnaires were self-reported.

Analysis of high quality (level I) questionnaires

The four level I questionnaires found were described in 109 studies (*k*). The psychometric data most reported were as follows: sample size, face/content validity, and internal consistency. In approximately two thirds of these studies, means and SD were reported. Only few studies reported findings on construct validity (*k*=17) [4,8,35,43,56,60,71,83,86,97-99,102,111,115,120,141], inter-rater or test-retest reliability (*k*=9) [44,59,73,99,106,133,141,143,168], measures of central tendency (*k*=1) [125], responsiveness (*k*=11) [36,100,102,119,120,125,153,155,157,169,171] and sensitivity (*k*=1) [168] (see Appendix B for a detailed overview) (Table 3).

CCFNI

The CCFNI, developed by Molter [69] and adapted by Leske [5], was the first questionnaire on family satisfaction with ICU care. It consisted of 45 items and measured what the needs of the family were in relation to five domains: (1) information, (2) comfort, (3) proximity, (4) assurance and (5) support. Questions on these domains had to be answered on a four-point Likert scale. Warren [52] in 1993 added the Needs Met Inventory (NMI), to assess the extent to which the needs were met. The NMI consists of an additional 45 items on a four point Likert scale.

In total, 60 studies of the CCFNI were identified; describing 18 different versions, in eight different languages (English, French, Swedish, Greek, Dutch, Chinese, Arabic and Portuguese). Furthermore, ten varieties of the CCFNI with a total number of questions varying between 14 and 90 items were reported. About half of the studies were of adequate sample size (k = 29; n > 100). [32-35,38,40,43,46,49,50,54,57,58,60,62,64-66,70,74,78,80-82,92,109,114,119,125] With regard to the psychometric data, face/content validity was found to be "good" for most versions with 45 or 46 items, and lower for versions with 30 items or less. Internal consistency was reported for 11 CCFNI versions of which eight demonstrated good internal consistency, whereas it was poor for the three remaining ones. Means and SD were reported for most versions. Last but not least, responsiveness was studied in three versions of which one study [36] reported positive outcomes (Chinese 45-item version). Responsiveness was not substantiated by other studies or in other versions of the CCFNI. The time needed to complete the questionnaire varied from 20 to 60 minutes (see Appendix B for a detailed overview).

SCCMFNA

The SCCMFNA, first described in 1998 by Johnson et al [141], consisted of 14 items and measures the needs of family members with respect to (1) attitude, (2) communication, (3) comforting skill, and (4) isolation. The response scale is a four-point Likert scale.

Six studies [7,133,138,141,146,166] on the SCCMFNA have been published, including three different language versions: English, French and Arabic. Five of these studies met the predefined sample size criterion. [7,133,138,141,146] In general, face/content validity was found to be "good". However, poor results were reported for construct validity and internal consistency. No information was found on other psychometric data such as

Table 3. Sample Size and Psychometric Properties of Well-Established Assessment Tools

			Validity		Reliability			
Instrument	**Version**	**Sample size**	**Content /Face**	**Construct validity, of scales/ subscales**	**Internal Consistency**	**Inter-Rater/ Test-Retest**	**Measures of Central Tendency**	**Responsiveness**
Critical Care Family Needs Inventory	48 item French [65,66]	+	+	0	+	0	0	0
	46 item French & English [58]	+	+	0	+	0	0	0
	46 item English [56,67,77,78]	+	+	+	+	0	+/-	0
	45 item English [5,32,45,47,51,53,55,57,59-61, 68,69,75,81,90,114,116,124]	+	+	+	+	+	+/-	0
	90 item English (+NMI) [39,52]	-	+	0	0	0	+/-	0
	45 item Dutch [40,43,74]	+	+	+/-	-	0	+/-	0
	45 item Chinese [35,36,41,42,44,76]	+	+	+	+/-	+	+/-	+
	45 item Arabic [33,38,119]	+	+	0	+	0	+/-	+/-
	45 item French [80,109]	+	0	0	0	0	0	0
	45 item Swedish [82]	+	0	0	-	0	+/-	0
	45 item Greek [125]	+	+	0	0	0	+	+/-
	43 item English [46]	+	+	0	0	0	+/-	0
	43 item Portugese [34,70,73,92]	+	+	0	-	-	+/-	0
	34 item Spanish [48]	-	0	0	0	0	0	0
	30 item English [49,50,62,63,72,79]	+	+/-	-	+	0	+/-	0
	60 item English (+NMI) [71]	-	+	-	+	0	0	0
	15 item English [54,64]	+	+/-	0	+	0	+/-	0
	14 item English [37]	-	0	0	+	0	+/-	0
Society of Critical Care Medicine Family Needs Assessment	14 item English [140]	+	0	-	0	+	0	0
	14 item French [7,137,143]	+	+	-	0	+	0	0
	14 item Arabic [157,133]	+	+	0	-	-	0	0
Critical Care Family Satisfaction Survey	20 item English [8,83,86,97,98,111,115,120]	+	+	+	+	0	+/-	+/-
	20 item Arabic [95]	-	+	0	+	0	0	0
	20 item Swedish [85]	-	+	0	+	0	0	0

Table 3. (cont.)

			Validity		Reliability			
Instrument	**Version**	**Sample size**	**Content /Face**	**Construct, Validity, of Scales/ Subscales**	**Internal Consistency**	**Inter-Rater/ Test-Retest**	**Measures of Central Tendency**	**Responsiveness**
Family Satisfaction in the Intensive Care Unit	37 item English [102,110]	+	+	-	-	0	+/-	-
	34 item English [6,93,94,104-106,113,130,146]	+	+	0	+	+	+/-	0
	34 item English +2 [121]	-	+	0	+	0	0	0
	34 item German [91,96,99,131]	+	+	+/-	+	-	+/-	0
	34 item Dutch [51]	+	+	0	+	0	0	+
	26 item Modified English [160,161]	+	+	-	-	0	+/-	+/-
	24 item English [4,84,87,100,127,141,147-149]	+	+	+/-	+	-	+/-	+
	24 item Hebrew [153]	-	+	0	+	0	+/-	0
	24 item German [159]	+	+	0	+	+	0	0
	24 item Greek [150]	+	+	0	0	0	+/-	0
	24 item Filipino [158]	-	+	0	+	0	+/-	0

Sample size and psychometric properties of well-established assessment tools. To improve legibility, sensitivity was not included in the table since scarcely and results indicating sensitivity was reported.

Sample size: '+' = $n > 100$, '-' = $n < 100$.

Content/face validity: '+' = assesses intended construct, '+/-' = does not match the original tool, but assesses intended construct, '-' = does not match the original tool and does not assess intended construct.

Construct validity: '+' = after factor analysis Cronbach $\alpha > 0.70$ for all factors, '+/-' = after factor analysis, most factors Cronbach $\alpha > 0.70$, but not all, '-'= factor analysis shows poor quality with most factors Cronbach $\alpha < 0.70$

Internal consistency: '+' = Cronbach α, Spearman Brown or Split Half > 0.80 of the scale and subscales both, '+/-' = Cronbach α is > 0.80 for either the scale or the subscales, but not both, '-' = Cronbach $\alpha < 0.80$ for the scale and the subscales

Reliability (inter-rater/test-retest): '+' = K > 0.61 or Pearson's r >0.80, '-' = K < 0.61; Pearson's $r < 0.80$, or proven change of scores when filled in by junior versus senior staff.

Measures of central tendency: '+' = mean and SD for all subscores, no ceiling or floor effect, '+/-' = Only mean and SD described or no floor and ceiling effects described, '-' = No mean and SD described

Responsiveness: '+' = scale shows to be able to detect differences over timer or between before and after measurements, '+/-' = differences in before and after intervention scores were found on some items, but no differences were demonstrated on the whole scale or on a domain, '-' = scale is not able to show differences over time, or between before and after measurements.

'0' = no data =available.

measures of central tendency. Means and SD of the items, as well as completion time of the questionnaire, were not reported (see Appendix B for a detailed overview).

CCFSS

The CCFSS is a questionnaire specifically designed to measure family satisfaction with intensive care. It was developed in 2001 by Wasser et al [8] and consists of 20 items within five domains: (1) assurance, (2) information, (3) proximity, (4) support and (5) comfort, answered on a five-point Likert scale.

The CCFSS has been published in 10 studies [8,83,85,86,95,97,98,111,115,120] and in three different languages: English, Arabic, and Swedish. Only studies on the English version were of good sample size (k = 6; n > 100). [8,83,97,98,111,115] This version shows "good" validity (face/content and construct). Five studies [8,86,95,98,120] reported adequate internal consistency, whereas four other studies [83,97,111,115] found it to be poor. The means and SD have been reported once for the English version only [86], and this version shows mediocre responsiveness. Finally, data on other psychometric data are lacking. Completion time of the questionnaire was not reported (see Appendix B for a detailed overview).

FS-ICU

The FS-ICU was developed in 2001 by Heyland and Tranmer [106] and assesses two conceptual domains: (1) satisfaction with care and (2) satisfaction with decision-making. The items in the questionnaire were derived from existing literature on patient satisfaction, quality of care near the end of life, the needs of families of critically ill patients and family satisfaction with decision-making. [106]

Eleven different versions of the FS-ICU have been published in 32 studies. [4,6,84,87,91,93,94,96,99,100,102,104-106,110,113,121,127,130,131,143,152-157,161,167-169,171] These versions contain a different number of questions: initially the questionnaire consisted of 34 multiple choice and three open-ended questions. Dowling et al [102] in 2005 modified the FS-ICU 34 into a version with 37 questions as part of a critical care family assistance improvement programme. Later in 2007 [4], a more concise version with 24 multiple choice questions was developed. All versions have a five-point Likert response scale. Furthermore, the questionnaire was published in the following languages: English, German, Dutch, Hebrew, Greek, and Filipino (see Appendix B for a detailed overview).
The majority of the studies had good sample size (k = 27; n > 100) [4,6,84,87,91,93,96,99,100,102,104,105,110,113,127,130,131,143,152-157,168,169,171], and most versions of the FS-ICU questionnaire showed good psychometric quality. Face/content validity was found to be "good". Only scarce data were found on construct validity (k = 3) [4,99,102], showing mediocre quality for the 34-item German version [99] and the 24-item English version. [4]

Internal consistency was found to be good for most versions, except for the 37-item modified English version where poor construct validity and internal consistency was reported (k = 1). [102] Twelve studies reported on means and SD. [4,102,106,110,127,131,153,156,161,167,169,171] In six studies, information on responsiveness was found. [100,153,155,157,169,171] This was reported mainly for individual items that showed differences in measurements taken before and after the event. The time needed to complete the questionnaire varied from 20 to 30 minutes (see Appendix B for a detailed overview).

On the basis of summaries of psychometric properties (Table 3), with focus on sample size, validity and measures of central tendency, we concluded that of the four questionnaires, the CCFNI and the FS-ICU displayed the most extensively researched and best psychometric properties.

Discussion

The aim of this review was to determine which questionnaires assessing family satisfaction with ICU care are currently available and to provide an overview of their quality by determining their psychometric properties. Therefore, we critically examined the quality of all known versions of family satisfaction assessment tools in a two-step model. First we determined the general quality and psychometric properties of the questionnaires. Second, we evaluated the questionnaires with the highest quality with respect to their psychometric properties.

Only four questionnaires could be classified as being of "well-established quality": the CCFNI, the SCCMFNA, the CCFSS, and the FS-ICU. However, these high-quality instruments consisted of 35 different versions, each with large disparities in psychometric qualities. Of the four, the CCFNI and the FS-ICU displayed the most extensively researched and best psychometric properties; hence we would recommend these for further use and study. The CCFNI and the FS-ICU differ in many ways. The CCFNI is primarily designed to measure family *needs,* whereas the FS-ICU focuses on family *satisfaction*. Although the definition of "family satisfaction with ICU care" is not clearly defined and overlaps with "family needs", they are not the same. Meeting needs does not necessarily reflect satisfaction. [6] Despite this potential drawback of focus on *needs*, studies on the CCFNI, especially in combination with the NMI, have been of great value for increased understanding of the needs contributing to overall satisfaction with ICU care. These studies also contributed to an increase in (content) validity of other questionnaires, such as the FS-ICU. [106]

The FS-ICU assesses satisfaction with *decision making,* besides satisfaction with *care*. These two domains are central to overall family satisfaction with ICU care. [106] First,

satisfaction with care provides data on how families experience general aspects of care. Second, family satisfaction with decision making, is a major component since the family is a substitute decision maker for their critically ill family member in a complex healthcare environment. The FS-ICU is available in many languages, but some language versions have not yet been published in peer-reviewed journals. [172] Although a lot of data exist on the 10 different versions of the FS-ICU, it should be noted that not all these versions display an overall high quality.

In general, limitations of the tools include insufficient data regarding (1) construct and content validity, (2) inter-rater reliability, (3) test-retest reliability, (4) measures of central tendency, (5) responsiveness, and especially sensitivity (6).

Because construct validity is the extent to which a tool actually measures what it claims to measure, and content validity refers to whether the questionnaire includes the appropriate information, they both are of great importance, especially in a subjective outcome such as satisfaction. However, many different language versions of the originally high-quality questionnaires are available in which construct and content validity data are lacking. Therefore, these versions cannot be necessarily called "equivalent". Differences may arise due to inherent semantic differences and cultural differences. For example, the degree of family participation in the decision-making process differs across the world. [7]

An example of importance of inter-rater reliability is Damghi's study [133], using the SCCMFNA. It was found that when the questionnaire was self-completed by highly educated family members, they were significantly less satisfied with the provided care compared to members of less educated families for whom the questionnaire was filled out by the investigator in a face to face interview. [173] Test-retest reliability is important in determining whether the outcome of a tool is susceptible to small timing differences. The lack of data on central tendency measures refers to the omission of information on ceiling and floor effects. However, when examining the score range of the published tools, the means and SD strongly implicate that ceiling effects are present. Indeed, most studies report that family members were generally highly satisfied. [91,100,104]

The most important question is whether these tools are capable of detecting dissatisfaction (sensitivity) or change in satisfaction (responsiveness). Unfortunately, even with all methodological issues combined, it can be concluded that it is not clear whether this is the case. A few causes might account for this. First, patients may tend to respond in a bimodal fashion e.g., globally satisfied or globally not satisfied. With a four- or five-point Likert scale, the depth of responses cannot be assessed [114] and the continuum between the minimum and maximum score is then, in essence, meaningless. As a consequence, this affects the distribution of the acquired data and therefore no parametric statistics can be applied. More importantly, the value of the derived mean

scores does not reflect the actual state. Second, as the majority of the questionnaires use four- or five-point Likert scales, it is conceivable that most family members' answers convey "good" or "excellent". [174] This could be explained by the possibility that the family might not have experience with other healthcare facilities to compare, or because they do not want to come across picky, and probably because they are grateful for the help they received in this stressful and frightening time in their lives. Third, no consensus of absolute cutoffs on Likert scale signifying importance have been stated for the questionnaires listed here. [125] Therefore, Lynn-McHale and Bellinger [67] suggested that an instrument should be developed that would take into consideration both the level of perceived satisfaction and the importance that the family members associate with it. Another solution for this problem could be to use a more differentiated scoring system, e.g., widening the range to six-point Likert scales [49], or even to seven or eight might correct this problem at least to some extent. In addition, it makes sense that the family fills in the questionnaire anonymously and in the absence of staff.

Beside the limitations of the tools described above, this study also holds limitations. First, in an ideal comparative study, a "gold standard" would be used to assess other measurement tools. Alas there are currently none available. Nevertheless, there were two comparative studies in which the Quality of Dying and Death (QODD), family and nurse version, and the FS-ICU were compared. [4,127] Although the QODD is not a tool specifically tailored for the ICU environment, there was a strong correlation between the QODD family and the FS-ICU, especially on the subscale of satisfaction with care. [4] Furthermore, the QODD and the FS-ICU both showed different performances across different age groups. [127] Once again implicating that satisfaction differs across (age) groups.

Another limitation of this study is that we did not report on measures connected to response rates because there was not enough information provided in the included studies. Response rate is an important aspect of feasibility. We only studied fill in time and mode of application. Furthermore, we have only included articles published in English, which might have led to omission of relevant studies on questionnaires in other languages. Also, studies on patient satisfaction combined with family satisfaction were excluded. Although this increased the clarity of the search, it is possible that some studies with data on this subject were not included. Nevertheless, this is the first study that critically examined the psychometric properties of all the different published versions of family satisfaction questionnaires. Finally, we defined high quality by psychometric properties. Although this is a commonly used and approved method, it may still not be possible to point out one single best questionnaire. The quality of a questionnaire is also highly dependent on the circumstances under which it is used. First, the quality of a questionnaire depends on the aim of the measurement. This can

be, for example, the measurement of an aspect of care or of changes in satisfaction. Second, it depends on what population it is used on. For example, differences in language, culture, and patient population have a high impact on the appropriateness of a questionnaire. To comply with these factors many adjusted versions to primarily high-quality questionnaires have been developed. The risk of these adjusted versions is that they are not per se of the same quality as the original version, especially because the psychometric properties of those versions are often scarce. The second aspect is the method of using psychometric properties itself. Although used worldwide, this method for assessing family satisfaction questionnaires is a reflective analysis method. Theoretically, a formative approach exists as well. Because family satisfaction is not well defined, it is possible that not all aspects of family satisfaction are in fact measured.

In conclusion, at present four well-established questionnaires are available to measure family satisfaction with ICU care. When using these questionnaires in clinical practice or for research activities, it is of importance to be aware of the limitations of each tool. Of these four tools, CCFNI and FS-ICU have the best psychometric properties. The CCFNI measures *needs* and the FS-ICU measures *satisfaction*. Finally, in the evaluation of family satisfaction with intensive care, the use of valid instruments is essential to gain proper and high-quality information. This information is necessary as an outcome quality indicator and to better target improvement initiatives in the ICU.

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Appendix A. General quality and global psychometric properties of tools to assess family satisfaction with intensive care

				Level of Evidence		
Author	**Year**	**Instrument**	**Version**	**A. Literature**	**B.Sufficient Detail**	**C. Validity/ Reliability**
Chartier [66]	1989	CCFNI	48 item French	++	+/-	++
Coutu-Wakulczyk [65]	1990	CCFNI	48 item French	++	+/-	++
Rukholm [58]	1991	CCFNI	46 item French & English	++	+/-	++
Daley [77]	1984	CCFNI	46 item English	-	++	-
Lynn-McHale [67]	1988	CCFNI	46 item English	++	++	++
Rukholm [78]	1991	CCFNI	46 item +2 English	++	+/-	++
Rukholm [56]	1992	CCFNI	46 item +2 English	++	+/-	++
Molter [69]	1979	CCFNI	45 item English	++	++	+/-
Rodgers [68]	1983	CCFNI	45 item English	++	++	++
Leske [5]	1986	CCFNI	45 item English	++	++	+
Macey [59]	1991	CCFNI	45 item English	++	++	++
Leske [60]	1991	CCFNI	45 item English	++	++	++
Koller [61]	1991	CCFNI	45 item English	++	+	++
Kahn [55]	1992	CCFNI	45 item English	++	+	++
Kleinpell [57]	1992	CCFNI	45 item English	++	+/-	++
Engli [53]	1993	CCFNI	45 item English	++	+/-	++
Lopez-Fagin [51]	1995	CCFNI	45 item English	++	+/-	-
Mendonca [47]	1998	CCFNI	45 item English	++	+/-	++
Hunsucker [45]	1999	CCFNI	45 item English	++	++	++
Higgins [75]	1999	CCFNI	45 item English	++	++	++
Hinkle [32]	2009	CCFNI	45 item English	++	++	++
Kinrade [116]	2009	CCFNI	45 item English	++	++	++
Bailey [90]	2010	CCFNI	45 item English	++	+/-	++
Hinkle [114]	2011	CCFNI	45 item English	++	++	++
Noor Siah [81]	2012	CCFNI	45 item English	++	+/-	++
Obringer [124]	2012	CCFNI	45 item English	++	+/-	++
Warren [52]	1993	CCFNI + NMI	90 item English	++	+/-	+/-
Kosco [39]	2000	CCFNI + NMI	90 item English	++	+/-	++
Bijttebier [43]	2000	CCFNI	45 item Dutch	++	++	++
Bijttebier [40]	2001	CCFNI	45 item Dutch	++	++	++
Delva [74]	2002	CCFNI	45 item Dutch	++	++	++
Tin Mi-kuen [44]	1999	CCFNI	45 item Chinese	++	++	++
Lee [42]	2000	CCFNI	45 item Chinese	++	+/-	++
Leung [41]	2001	CCFNI	45 item Chinese	++	+/-	++
Chiu [76]	2004	CCFNI + C-SAI	45 item Chinese	+/-	-	-
Chien [35]	2005	CCFNI	45 item Chinese	++	++	++
Chien [36]	2006	CCFNI	45 item Chinese	++	+/-	++
Al Hassan [38]	2004	CCFNI	45 item Arabic	++	+/-	++
Omari [33]	2009	CCFNI	45 item Arabic	++	+/-	++
Al-Mutair [119]	2013	CCFNI	45 item Arabic	++	++	++
Moreau [80]	2004	CCFNI (RCT)	45 item French	++	+/-	++
Garrouste-Orgeas [109]	2010	CCFNI	45 item French	++	+/-	-
Hoghaug [82]	2011	CCFNI	45 item Swedisch	++	+/-	++
Chatzaki [125]	2012	CCFNI	45 item Greek	++	++	-
Burr [46]	1998	CCFNI	43 item English	++	+/-	-
Fumis [34]	2006	CCFNI	43 item Portugese	++	+/-	-
Freitas [73]	2007	CCFNI	43 item Portugese	++	++	++
Fumis [70]	2008	CCFNI	43 item Portugese	++	-	-

Appendix A. (cont.)

Author	Year	Instrument	Version	Level of Evidence A. Literature	B.Sufficient Detail	C. Validity/ Reliability
Fumis [92]	2009	CCFNI	43 item Portugese	++	-	+/-
Zazpe [48]	1997	CCFNI	34 item Spanish	+/-	++	-
Forrester [63]	1990	CCFNI	30 item English	++	++	++
Price [62]	1991	CCFNI	30 item English	++	++	++
Murphy [79]	1992	CCFNI	30 item English	++	+/-	++
Quinn [49]	1996	CCFNI	30 item English	-	++	-
Quinn [50]	1996	CCFNI	30 item English	++	+/-	-
Gelling [72]	1999	CCFNI	30 item English	+/-	++	-
Maxwell [71]	2007	CCFNI + NMI	60 item English	++	++	++
Halm [64]	1990	CCFNI	15 item English	++	++	-
Henneman [54]	1992	CCFNI	15 item English	+/-	++	++
Auerbach [37]	2005	CCFNI	14 item English	++	++	++
Azoulay [137]	2001	SCCMFNA	14 item French	++	++	++
Azoulay [143]	2003	SCCMFNA	14 item French	++	+/-	-
Azoulay [7]	2004	SCCMFNA	14 item French	++	+/-	-
Yousefi [157]	2012	SCCMFNA	14 item Arabic	++	+/-	-
Johnson [140]	1998	SCCMFNA	14 item English	++	+	++
Damghi [133]	2008	SCCMFNA	14 item Arabic	++	++	+/-
Wasser [8]	2001	CCFSS	20 item English	++	++	++
Wasser [111]	2004	CCFSS	20 item English	++	+	++
Gajic [97]	2008	CCFSS	20 item English	++	++	++
Steel [98]	2008	CCFSS	20 item English	++	+/-	++
Roberti [86]	2010	CCFSS	20 item English	++	++	++
Hickman [115]	2010	CCFSS	20 item English	++	+	++
Hickman [83]	2012	CCFSS	20 item English	++	+	++
Huffines [120]	2013	CCFSS	20 item English	++	+	++
Brown [95]	2008	CCFSS	20 item Arabic	++	+/-	++
Karlsson [85]	2011	CCFSS	20 item Swedish	++	+	++
Dowling [102]	2005	FS-ICU	37 item English	++	-	?
Dowling [110]	2005	FS-ICU	37 item English	++	-	-
Heyland [106]	2001	FS-ICU	34 item English	++	+	++
Heyland [6]	2002	FS-ICU	34 item English	++	+/-	+
Heyland [104]	2003	FS-ICU	34 item English	++	+/-	+
Heyland [105]	2003	FS-ICU	34 item English	++	+/-	+
Gerstel [93]	2008	FS-ICU	34 item English	++	+/-	++
Kaufer [94]	2008	FS-ICU	34 item English	++	+/-	++
Kross [113]	2009	FS-ICU	34 item English	++	+/-	++
Curtis [130]	2011	FS-ICU	34 item English	++	+/-	++
Hunziker [146]	2012	FS-ICU	34 item English	++	+/-	++
LeClaire [121]	2005	FS-ICU	34 +2 item English	++	+/-	++
Stricker [99]	2007	FS-ICU	34 item German	++	+/-	++
Gries [96]	2008	FS-ICU	34 item German	++	+/-	++
Stricker [91]	2009	FS-ICU	34 item German	++	+/-	++
Stricker [131]	2011	FS-ICU	34 item German	++	+/-	++
Jongerden [51]	2013	FS-ICU	34 item Dutch	++	++	++
Shelton [161]	2010	FS-ICU	26 item modified English	++	-	-
Moore [160]	2012	FS-ICU	26 item modified English	++	+/-	-
Wall [100]	2007	FS-ICU	24 item English	++	++	++

Appendix A. (cont.)

Author	Year	Instrument	Version	Level of Evidence A. Literature	B.Sufficient Detail	C. Validity/ Reliability
Wall [4]	2007	FS-ICU	24 item English	++	++	++
Jacobowski [87]	2010	FS-ICU	24 item English	++	+/-	++
Henrich [84]	2011	FS-ICU	24 item English	++	+/-	++
Lewis-Newby [127]	2011	FS-ICU	24 item English	++	++	++
Dodek [141]	2012	FS-ICU	24 item English	++	+/-	+/-
Osborn [148]	2012	FS-ICU	24 item English	++	++	++
Shaw [147]	2013	FS-ICU	24 item English	++	+/-	++
Higginson [149]	2013	FS-ICU	24 item English	++	+/-	++
Khalaila [153]	2013	FS-ICU	24 item Hebrew	++	+	++
Schwarzkopf [159]	2013	FS-ICU	24 item German	++	++	++
Gerasimou-Angelidi [150]	2013	FS-ICU	24 item Greek	++	+	+/-
Dalisay-Gallardo [158]	2012	FS-ICU	24 item Fillipino	++	++	++
McDonagh [103]	2004	QODD-comm	5 item English	+	+	+
White [122]	2007	QODD-comm	5 item English			
Myhren [136]	2004	Myhren	78 item Norwegian	+	+/-	-
Myhren [129]	2011	Myhren	29 item Norwegian	++	+/-	++
Fox-Wasylyshyn [117]	2005	Family members perception of nurses roles	14 item English	+/-	+	+
Stapleton [101]	2006	QOC	7 item English	+/-	+	+/-
Liddle [158]	1988	Liddle	10 item, English	-	-	-
Dockter [108]	1988	Dockter	44 item English	+/-	-	-
Dixon [112]	1997	Dixon	12 item English	+/-	+	-
Malacrida [140]	1998	Malacrida	43 item	+/-	+	-
Keenan [139]	2000	Keenan	English, not listed	+/-	-	-
Roland [151]	2001	Roland	Not listed	+/-	-	-
Deitrick [118]	2005	Deitrick	18 item English	+/-	+	-
Kirchhoff [137]	2002	Kirchhoff	2 item English	-	-	-
Kjerulf [134]	2005	Kirchhoff	9 item English	+/-	-	-
Humble [144]	2009	Humble	10 item English	+/-	+	-
Whitcomb [156]	2010	Whitcomb	19 item English	+/-	+	-
Cheung [89]	2010	Cheung	Undescribed	-	-	-
Keenan [133]	2010	FNQ	9 item English	+/-	-	-
Sundararajan [126]	2012	Sundararajan	10 item English	+/-	+	-
Cuthbertson [107]	2000	Cuthbertson	18 item English	++	+	-
Klink [88]	2010	Cuthbertson	26 item Modified Dutch version	+	++	-
Kutash [149]	2007	Interviews	English, not listed	-	+	-
Sacco [164]	2009	Sacco	7 item English	+/-	-	++
Nelson [132]	2010	Interview	32 item English	+/-	++	-
Siddiqui [128]	2011	Siddiqui	25 item Pakistani	+/-	+	-

Appendix B. Psychometric criteria of level I tools to assess family satisfaction with intensive care

					Validity		Reliability					
Author	**Year**	**Instrument**	**Version**	**Sample size**	**Content face**	**Construct validity of scale/subscales**	**Internal consistency**	**Interrater / test-retest**	**Measures of central tendency**	**Sensitivity**	**Respon-siveness**	**Time to administer**
Chartier [66]	1989	CCFNI	48 item French	+	+	0	0	0	0	0	0	unknown
Coutu-Wakulszyk [65]	1990	CCFNI	48 item French	+	+	0	+	0	0	0	0	25 min
Rukholm [58]	1991	CCFNI	46 item French + English	+	+	0	+	0	0	0	0	unknown
Rukholm [78]	1991	CCFNI	46 + 2 item English	+	+	0	0	0	0	0	0	unknown
Rukholm [56]	1992	CCFNI	46 + 2 item English	-	+	+	+	0	+/-	0	0	unknown
Daley [77]	1984	CCFNI	46 item English	-	+	0	0	0	0	0	0	unknown
Lynn-McHale [67]	1988	CCFNI	46 item English	-	+	0	+	0	0	0	0	unknown
Molter [69]	1979	CCFNI	45 item English	-	+	0	0	0	0	0	0	20-60 min.
Rodgers [68]	1983	CCFNI	45 item English	-	+	0	+	0	0	0	0	20-60 min.
Leske [5]	1986	CCFNI	45 item English	-	+	0	+	0	0	0	0	30 min
Macey [59]	1991	CCFNI	45 item English	-	+	0	0	+	0	0	0	unknown
Leske [60]	1991	CCFNI	45 item English	+	+	+	0	0	0	0	0	unknown
Koller [61]	1991	CCFNI	45 item English	-	+	0	0	0	+/-	0	0	unknown
Kahn [55]	1992	CCFNI	45 item English	-	+	0	0	0	0	0	0	unknown
Kleinpell [57]	1992	CCFNI	45 item English	+	+	0	+	0	0	0	0	unknown
Engli [53]	1993	CCFNI	45 item English	-	+	0	+	0	0	0	0	unknown
Lopez-Fagin [51]	1995	CCFNI	45 item English	0	+	0	0	0	0	0	0	unknown
Mendonca [47]	1998	CCFNI	45 item English	-	+	0	0	0	0	0	0	unknown
Higgins [75]	1999	CCFNI	45 item English	-	+	0	0	0	0	0	0	unknown
Hunsucker [45]	1999	CCFNI	45 item English	-	+	0	0	0	+/-	0	0	unknown
Hinkle [32]	2009	CCFNI	45 item English	+	+	0	+	0	+/-	0	0	unknown
Kinrade [116]	2009	CCFNI	45 item English	-	+	0	0	0	+/-	0	0	unknown
Bailey [90]	2010	CCFNI	45 item English	-	+	0	0	0	+/-	0	0	unknown
Hinkle [114]	2011	CCFNI	45 item English	+	+	0	-	0	+/-	0	0	30 min
Noor Siah [81]	2012	CCFNI	45 item English	+	+	0	0	0	+/-	0	0	unknown
Obringer [124]	2012	CCFNI	45 item English	-	+	0	0	0	+/-	0	0	unknown
Warren [52]	1993	CCFNI + NMI	90 item English	-	+	0	0	0	0	0	0	unknown
Kosco [39]	2000	CCFNI + NMI	90 item English	-	+	0	0	0	+/-	0	0	30 min
Bijttebier [43]	2000	CCFNI	45 item Dutch	+	+	+/-	-	0	+/-	0	0	unknown
Bijttebier [40]	2001	CCFNI	45 item Dutch	+	+	0	0	0	+/-	0	0	unknown

Appendix B. (cont.)

					Validity		Reliability					
Author	**Year**	**Instrument**	**Version**	**Sample size**	**Content face**	**Construct validity of scale/subscales**	**Internal consistency**	**Interrater / test-retest**	**Measures of central tendency**	**Sensitivity**	**Respon-siveness**	**Time to administer**
Delva [74]	2002	CCFNI	45 item Dutch	+	+	0	0	0	+/-	0	0	unknown
Tin Mi-kuen [44]	1999	CCFNI	45 item Chinese	-	+	0	0	+	+/-	0	0	unknown
Lee [42]	2000	CCFNI	45 item Chinese	-	+	0	0	0	+/-	0	0	unknown
Leung [41]	2001	CCFNI	45 item Chinese	-	+	0	-	0	+/-	0	0	unknown
Chiu [76]	2004	CCFNI + C-SAI	45 item Chinese	-	+	0	0	0	0	0	0	unknown
Chien [35]	2005	CCFNI	45 item Chinese	+	+	+	+	0	+/-	0	0	unknown
Chien [36]	2006	CCFNI	45 item Chinese	-	+	0	+	0	+/-	0	+	unknown
Al Hassan [38]	2004	CCFNI	45 item Arabic	+	+	0	+	0	+/-	0	0	unknown
Omari [33]	2009	CCFNI	45 item Arabic	+	+	0	+	0	+/-	0	0	unknown
Al-Mutair [119]	2013	CCFNI	45 item Arabic	+	+	0	+	0	+/-	0	+/-	unknown
Moreau [80]	2004	CCFNI (RCT)	45 item French	+	0	0	0	0	0	0	0	unknown
Garrouste-Orgeas [109]	2010	CCFNI	45 item French	+	0	0	0	0	0	0	0	unknown
Hoghaug [82]	2011	CCFNI	45 item Swedish	+	+	0	-	0	+/-	0	0	unknown
Chatzaki [125]	2012	CCFNI	45 item Greek	+	+	0	0	0	+	0	+/-	unknown
Burr [46]	1998	CCFNI	43 item English	+	+	0	0	0	+/-	0	0	unknown
Fumis [34]	2006	CCFNI	43 item Portugese	+	+	0	-	0	0	0	0	unknown
Freitas [73]	2007	CCFNI	43 item Portugese	-	+	0	-	-	+/-	0	0	unknown
Fumis [70]	2008	CCFNI	43 item Portugese	+	+	0	0	0	0	0	0	unknown
Fumis [92]	2009	CCFNI	43 item Portugese	+	+	0	0	0	0	0	0	unknown
Zazpe [48]	1997	CCFNI	34 item Spanish	-	0	0	0	0	0	0	0	unknown
Forrester [63]	1990	CCFNI	30 item English	-	+	0	+	0	0	0	0	unknown
Price [62]	1991	CCFNI	30 item English	+	+	0	+	0	0	0	0	unknown
Murphy [79]	1992	CCFNI	30 item English	-	+	0	+	0	0	0	0	unknown
Quinn [49]	1996	CCFNI	30 item English	+	+	0	0	0	0	0	0	16 min
Quinn [50]	1996	CCFNI	30 item English	+	+	0	0	0	+/-	0	0	16 min
Gelling [72]	1999	CCFNI	30 item English	-	+	0	0	0	0	0	0	unknown
Maxwell [71]	2007	CCFNI + NMI	60 item English	-	+	-	+	0	0	0	0	20-30 min
Halm [64]	1990	CCFNI	15 item English	+	+/-	0	0	0	0	0	0	unknown
Henneman [54]	1992	CCFNI	15 item English	+	+/-	0	+	0	+/-	0	0	unknown
Auerbach [37]	2005	CCFNI	14 item English	-	0	0	+	0	+/-	0	0	unknown
Azoulay [137]	2001	SCCMFNA	14 item French	+	0	0	0	0	0	0	0	unknown

Appendix B. (cont.)

					Validity		Reliability						
Author	**Year**	**Instrument**	**Version**	**Sample size**	**Content face**	**Construct validity of scale/subscales**	**Internal consistency**	**Interrater / test-retest**	**Measures of central tendency**	**Sensitivity**	**Respon-siveness**	**Time to administer**
Azoulay [143]	2003	SCCMFNA	14 item French	+	+	0	0	0	0	0	0	unknown
Azoulay [7]	2004	SCCMFNA	14 item French	+	+	0	0	0	0	0	0	unknown
Yousefi [157]	2012	SCCMFNA	14 item Arabic	-	0	0	0	0	0	0	0	unknown
Johnson [140]	1998	SCCMFNA	14 item English	+	0	-	0	+	0	0	0	unknown
Damghi [133]	2008	SCCMFNA	14 item Arabic	+	+	0	-	-	0	0	0	unknown
Wasser [8]	2001	CCFSS	20 item English	+	+	+	+	0	0	0	0	unknown
Wasser [111]	2004	CCFSS	20 item English	+	+	+	-	0	0	0	0	unknown
Gajic [97]	2008	CCFSS	20 item English	+	+	+	-	0	0	0	0	unknown
Steel [98]	2008	CCFSS	20 item English	+	+	+	+	0	0	0	0	unknown
Roberti [86]	2010	CCFSS	20 item English	-	+	+	+	0	+/-	0	0	unknown
Hickman [115]	2010	CCFSS	20 item English	+	+	+	-	0	0	0	0	unknown
Hickman[83]	2012	CCFSS	20 item English	+	+	+	-	0	0	0	0	unknown
Huffines [120]	2013	CCFSS	20 item English	-	+	+	+	0	0	0	+/-	unknown
Brown [95]	2008	CCFSS	20 item Arabic	-	+	0	+	0	0	0	0	unknown
Karlsson [85]	2011	CCFSS	20 item Swedish	-	+	0	0	0	0	0	0	unknown
Dowling [102]	2005	FS-ICU	37 item English	+	+	-	-	0	+/-	0	-	unknown
Dowling [1110]	2005	FS-ICU	37 item English	+	+	0	0	0	+/-	0	0	unknown
Heyland[106]	2001	FS-ICU	34 item English	-	+	0	+	+	+/-	0	0	unknown
Heyland [6]	2002	FS-ICU	34 item English	+	+	0	0	0	0	0	0	unknown
Heyland [104]	2003	FS-ICU	34 item English	+	+	0	0	0	0	0	0	unknown
Heyland [105]	2003	FS-ICU	34 item English	+	+	0	0	0	0	0	0	unknown
Gerstel [93]	2008	FS-ICU	34 item English	+	+	0	0	0	0	0	0	unknown
Kaufer [94]	2008	FS-ICU	34 item English	-	+	0	0	0	0	0	0	unknown
Kross [113]	2009	FS-ICU	34 item English	+	+	0	0	0	0	0	0	20 min
Curtis [130]	2011	FS-ICU	34 item English	+	+	0	0	0	0	0	0	unknown
Hunziker [146]	2012	FS-ICU	34 item English	+	+	0	0	0	0	0	0	unknown
LeClaire [121]	2005	FS-ICU	34 + 2 item English	-	+	0	+	0	0	0	0	unknown
Stricker [99]	2007	FS-ICU	34 item German	+	+	+/-	+	-	0	0	0	unknown
Gries [96]	2008	FS-ICU	34 item German	+	+	0	0	0	0	0	0	unknown

Appendix B. (cont.)

Author	Year	Instrument	Version	Sample size	Validity		Reliability			Sensitivity	Respon-siveness	Time to administer
					Content face	Construct validity of scale/subscales	Internal consistency	Interrater / test-retest	Measures of central tendency			
Stricker [91]	2009	FS-ICU	34 item German	+	+	0	0	0	0	0	0	unknown
Stricker [131]	2011	FS-ICU	34 item German	+	+	0	0	0	+/-	0	0	unknown
Jongerden [51]	2013	FS-ICU	34 item Dutch	+	+	0	+	0	0	0	+	unknown
Shelton [161]	2010	FS-ICU	26 item modified English	+	+	0	0	0	+/-	0	+/-	unknown
Moore [160]	2012	FS-ICU	26 item modified English	+	+	0	0	0	+/-	0	+/-	unknown
Wall [100]	2007	FS-ICU	24 item English	+	+	+/-	+	0	+/-	0	0	unknown
Wall [4]	2007	FS-ICU	24 item English	+	+	0	0	0	0	0	+	unknown
Jacobowski [87]	2010	FS-ICU	24 item English	+	+	0	0	0	0	0	0	unknown
Henrich [84]	2011	FS-ICU	24 item English	+	+	0	0	0	0	0	0	unknown
Lewis-Newby [127]	2011	FS-ICU	24 item English	+	+	0	0	0	+/-	0	0	unknown
Dodek [141]	2012	FS-ICU	24 item English	+	+	0	0	-	0	0	0	unknown
Osborn [148]	2012	FS-ICU	24 item English	+	+	0	0	0	0	0	0	unknown
Shaw [147]	2013	FS-ICU	24 item English	+	+	0	0	0	+/-	0	+/-	unknown
Higginson [149]	2013	FS-ICU	24 item English	+	+	0	0	0	0	0	+/-	unknown
Khalaila [153]	2013	FS-ICU	24 item Hebrew	-	+	0	+	0	+/-	0	0	30 min
Schwarzkopf [159]	2013	FS-ICU	24 item German	+	+	0	+	+	0	+/-	0	unknown
Gerasimou-Angelidi [150]	2013	FS-ICU	24 item Greek	+	+	0	0	0	+/-	0	0	unknown
Dalisay-Gallardo [158]	2012	FS-ICU	24 item Filipino	-	+	0	+	0	+/-	0	0	unknown

Sample size and psychometric properties of well-established assessment tools. To improve legibility, sensitivity was not included in the table since scarcely and results indicating sensitivity was reported.

Sample size: '+' = $n > 100$, '-' = $n < 100$. Content/face validity: '+' = assesses intended construct, '+/-' = does not match the original tool, but assesses intended construct, '-' = does not match the original tool and does not assess intended construct. Construct validity: '+' = after factor analysis Cronbach $\alpha > 0.70$ for all factors, '+/-' = after factor analysis, most factors Cronbach $\alpha > 0.70$, but not all, '-'= factor analysis shows poor quality with most factors Cronbach $\alpha < 0.70$. Internal consistency: '+' = Cronbach α, Spearman Brown or Split Half > 0.80 of the scale and subscales both, '+/-' = Cronbach α is > 0.80 for either the scale or the subscales, but not both, '-' = Cronbach $\alpha < 0.80$ for the scale and the subscales

Reliability (inter-rater/test-retest): '+' = K > 0.61 or Pearson's $r > 0.80$, '-' = K < 0.61; Pearson's $r < 0.80$, or proven change of scores when filled in by junior versus senior staff.

Measures of central tendency: '+' = mean and SD for all subscores, no ceiling or floor effect, '+/-' = Only mean and SD described or no floor and ceiling effects described, '-' = No mean and SD described. Responsiveness: '+' = scale shows to be able to detect differences over timer or between before and after measurements, '+/-' = differences in before and after intervention scores were found on some items, but no differences were demonstrated on the whole scale or on a domain, '-' = scale is not able to show differences over time, or between before and after measurements. '0' = no data =available.

Chapter 10

Summary and General Discussion

Introduction

Healthcare systems have become more complex due to greater use of new technologies and a multitude of interventions. [1] Therefore, patients are more prone to errors and incidents during their hospital stay. In the last twenty years more attention has been paid to increase patient safety not only by healthcare professionals but also by healthcare organizations to avoid unintended harm to patients. Assessing the quality of healthcare systems is complex due to the unpredictable nature of health care. A framework was developed to assess quality of care. This framework consists of four categories namely structure, process, outcome and culture. By measuring 'structure' we know how the care is organized, the 'process' measures what health professionals do for their patients, and 'outcome' measures what happened to people in terms of their health. [2,3] Additionally, 'culture' evaluates the context in which care is delivered to patients. [4]

Improving the quality of care has to be done in a structured way rather than disorganized and data driven, rather than based on informal observations, anecdotes and personal experiences. This means that improving patient safety is a continuous process of analysis, monitoring and evaluation, which eventually benefits the individual patients directly. [5] Evaluating safe care of acutely ill patients should be carried out on several levels. Firstly, the focus should be on the four pillars of the quality framework (structure, process, outcome and culture) and their interrelationship. Secondly, the Plan-Do-Check-Act (PDCA) cycle should be used for continuous improvement initiatives since it provides a structure for assessing the value of improvement measures in a iterative loop and thereby it is an ultimate tool for assessing the quality on ward and department level. [6] Thirdly, since communication is an overriding theme in quality of care and patient safety, major attention should be given to measure communication and improve and structure communication, particularly communication during the most critical time points of a patient, for example during clinical rounds or during transportation. Finally, since satisfaction of the patient and his or her relatives with the delivered care is still an ultimate measure of quality of care, satisfaction should at all times receive our undivided attention.

In this thesis we addressed the above outlined approaches to measure quality of care and assessed the available tools to measure and monitor quality of care in critically ill patients on the hospital ward and intensive care.

In this final chapter we describe the main findings of the studies that are presented in this thesis and discuss the study results. Subsequently we describe the implications of the findings for clinical practice and future research.

Main Findings

In **Chapter 2** we described the protocol to study the effectiveness of the sequential implementation of the Rapid Response Systems (RRS) in 12 Dutch hospitals. Four clinical wards (two surgical and two medical) were included per hospital. The study consisted of a before period followed by two study phases. The first five months before the introduction of the RRS, the "before period", clinical endpoints were collected as part of a baseline assessment. The RRS was implemented in two steps. In the first step, two tools were introduced during 7 months for early detection of the deteriorating patient: the Modified Early Warning Score (MEWS) and the Situation-Background-Assessment-Recommendation (SBAR) for structured communication. After these seven months the Rapid Response Team was implemented for 17 months. The last five months of the RRT implementation phase, named "final RRT" period, were used for comparison with the "before period". The primary endpoint was defined as the composite endpoint of cardiopulmonary arrest, unplanned ICU admission, or death on the included nursing wards.

The results of the COMET study were shown in **Chapter 3**. In total, 166,569 patients were included, representing 1,031,172 hospital admission days. The primarily analysis focused on the comparison of the prospectively gathered clinical outcomes between the before period and the final RRT period. The results were corrected for case mix variables and for specific hospital related confounding variables including contribution of each hospital and differences between before and the final RRT period. The composite endpoint was significantly reduced after implementation of the RRS, adjusted odds Ratio (OR) 0.847 (95% CI, 0.725-0.9789; p=0.036). Cardiopulmonary arrests and in-hospital mortality were also significantly reduced, OR 0.607 (95% CI, 0.393-0.937; p=0.018) and OR 0.802 (95% CI, 0.644-1.0; p=0.05) respectively. Unplanned ICU admission showed a declining trend OR 0.878 (95% CI, 0.755-1.021; p=0.092). No differences between the two periods were found regarding patient demographics or disease (severity) markers. Only for death, the mean age in the final RRT period was 75.0 (14) compared to 76.8 (12) in the before period, p=0.021. The call rate in the RRT implementation phase in which the RRT was available was 6.8/1,000 (95% CI, 6.2-7.5) admitted patients and increased in the final RRT period to 7.3/1,000 (95% CI, 6.4-8.3).

In **Chapter 4** we reported the results of the effectiveness of the sequential implementation of the Rapid Response Systems (RRS) when the outcome "all-cause mortality" is replaced by "death without limitation of medical treatments (LOMT)" and how these LOMT orders change over time. We repeated the analysis in the study population described in chapter 3. We found that, installation of a RRS decreased the risk of death in the patients without an LOMT even to a greater extent than in the whole

population: in the original study studying the effect of a RRS on all-cause mortality the adjusted OR was 0.865 (95% CI 0.77-0.98) and when choosing death without LOMT as endpoint the OR was 0.557 (95% CI, 0.40-0.78). A total of 3,408 patients died before discharge. At time of death, 2,910 (85%) had an LOMT order. In both medical and surgical patients, most of patients who subsequently died already had already a LOMT at hospital admission. Median time between last LOMT order and death was 3 days in patients with Code C and 1 day with Code D. After introduction of the RRT the delta time between last change in LOMT status and death was 2 days (IQR 1-5) in the before period and 1 day (IQR 1-4) in the final RRT period (NS).

In **Chapter 5** we reported the level of satisfaction of nurses and physicians with the introduction of the RRS in Dutch hospitals. Satisfaction with implementation of the RRS was generally higher at 14 months than at 7 months and also higher in respondents working on surgical versus medical wards. In a multivariate analysis, independent predictors of satisfactions were longer experience with the RRS, support of the RRS by local ward management, and having a RRT considered to be 'open' and 'approachable'. From this questionnaire we concluded that healthcare workers generally are very satisfied with RRTs in the hospital. This is an argument in favour of implementing the RRTs in hospitals.

In **Chapter 6** we described a prospective before-after study in two University hospitals in the Netherlands to estimate the effect of implementation of daily goals in daily care planning on length of stay in the ICU. The implementation of daily goals was not associated with a change in ICU length of stay or hospital length of stay when corrected for confounders. The percentage of daily goals that was "successfully met" was 79% in the first study period and 77% in the second study period. Daily goals "not met with a documented reason" increased in the after period from 3% to 15 %, RR 0.25 (95% CI, 0.21-0.30). Daily goals "not met without a documented explanation" decreased from 18% to 7% RR 2.4 (95% CI, 2.15-2.67).

In **Chapter 7** we described the development of a checklist to increase patient safety of intra-hospital transport (IHT) in critically ill patients. A three step-approach was used to develop a checklist which consisted of a systematic search for published IHT guidelines and checklists, prospectively collected IHT incidents and structured interviews with ICU physicians and ICU nurses about their experiences with IHT. In the literature, most checklist items and recommendations were focused on the pre-transport phase. Collected incidents were frequently related to patient physiology and equipment malfunction and occurred most often during transport. This approach resulted in a generally applicable checklist which is a framework to guide physicians and nurses through intra-hospital transport and provides a continuity of care to enhance patient safety. We piloted the checklist and nurses were in generally positive about the

use of the checklist; it provided a framework, and improved communication, and the fill in time was only 4.5 minutes per phase.

In a systematic review in **Chapter 8** we described the different incident reporting systems (IRSs) that have been used on the adult ICU. We found that nearly all IRSs used different definitions for incidents, errors and complications and were applied in different settings which made direct comparison difficult. With respect to the iterative PDCA cycles of planning, measuring, analyzing, implanting changes and re-assessing, data input and data collection were well established. The other two phases, data analysis, formulation of improvement measures and feedback with reassessment, needed to be given more attention before an IRS can effectively contribute to improve patient safety and quality of care. This systematic review showed that it is not possible yet to establish an 'optimal' IRS to choose for use in daily practice.

In **Chapter 9** we described in a systematic review of the available questionnaires to measure family satisfaction in the adult ICU and their psychometric properties. To evaluate family satisfaction in the ICU, it is important to use valid instruments to obtain proper and high-quality information. Twenty-seven tools were identified of which four questionnaires were of overall good quality. The quality of the four questionnaires was assessed by further examination of the psychometric properties and sample size of the studies. After analysis we concluded that the CCFNI which measures *needs* and the FS-ICU which measures *satisfaction* were the most reliable and valid with respect to their psychometric properties.

General discussion and future directives

Creating a safe and effective environment for patients in hospitals can be accomplished by health care providers by performing processes that aim to achieve patient safety and avoid processes that are predisposing towards affecting harm. Measuring and monitoring the quality of care of critically ill patients can be executed in different ways which aim to improve the safety of the patient.

The effectiveness of the implementation of an RRS worldwide to reduce serious adverse events has showed no improvement in the rates of cardiac arrest, unplanned ICU admission and death. Possible explanations for the negative results were lack of power and contamination of control hospitals. [7,8] The COMET study was executed in Dutch hospitals at the time that hospitals were mandated to implement an RRT. Due to the mandated nature we choose for the most appropriate study design with correction for hospital and multiple patients confounders. In our study we showed a positive effect, a reduction of 15% on the incidence of cardiac arrests, unplanned ICU admission and death. Nurses and physicians were only trained in the MEWS phase and in the RRT

implementation phase. It is unsure how the compliance of the MEWS/SBAR was during the implementation phases. It is possible that a more intensive training program and evaluating and discussing RRT calls with the involved nurses and physicians could have led to a better outcome. Measuring non-compliance is a time consuming and intensive investment but implementing the MEWS in electronic patient charts gave a real insight how the compliance is. The low call rate of the RRT members suggests in our study that the RRS was not fully implemented in the hospitals. Possible explanations are that this has to do with the hospital culture factors, insufficient training, change of staff documenting subsequent vital signs or the willingness to call an RRT. [9] Moreover, we measured during the implementation of an RRT the satisfaction of physicians and nurses. The satisfaction of physicians and nurses after the implementation of an RRT increased over time. We established that independent factors for this higher satisfaction were associated with the attitude of the members of the RRT and the support by the ward staff. Despite the limitations of the study design the COMET study has contributed to increased knowledge about the RRSs.

Communication is one of the corner stones in patient safety and quality of care. A method to improve the commination an insight in patient specific goals, within a team is to implement in clinical practice the formulation of daily goals, to be assessed within the team during clinical rounds. In our study where daily goals were introduced into daily care planning on the ICU, we showed that physicians documented more frequently in the medical chart the reason why a daily was not met. Daily goals have been proven in other studies to due improve the communication between healthcare professionals and to clarify the tasks. [10-14] Although in other studies a reduction was shown of the ICU length of stay by the introduction of daily goals. We could not confirm this in our study and a possible explanation for this is that ICU-LOS already decreased in the past decades.

Protocols and checklists are helpful in the reduction of patient harm because of the improved standardization of care. Checklists are tools that can provide guidance to professionals in a certain task. Furthermore, they have the purpose for reducing errors during the task and translate evidence-based - and best practices into a list of actions. By developing an IHT checklist which covered all the three phases of IHT, we developed a tool which resulted in a framework to guide physicians and nurses through intra-hospital transport to enhance patient safety. We specifically asked ICU physicians and ICU nurses their experiences with transport. This knowledge is of value not only to develop the checklist but also in the implementation of it in daily practice. We did not establish in this study the effect of the checklist on reduction of incidents or patient outcomes. However, the use of checklist has been proven effective in high-intensity field of medicine in the reduction of complications [15] and processes of care. [16,17] Further studies should focus on the effect of the implementation of the checklist on patient

outcomes and occurrence of incidents and also on the satisfaction of healthcare professionals in the use of the checklist during transport.

A strategy to evaluate the process of care is the introduction of an incident reporting systems which provides organizations with a tool to identify hazards in clinical care and to understand where the system fails. Although incident reporting underestimates the true rate of the incidents it is useful to collect them. By reporting incidents it will give the healthcare professionals the opportunity to report deficiencies in the provided care. We could not establish the ultimate IRS due to the multitude of existing IRSs. With respect to the PDCA cycle the *Plan-Do* phase was well established in most of the IRSs while on the other hand more attention needs to be given to the *Check-Act* phase. The Check-Act phase included giving feedback and install improvement measures. Lack of feedback is one of the main barriers of healthcare professionals to report incidents. An incident reporting system is successful if feedback is given to the healthcare professionals from the message that the incident was received until the improvement measure that is installed. [18,19] Future research should focus on whether the implementation of an IRS will improve patient safety and measure quality of care.

Another form to get feedback on the process of care is to ask patients and family members how they judge the delivered care. Family members of the ICU patient are the most reliable persons to get objective information of the delivered care because the ICU patient cannot make decisions themselves due to their illness and not always have a clear recollection of the events and delivered care during their ICU stay. If patients were asked to give their opinion after they were discharged of the ICU there is a chance that the obtained information is not objective because the memories of the ICU will be mixed with the memories of the hospital ward. Therefore, we gave an overview of the available questionnaires to establish needs and/or satisfaction with care from the family members to collect objective information about the delivered care on the ICU. We found four instruments that reported psychometric properties and were of good quality. Of these four, two instruments had the best psychometric properties. One of the questionnaires measures needs and the other measures satisfaction. Measuring needs will not provide information about satisfaction of the family members and vice versa. So, measuring satisfaction of the family members with the provided care it is of interest that ICUs establish what they want to know of the family members. Future research should not only focus whether the level of satisfaction of family members corresponds with the established needs but should also try to the level of patient satisfaction and compare this to family satisfaction.

The tools that we explored in this thesis have all the potential to measure the quality of care and to improve patient safety. Insight in the process-of-care measures is acceptable for caregivers because they can influence the process with the intention to

improve patient outcomes. Therefore, healthcare professionals should be involved in interactive processes to develop interventions within their own situation. It is better to start these processes on a small scale because it is sometimes easier to initiate quality initiatives bottom up instead of reinforcing a top down intervention. [20] Overall, we can state that communication and the use of the PDCA cycle are both important aspects leading to doing the right thing at the right time.

Lack of communication between physicians and nurses creates situations where incidents and errors can occur, delivered care is inefficient and frustration rules among them. Improving communication between nurses and physicians is essential but also hard to put into practice. Communication is not only the verbal form but also the non-verbal and written form. A good collaboration between nurses and physicians leads to continuous improvement in decision-making. [21] Components of good teamwork between nurses and physicians does not only consist of good communication but also a non-punitive environment, clear roles and tasks for team members, shared responsibilities and clear decision-making procedures. [22] An effective strategy in enhancing teamwork and reducing risks is the use of standardized tools and behaviors. The tools described in this thesis are helpful to structure communication, to ensure accuracy and implement quality improvement strategies.

The use of the PDCA cycle is one of the strategies to make a positive change in health care processes. This tool can be used for rapid cycle improvement and establishes a functional relationship between changes in processes and outcomes. [23] Rapid response systems, incident reporting system and family satisfaction questionnaire are tools which were described in this thesis that can be used to evaluate the care.

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Chapter 11

Nederlandse Samenvatting

Introductie

De gezondheidszorg is steeds complexer geworden door het gebruik van nieuwe technologieën en door een toename van het aantal interventies. Hierdoor zijn patiënten kwetsbaarder geworden voor het optreden van fouten en incidenten gedurende hun ziekenhuisverblijf. In de laatste 20 jaar is steeds meer aandacht gekomen voor het verbeteren van de patiënt veiligheid niet alleen bij de zorgprofessionals maar ook bij gezondheidszorg organisaties om ongewenste schade bij de patiënt te voorkomen. Het beoordelen van de kwaliteit van de gezondheidszorg is complex vanwege het onvoorspelbare karakter van de gezondheidszorg. Om de kwaliteit van zorg te kunnen meten zijn indicatoren vastgesteld. Deze indicatoren zijn opgedeeld in 4 categorieën namelijk structuur, proces, uitkomst en cultuur. Door het meten van 'structuur' weten we hoe de zorg is georganiseerd en door het meten van het 'proces' weten we wat de zorgprofessionals doen voor hun patiënt terwijl de 'uitkomst' meet wat het effect is op de patiënt. Met de indicator 'cultuur' wordt geëvalueerd de context waarin de zorg is gegeven aan de patiënt.

Het verbeteren van de kwaliteit van zorg moet gedaan worden op een gestructureerde manier in plaats van ongeorganiseerd, sturend op getallen en uitsluitend gebaseerd op informeel verkregen observaties, anekdotes en persoonlijke ervaringen. Dit betekent dat het verbeteren van de patiënt veiligheid een continu proces is van het analyseren, monitoren en evalueren waarbij dit zo direct mogelijk tot voordeel is voor de individuele patiënt.

Of de zorg voor een acuut zieke patiënt veilig is, moet op verschillende niveaus worden geëvalueerd. **Ten eerste**, de focus moet zijn op de vier pijlers van het kwaliteit raamwerk (structuur, proces, uitkomst en cultuur) en hun onderlinge relaties. **Ten tweede**, de Plan-Do-Check-Act (PDCA) cyclus moet worden gebruikt voor continue verbeter-initiatieven aangezien de cyclus voorziet in een structuur voor het beoordelen van de waarde van de verbetermaatregelen in een herhaal cyclus. Hiermee is het een ultiem hulpmiddel voor het beoordelen van de kwaliteit van zorg op de afdeling en organisatie niveau. **Ten derde**, omdat communicatie een belangrijk en overkoepelend thema is in kwaliteit van zorg en patiëntveiligheid, is het van belang dat er veel aandacht gegeven wordt aan het meten van communicatie en het verbeteren van de structuur van deze communicatie vooral de communicatie gedurende de meest kritische momenten van de patiënt, bijvoorbeeld gedurende de visites en tijdens het transport. **Tot slot**, aangezien tevredenheid van de patiënt en zijn of haar familieleden met de geleverde zorg nog steeds een ultieme maatstaf is voor kwaliteit van zorg, dient tevredenheid te allen tijde onze onverdeelde aandacht te krijgen.

In dit proefschrift richten wij ons op alle hierboven beschreven pijlers om de kwaliteit van zorg te meten bij ernstige zieke patiënten op de verpleegafdeling en de intensive care. We bekijken welke instrumenten beschikbaar zijn om kwaliteit van zorg te meten en te evalueren en, waar mogelijk, bestuderen we wat het effect is van de verschillende instrumenten op de patiëntveiligheid en kwaliteit van zorg.

In dit laatste hoofdstuk beschrijven we de belangrijkste bevindingen van de studies die opgenomen zijn in dit proefschrift.

In **hoofdstuk 2** beschrijven wij het studie protocol van de Cost and Outcome analysis of Medical Emergency Teams (COMET studie) waarin de klinische effectiviteit van de opeenvolgende implementatie van verschillende onderdelen van een Spoed Interventie Systeem (SIS) in 12 Nederlandse ziekenhuizen wordt onderzocht. In deze studie werden vier verpleegafdelingen (twee chirurgisch en twee medische) geïncludeerd per ziekenhuis. De studie bevat een 'voormeting' die gevolgd wordt door een nameting met twee fases. Tijdens de eerste vijf maanden voor de introductie van het SIS, de 'voormeting', worden diverse eindpunten verzameld die onderdeel uitmaken van de nulmeting. Het SIS wordt daarna in twee fases geïmplementeerd. In de eerste fase (7 maanden) worden twee instrumenten geïntroduceerd om de vitaal bedreigde patiënt zo vroeg mogelijk te herkennen, namelijk de Modified Early Warning Score (MEWS) en het communicatie instrument de Situation-Background-Assessment-Recommendation (SBAR). Na deze 7 maanden wordt het Spoed Interventie Team (SIT) geïmplementeerd voor een periode van 17 maanden. De laatste 5 maanden van de SIT implementatie fase wordt de RRT fase genoemd en deze RRT fase wordt vergeleken met de 'voormeting'. Als primaire eindpunt is het gecombineerd eindpunt van een cardiopulmonaire reanimatie, ongeplande intensive care opname en mortaliteit op de geïncludeerde verpleegafdeling gebruikt om dit te analyseren.

De resultaten van deze COMET studie zijn in **hoofdstuk 3** beschreven. In totaal werden 166,569 patiënten geïncludeerd waarbij er sprake was van in totaal 1,031,172 opnamedagen. De primaire analyse betrof de vergelijking tussen de prospectieve 'voormeting' en de laatste 5 maanden van de SIT fase. De resultaten werden gecorrigeerd voor enkele case-mix variabelen evenals voor specifiek ziekenhuis confounders zoals de specifieke contributie van het ziekenhuis aan de resultaten. Het gecombineerde eindpunt (cardiopulmonaire reanimatie, ongeplande intensive care opname en mortaliteit op de geïncludeerde verpleegafdeling) kwam significant minder voor na de implementatie van het SIS gereduceerd, gecorrigeerde OR 0.847 (95% CI, 0.725-0.9789; p=0.036). Aanvullend werden de individuele eindpunten apart geanalyseerd. Cardiopulmonaire reanimatie en ziekenhuismortaliteit warden beiden significant gereduceerd, OR 0.607 (95% CI, 0.393-0.937; p=0.018) en OR 0.802 (95% CI,

0.644-1.0; *p*=0.05) respectievelijk. De ongeplande IC opnames lieten een duidelijk dalende trend zien, OR 0.878 (95% CI, 0.755-1.021; *p*=0.092). Geen verschil werd gevonden met betrekking tot patiënten demografie en ernst van de ziekte zoals gemeten door middel van de APACHE scores. Alleen voor overlijden was de gemiddelde leeftijd in de SIT fase 75.0 (14) lager dan in de voormeting 76.8 (12), *p*=0.021. Het aantal SIT oproepen per 1,000 opnames was 6.8/1,000 (95% CI, 6.2-7.5) in de eerste 12 maanden waarin het SIT beschikbaar was en steeg in de laatste 5 maanden naar 7.3/1,000 (95% CI, 6.4-8.3).

In **hoofdstuk 4** rapporteren we de resultaten van het effect van het vervangen van "overlijden door welke oorzaak dan ook" door "overlijden zonder afgesproken behandelbeperkingen" in een studie naar het effect van de implementatie van het SIS bij ziekenhuispatiënten en hoe deze behandelbeperkingen veranderen over de tijd. De originele data beschreven in hoofdstuk 3 hebben we opnieuw geanalyseerd. Het effect van het SIS op overlijden van alle patiënten (met en zonder behandelbeperking) was, zoals eerder beschreven risico verlagend met een gecorrigeerde OR 0.865 (95% CI 0.77-0.98). Het effect van het SIS op overlijden van patiënten die geen behandelbeperking hadden was nog sterker met een gecorrigeerde OR 0.557 (95% CI, 0.40-0.78). In totaal overleden 3,408 patiënten voordat zij werden ontslagen uit het ziekenhuis. Bij 2,910 (85%) van deze patiënten was er een behandelbeperking op het moment van overlijden. Bij zowel medische als chirurgische patiënten had het merendeel van de patiënten al een behandelbeperking op het moment van ziekenhuis opname. De mediane tijd van de laatste verandering van de behandelbeperking en het moment van overlijden was 3 dagen voor patiënten met een Code C en 1 dag voor patiënten met code D. Na de introductie van het Spoed interventie team het verschil in tijd tussen de laatste verandering van de behandelbeperking en overlijden was 2 dagen (IQR 1-5) in de voormeting en een mediaan van 1 (IQR 1-4) na de introductie van het SIT (niet significant). In **hoofdstuk 5** rapporten we de mate van tevredenheid van de verpleegkundigen en artsen met de introductie van het SIT in Nederlandse ziekenhuizen. Tevredenheid met de implementatie van het SIT was over het algemeen hoger na 14 maanden in vergelijking met de meting op 7 maanden en was eveneens hoger indien de respondenten werkten op de chirurgische verpleegafdeling in vergelijking met de medische verpleegafdeling. In een multivariate analyse waren, de onafhankelijke voorspellers van tevredenheid: langere ervaring met het SIT, ondersteuning van het SIT door de afdelingsmanagers en indien het SIT werd beschouwd als 'open' en 'aanspreekbaar'. Door deze vragenlijsten kunnen we concluderen dat de medewerkers over het algemeen zeer tevreden zijn met het SIT in het ziekenhuis. Dit is een argument in het voordeel van het invoeren van het SIT in ziekenhuizen.

In **hoofdstuk 6** geven wij een beschrijving van een prospectieve voor- en na meting in twee Universiteit ziekenhuizen in Nederland om vast te stellen wat het effect is van het implementeren het benoemen en vastleggen van doelen in de dagelijkse zorg op de duur van de IC opname. De implementatie van deze dagelijkse doelen was niet geassocieerd met een verandering in de duur van de IC opname indien er gecorrigeerd werd voor confounders. Het percentage van dagelijkse doelen die "gehaald waren met succes" was 79% in de eerste studie periode en 77% in de tweede studie periode. Dagelijkse doelen die "niet gehaald met een gedocumenteerde reden" namen toe in de laatste periode van 3% naar 15%, RR 0.25 (95% CI, 0.21-0.30). Dagelijkse doelen die "niet gehaald waren zonder een gedocumenteerde uitleg" namen af van 18% naar 7% RR 2.4 ((5% CI, 2.15-2.67).

In **hoofdstuk 7** beschrijven wij de ontwikkeling van een checklist om de veiligheid te verbeteren van ernstig zieke patiënten gedurende hun transport binnen het ziekenhuis. Een drie stappen aanpak is gebruikt om deze vragenlijst te ontwikkelen die bestaat uit (1) het systematisch zoeken van gepubliceerde transport richtlijnen en checklists, (2) prospectief verzamelen van incidenten die voorkwamen tijdens het transport en (3) het houden van gestructureerde interviews met IC artsen en IC verpleegkundigen over hun ervaringen met het transporteren van ernstig zieke patiënten. In de literatuur bleken de checklists onderdelen en aanbevelingen gefocust op de fase voor het transport. De verzamelde incidenten werden vaak gerelateerd aan de patiënten fysiologie en het uitvallen van apparatuur en kwamen het meest vaak voor gedurende het transport. Onze incidenten den de gehouden interviews wezen erop dat ook de fase na het transport ook een hele belangrijke fase is om patiëntveiligheid te vergroten. Onze aanpak heeft geresulteerd in een algemeen toepasbare checklist die een kader geeft om artsen en verpleegkundigen door het transport heen te leiden en voorziet in een continuïteit van zorg om ervoor te zorgen dat de patiëntveiligheid verbeterd wordt. We hebben deze checklist getest in de praktijk en de verpleegkundigen waren over het algemeen positief over het gebruik van de checklist, het gaf een kader, verbeterde de communicatie en de invultijd was slechts 4.5 minuut per fase.

In een systematische review in **hoofdstuk 8** beschrijven we de verschillende incident registratie systemen (IRS) die zijn gebruikt op volwassen intensive care. We hebben gevonden dat bijna alle IRS-en een verschillende definitie gebruiken voor incidenten, fouten en complicaties en dat deze IRS-en in verschillende omstandigheden werden gebruikt waardoor het moeilijk is om deze met elkaar te vergelijken. Met betrekking tot de Plan-do-check-act cyclus (planning, meten, analyseren, implementeren van veranderingen en herbeoordeling) blijkt dat de fase van 'gegevensinvoer' en 'data verzameling' het beste zijn ingesteld. De andere twee fasen, het 'analyseren van de data' en het 'formuleren van verbeteringen en het geven van feedback' met her-evaluatie van

de verbeteringen heeft meer aandacht nodig om ervoor te zorgen dat een IRS effectief kan bijdragen aan de het verhogen van de patiëntveiligheid en kwaliteit van zorg. Deze systematische review laat zien dat het niet mogelijk is om te komen tot een overall optimale IRS die gebruikt kan worden in de dagelijkse praktijk.

In **hoofdstuk 9** beschrijven wij een systematische review van de beschikbare vragenlijsten om de familietevredenheid te meten in de volwassen intensive care en de psychometrische eigenschappen van deze vragenlijsten. Om familie tevredenheid te evalueren in de IC is het belangrijk dat gebruik gemaakt wordt van een valide instrument om zo goed en hoog mogelijke kwalitatieve gegevens te verkrijgen. Zevenentwintig verschillende instrumenten werden geïdentificeerd waarvan vier vragenlijsten van goede kwaliteit werden gevonden. De kwaliteit van deze vier vragenlijsten werden verder beoordeeld door hun psychometrische eigenschappen en de steekproefomvang van deze studies te beoordelen. Na deze analyse concluderen wij dat twee vragenlijsten het meest betrouwbaar en valide waren wat betreft hun met psychometrische eigenschappen: de CCFNI voorziet het beste in het meten van de *behoefte* van de familie en de FS-ICU het beste de *tevredenheid* meet.

Appendices

Curriculum Vitae

List of publications

Dankwoord

Curriculum Vitae

Aleida Henriët (roepnaam: Anja) Reinders is op 27 juni 1971 geboren te Gramsbergen. In 1987 behaalde zij haar mavo-diploma bij het Rijksscholengemeenschap te Coevorden. Daarna startte zij bij het Morgenland College te Hoogeveen met de opleiding tot verpleegster (Middelbare Dienstverlenend en Gezondheidszorg Onderwijs, richting verpleging - mdgo-vp). Na het afronden van deze opleiding in 1990 ging zij op 1 januari 1991 werken als verpleegster in het Ziekenhuis Amstelveen. In juli 1991 vatte zij de verkorte A-inservice opleiding aan en heeft die in 19 maanden afgerond. Na haar diplomering werkte zij enkele jaren als verpleegkundige op de chirurgische afdeling. In 1997 volgde zij de brede basis ic-opleiding aan de Vrij Universiteit te Amsterdam welke zij in 1998 heeft afgerond. In 1999 trad zij in dienst bij het Leids Universitair Medisch Centrum, de eerste jaren als ic-verpleegkundige op de thoraxchirurgische intensive care, vanaf 2002 als teamleider. In hetzelfde jaar is zij gestart met de opleiding middenkader management gezondheidsonderwijs aan de Hogeschool Leiden die zij in 2004 heeft afgerond. In juli 2006 kreeg zij de opdracht om onderzoek met betrekking tot patiëntveiligheid op de afdeling intensive care te coördineren. Deze opdracht combineerde zij met het teamleiderschap tot november 2007, daarna kon zij zich als researchverpleegkundige volledig richten op onderzoek met betrekking tot patiëntveiligheid. Gedurende haar functie als researchverpleegkundige volgde zij de post-hbo research-opleiding bij de Transfergroep Rotterdam, unit Gezondheidszorg en heeft deze in 2009 afgerond. In 2010 begon zij met de masterstudie Evidence Based Practice aan de Universiteit van Amsterdam en die zij in 2012 afrondde. In juli 2012 werd zij donatiecoördinator in het LUMC en heeft zij deze functie in vijf andere ziekenhuizen ingevoerd.
Naast haar werk en het volgen van opleidingen deed zij van 2000 tot 2013 aan veldrijden en nam hierbij deel aan nationale en internationale wedstrijden in de categorie elite dames.

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Dankwoord

Niets is vanzelfsprekend en al helemaal niet het schrijven van een proefschrift. Mijn dank gaat dan ook uit naar de mensen die mij direct of indirect geholpen of gesteund hebben bij het voltooien van dit proefschrift. Een aantal mensen wil ik in het bijzonder bedanken.

Mijn promotor, Evert de Jonge, voor de gelegenheid die ik gekregen heb om dit proefschrift te mogen schrijven, de begeleiding en je geduld vanwege de ontelbare keren corrigeren en becommentariëren van de stukken.

Mijn copromotor, Sesmu Arbous, voor de aanzet om na te gaan denken over promoveren in 2006. Het was een voorrecht om samen met jou dit proces in te gaan door je enthousiasme, positiviteit en de inspirerende gesprekken.

Mijn copromotor, Marcel Dijkgraaf, voor de talloze telefoongesprekken en vele leerzame uurtjes die ik met je heb mogen doorbrengen om de data te analyseren. Je bijdrage was voor mij goud waard.

De artsen en verpleegkundigen van de intensive care voor jullie bijdrage aan dit onderzoek door het invullen van dagelijkse doelen, incidenten en vragenlijsten. In het bijzonder wil ik Monique bedanken voor het invoeren van de ontelbare CRF's in de database.

Mijn paranimfen, Jeroen en Hanneke voor jullie hulp tijdens het promoveren al dan niet in de vorm van samen onderzoek doen, als wel de morele steun die ik van jullie heb mogen ervaren. Ik vind het fantastisch dat jullie vandaag naast mij willen staan.

Mijn lieve vriendinnen Marjan, Marijke, Ingrid, Neely, Saskia, Annechien, Anneke, Gezieneke en Susan, jullie wil ik bedanken voor de steun, interesse, vriendschap, gezelligheid, fijne en waardevolle gesprekken en de afleiding buiten het werk om.

Lieve JP, dank je wel voor je onvoorwaardelijke steun, geduld en geloof in mijn kunnen en in het bijzonder je relativeringsvermogen en humor.