Effective use of quality indicators in intensive care

MAARTJE L.G. DE VOS

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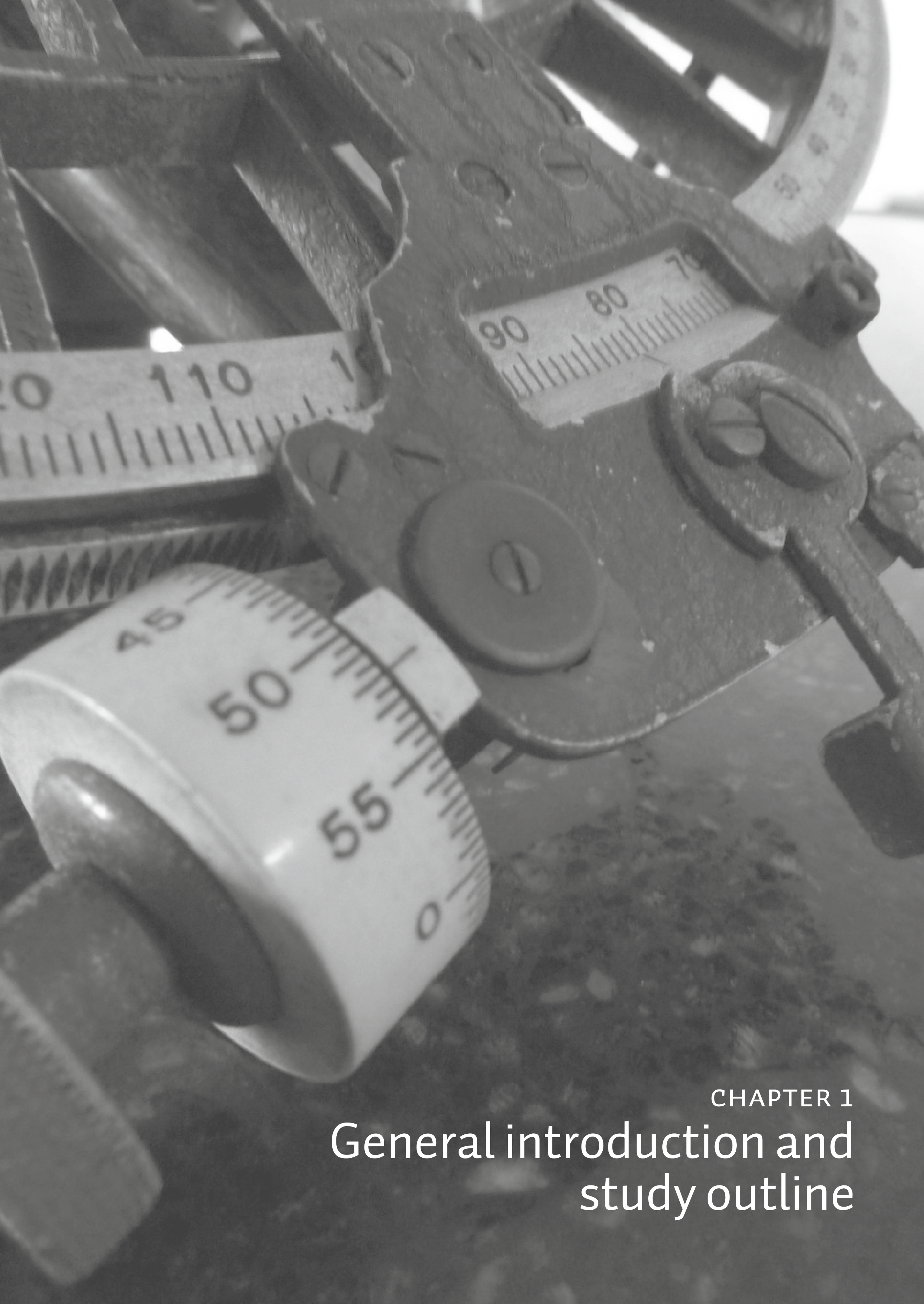

CHAPTER 1

General introduction and study outline

BACKGROUND

Over the past decade, quality and safety issues have become increasingly important in healthcare. Healthcare suffers from a quality gap, referring to a difference between evidence-based practices and those practices that actually are observed in daily clinical practice. [1] To close this gap, health authorities and organizations give high priority to quality improvement (QI), which refers to systematic, data-driven activities for immediate monitoring and improvement of healthcare quality. [2] For healthcare providers it is a challenging task as well as responsibility to respond to growing demands to ensure transparency about healthcare outcomes and reduce variation in clinical practice. [3,4]

This development is strengthened by rising healthcare expenditure in many countries. Reforms of healthcare systems are accompanied by questions related to the quality of care and the efficiency of care delivery. It has become more and more important in the western world to demonstrate that healthcare is of high quality as well as efficient. Consequently, measuring and monitoring the quality of healthcare has become a routine business. In order to measure the quality of care, often quality indicators are used, ideally combining measures of structure, process and outcome of care. [5,6]

The goals of measuring healthcare quality are to determine the effects of healthcare on desired outcomes and to assess the degree to which healthcare adheres to processes based on scientific evidence or agreed to by professional consensus. [7,8] Moreover, the rationale for measuring healthcare is the belief that good performance reflects good-quality practice, and that comparing performance among providers and organizations will encourage better performance. [8] However, the impact of monitoring quality on the actual performance of healthcare is not completely clear.

Looking back to the history of indicators in healthcare, it appears that 10-15 years ago hospital performance assessment was an innovative field. Currently, many indicators have been developed worldwide to assess the quality of hospital care. [9]

These indicators cover a wide range of dimensions linked to clinical effectiveness, efficiency and safety. The first large national initiative for hospital performance assessment, the Quality Indicator Project (QIP), was launched in the United Stated (USA) in 1984. [10,11] Some years later, the Australian Council on Healthcare Standards (ACHS) launched a hospital indicator project which contained more than 300 indicators divided over 22 topics. [12] In Europe, assessing the performance of hospitals appears to be a relatively new area in the field of healthcare delivery science and hospital management, as the majority of projects were launched from 2000 onwards. [13-15]

Indicators for quality of care are used in many different settings, for different purposes and are developed in different ways. The initiatives differ in the extent to which users, such as healthcare professionals and managers on the one hand and patients on the other hand, were involved in the selection and design of indicators. Differences also exist in obligatory or non-obligatory participation. In addition, quality indicators differ in the underlying philosophy of a policy towards disclosure of the results to the public versus restricted use of data for internal QI. [9,16,17] Governments, patient organizations and payers for healthcare use indicators as a tool for external accountability in order to assess and compare the quality of care of healthcare providers. In contrast, healthcare providers mostly use indicators as a tool to monitor and improve their internal care processes. [14]

The collection and interpretation of indicator data may not always be simple, and may be subject to gaming with numbers. [18,19] For example when indicator data are used for financial management, it may be profitable to present data in a selective manner. Especially when data are used for different purposes and by different people, there may be a risk of differences in interpretation and presentation of the same indicator.

Indicators in the Dutch context

Also in the Netherlands, assessing the quality of healthcare has become increasingly important. There is a growing political pressure on healthcare professionals and institutions to perform better by developing and implementing quality indicators and performance schemes for external accountability and transparency as well as internal QI. In this thesis we focus on the development and implementation of a set of quality indicators in the Dutch intensive care.

Though the use of internal indicators in the intensive care started in 1996, in 2003 the Dutch Health Care Inspectorate (IGZ) developed and implemented the first external set of hospital performance indicators in the Netherlands, focusing on monitoring and meeting standards for effectiveness and safety. [14] Participation is obligatory for all Dutch hospitals. The results of the data analyses are available to the public by publication of annual reports as well as individual reports on (hospital) websites. Around the same time, the IGZ encouraged several Dutch medical disciplines to develop additional indicators for their own purposes in order to monitor their internal performance without external interference and public disclosure.

QUALITY INDICATORS AS A TOOL TO IMPROVE THE QUALITY OF CARE

Despite worldwide development of hospital performance assessment projects, it remains unclear if the quality of care can be supported effectively by the use of quality indicators. Quality indicators are suggested as useful tools to improve the quality of care. They can be defined as 'screening tools to identify and signal potential suboptimal clinical care'. [20] Indicators aim to provide insight in the structure and process aspects of care that are related to outcome and can be used as a tool to guide the process of QI in healthcare, [6] Structure indicators are related to the physical aspects of care such as accessibility and availability. Process indicators refer to what is actually done in giving and receiving care such as using protocols and guidelines. Outcome indicators are related to the health status of the patient, e.g. mortality, and improved health status. The primary focus of quality indicators in the context of this thesis is to periodically report and monitor indicator data in order to improve quality of care.

Although quality indicators are applied as a tool to guide the process of quality improvement, only few randomized controlled trials (RCTs) showed that the use of indicators significantly improved the quality of hospital care. Carlhed et al. (2006) described the impact of real- time feedback and educational meetings on the adherence to acute myocardial infarction (AMI) guidelines. [21] These efforts resulted in significant improvements in four out of five process indicators. Another study assessed the effects of an educational intervention on management of three common diseases (malaria, pneumonia and diarrhoea), using performance indicators and an audit feedback approach. [22] The study showed that the aggregated mean scores for all diseases improved significantly. Horbar et al. (2004) showed that a multifaceted intervention including audit and feedback, evidence reviews, QI training and follow-up support changed the behaviour of healthcare professionals and promoted evidence based practice. [23] However, many studies failed to demonstrate an effect of the use of quality indicators on the quality of care.

In the above mentioned positive studies, different strategies for implementing indicators are used and at present there is no clear evidence on how indicators should be implemented to optimize effect. This implies a lack of high-level evidence on the most optimal strategy to implement indicators and their effect on the quality of hospital care.

HOW TO IMPLEMENT AND USE INDICATORS?

Hospitals or wards that adopt quality indicators are faced with issues concerning implementation, e.g. creation of a sense of urgency for the fact that the use of indicators is indispensable for systematic QI, a reliable and valid registration, and how to provide feedback and make use of the analyzed data. Several types of strategies can be used to facilitate implementation such as professional oriented interventions (e.g. distribution of educational materials, educational outreach visits), financial incentives (e.g. based on achievements of performance goals), organizational interventions (e.g. changes in the practice setting such as multidisciplinary teams), and regulatory interventions (changes by law and legislation). [8,24] In this thesis we define an *implementation strategy* as a method for processing and using indicator data aiming to improve the quality of healthcare and ultimately reduce the quality gap.

The prevailing view on implementation strategies to improve the quality of care is that they should be tailored to potential barriers. [25,26] However, in practice many developers of interventions select their strategies intuitively, usually based on their familiarity with specific interventions. [26,27] Often these interventions are not tailored to potential barriers. Most interventions are multifaceted but it is unclear which combination of strategies for implementing quality indicators is optimal.

Reviews reported that audit and feedback based on indicator data can be effective in changing professional practice in healthcare. [28,29] Moreover, in order to increase the impact of feedback reports on healthcare quality, they should be combines with other strategies. [29, 30] These reviews included RCTs of audit and feedback that reported objectively measured professional practice in a healthcare setting. Most of these studies focused on the use of feedback based on indicator data in primary care. [31-34] RCTs conducted in the hospital setting were mostly aimed at improving cardiovascular care by using feedback based on indicator data. [35,36] Only one of these RCTs was applicable to the adult intensive care in which an outreach education using indicator data was evaluated. [37] Since contextual factors are known to influence the success of QI interventions. [38] it was not self-evident that the results of these reviews could be extrapolated to the intensive care setting. More recently, three randomized studies showed that such QI interventions can positively affect intensive care practice. [39-41]

Implementation of indicators in Intensive Care Medicine

As intensive care medicine is a young medical discipline, only recently the QI principles and practices have been introduced in this field. In earlier years, there has been a limited evidence base underlying practice in the intensive care unit (ICU). [42] However, the last years the field of intensive care medicine has caught up in scientifically evidence, performance monitoring and in QI which is reflected by the several quality indicator sets developed. [43-46]

Most western countries now have a national registry on ICU outcomes for internal use such as risk adjusted mortality. [47,48] In the Netherlands, the Dutch National Intensive Care Evaluation (NICE) manages a national quality registry since 1996. [49] There are approximately 94 Dutch ICUs, varying from one room four bed ICUs to departments with up to 60 beds in university and teaching hospitals. Currently, almost 90% of all Dutch ICUs voluntarily submit their data to the registry. In 2011, approximately 75.000 patients were admitted in these ICUs of which 37.000 patients were ventilated. All of the Dutch ICUs are closed-format, and the large majority has an intensivist on call around the clock.

The NICE registry aims to systematically and continuously monitor, compare, and improve the quality of ICU care. From the start of this registry, risk-adjusted mortality and length of stay (LOS) were the main outcome parameters that were benchmarked and quarterly and monthly reported to the participants. However, the potential of these reports has not been investigated and the impact of feedback is not further explored. Therefore, an initiative was developed by using a multifaceted performance feedback intervention including reports based on indicator data as collected by the NICE registry.

THIS THESIS: THE INFOQI PROGRAM

This thesis outlines the process of the development and implementation of indicators as a tool for QI and describes the results of the InFoQI program (Information Feedback on Quality Indicators). By targeting the potential barriers to using performance feedback as input for systematic QI activities, the InFoQI study ultimately aims to improve the quality of care. The study is executed in the intensive care context in the Netherlands.

We used both qualitative as well as quantitative methods to develop and evaluate the effect of a multifaceted feedback intervention on patient outcomes and organizational process indicators of ICU care. Additionally, we gain insight into the barriers and success factors that affected the program's impact. In contrast to other studies that focus on one specific element of individual ICU care, the InFoQI study focuses on modifying the quality of ICU practice in general as well as at the organizational level. The results of this study will inform those involved in providing ICU care on the feasibility of the InFoQI program and its ability to accelerate systematic, local QI at ICUs. More in general, our results aim to be of interest to healthcare providers and organizations in any setting that use a quality registry including quality indicators to continuously monitor and improve the quality of care.

RESEARCH OBJECTIVES

The specific research objectives of this thesis are as follows:

1. To identify a set of quality indicators that measure the quality of ICU care, combining structure, process and outcome indicators.
2. To adopt and develop tailored interventions for the effective use of quality indicators by healthcare professionals with special focus on information feedback in the intensive care setting.
3. To evaluate the effectiveness of the developed feedback intervention (as mentioned above, objective 2) on the quality of ICU care.
4. To gain insight into the barriers and success factors that affected the intervention's impact.

Our study consists of two major parts (Figure 1). First, we identify a set of indicators and test the feasibility of their registration in a pilot study (objective 1). Secondly, we develop a QI intervention for the use of indicators based on prospectively identified barriers (objective 2). Finally, the purpose of the second part is to implement and to test the developed intervention on its effectiveness on the quality of ICU care and evaluate its feasibility (objectives 3 and 4).

The terms 'QI strategy', 'QI program' and 'QI intervention' are considered as synonyms in this thesis.

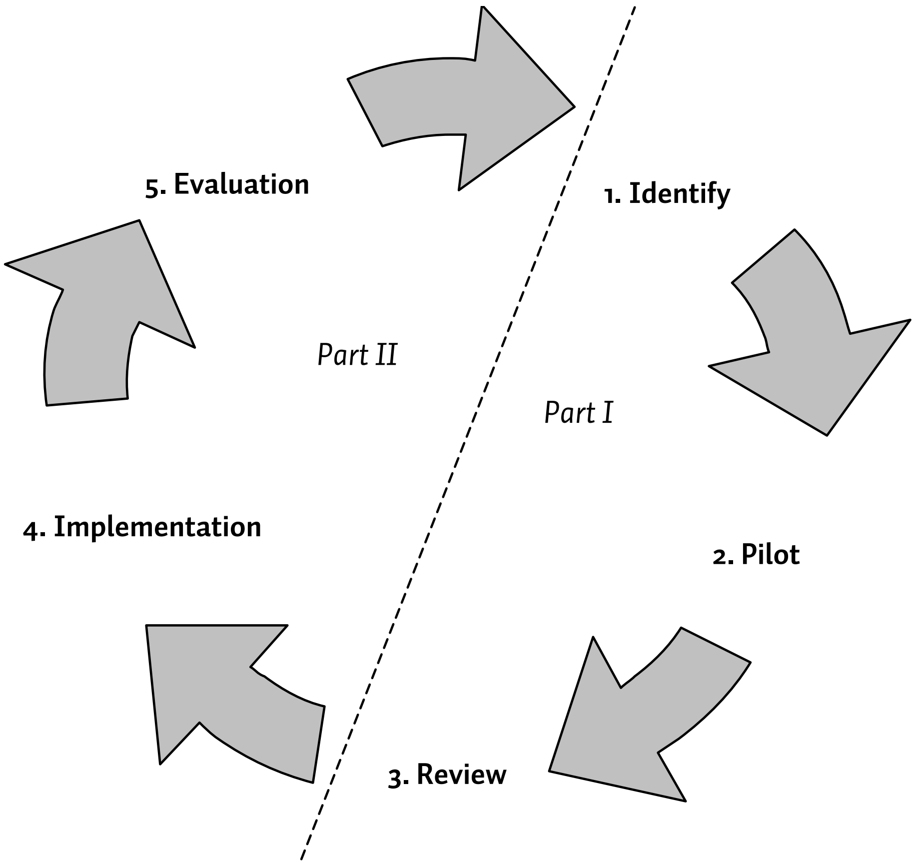

***Figure** 1- Research framework*

THESIS OUTLINE

This thesis starts with the development of a set of quality indicators for the Dutch intensive care setting **(Chapter 2).** In this chapter, indicators are defined based on literature and expert opinions and the feasibility of the registration of these indicators is described.

Chapter 3 is a systematic review of the literature concerning strategies for implementing quality indicators and describes their effectiveness in improving the quality of hospital care.

Chapter 4 explores the potential barriers to and facilitating factors of implementing quality indicators in Dutch ICUs. Based on the finding of a survey study, the knowledge related, attitude related, behaviour related barriers and facilitating factors that healthcare professionals and managers of ICUs perceive, are described.

In **Chapter 5** we present a study protocol of a multifaceted feedback intervention tailored to prospectively identified barriers to using indicators: the InFoQI program. Based on findings in chapter 3 and 4 inter alia, a multifaceted intervention is developed. In this chapter the content of the program is described as well as the study design in order to evaluate the program's impact on the quality of ICU care.

Chapter 6 presents the findings of a randomized controlled trial to assess the impact of the InFoQI program on ICU patient outcomes compared to standard feedback reports.

Chapter 7 reports the findings of the impact of the InFoQI program on organizational process indicators of care. Based on the findings in chapter 6 and 7, conclusions are drawn on the feasibility of a tailored multifaceted performance feedback intervention and its ability to accelerate systematic and local QI.

Chapter 8 explores the actual exposure to and experience with the InFoQI program aiming to contribute to a better understanding of the implementation process of a multifaceted indicator feedback intervention, and its impact on the quality of ICU care.

Finally, in **Chapter 9**, the main findings of this thesis are summarized and discussed. In addition, we describe study limitations as well as the implications of our findings for practice and future research.

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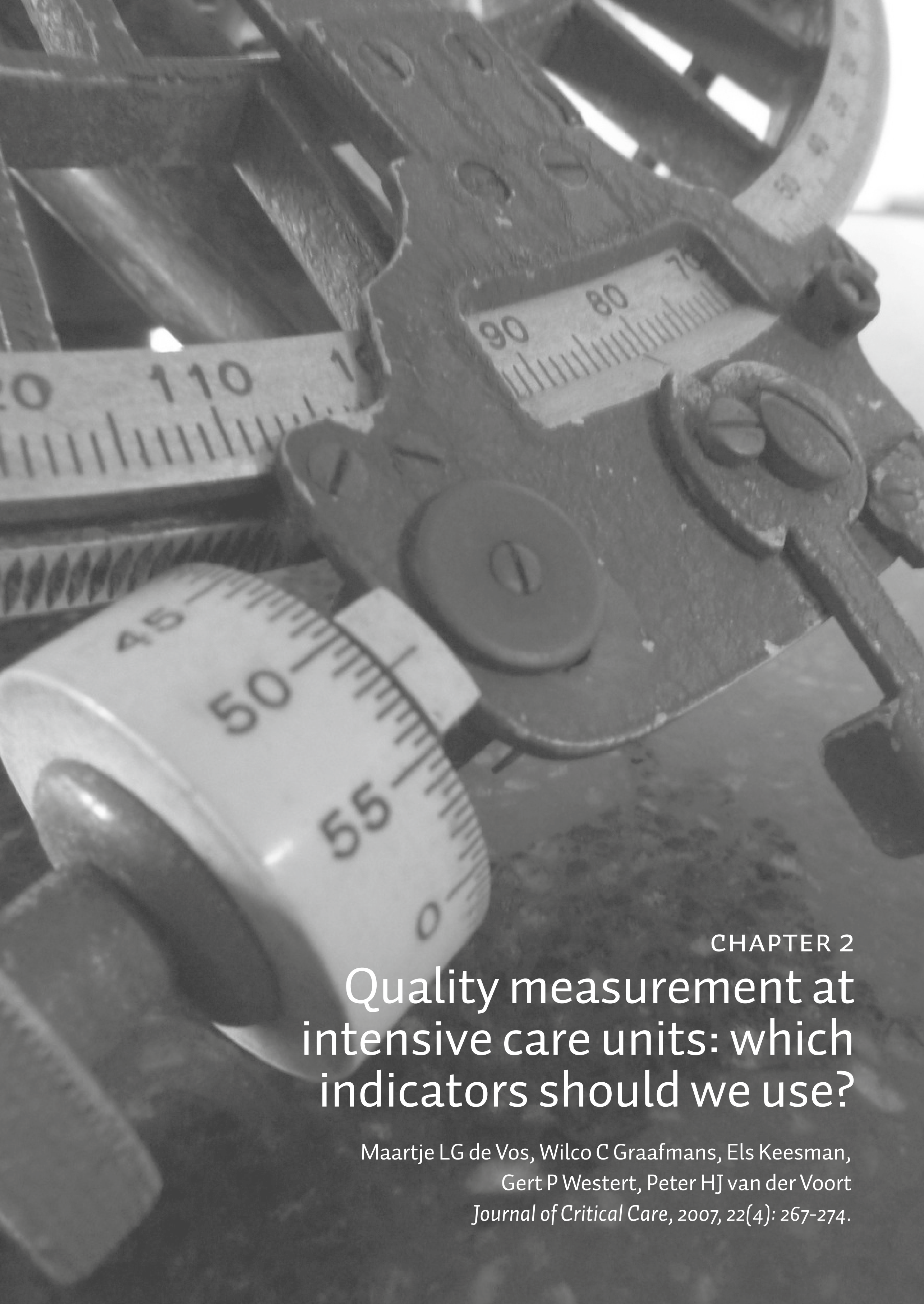

CHAPTER 2

Quality measurement at intensive care units: which indicators should we use?

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Gert P Westert, Peter HJ van der Voort

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ABSTRACT

Objective: This study was conducted to develop a set of indicators that measure the quality of care in intensive care units (ICUs) in Dutch hospitals and to evaluate the feasibility of the registration of these indicators.

Methods: To define potential indicators for measuring quality, three steps were made. First, a literature search was carried out to obtain peer-reviewed articles from 2000 to 2005, describing process or structure indicators in intensive care, which are associated with patient outcome. Additional indicators were suggested by a panel of experts. Second, a selection of indicators was made by a panel of experts using a questionnaire and ranking in a consensus procedure. Third, a study was done for six months in eighteen ICUs to evaluate the feasibility of using the identified quality indicators. Site visits, interviews, and written questionnaires were used to evaluate the use of indicators.

Results: Sixty-two indicators were initially found, either in the literature or suggested by the members of the expert panel. From these, twelve indicators were selected by the expert panel by consensus. After the feasibility study, eleven indicators were eventually selected. "Interclinical transport," referring to a change of hospital, was dropped because of lack of reliability and support for further implementation by the participating hospitals in the study. The following structure indicators were selected: availability of intensivist (hours per day), patient-to-nurse ratio, strategy to prevent medication errors, measurement of patient/family satisfaction. Four process indicators were selected: length of ICU stay, duration of mechanical ventilation, proportion of days with all ICU beds occupied, and proportion of glucose measurement exceeding 8.0 mmol/L or lower than 2.2 mmol/L. The selected outcome indicators were as follows: standardized mortality (APACHE II), incidence of pressure ulcers, and number of unplanned extubations. The time for registration varied from less than 30 minutes to more than one hour per day to collect the items. Among other factors, this variation in workload was related to the availability of computerized systems to collect the data.

Conclusion: In this study, a set of eleven quality indicators for intensive care was defined based on literature research, expert opinion, and testing. The set gives a quick view of the quality of care in individual ICUs. The availability of a computerized data collection system is important for an acceptable workload.

INTRODUCTION

Interest in measuring the quality of healthcare is increasing among both healthcare professionals as well as managers. To quantify the desired (positive) and undesired (negative) consequences of activities in healthcare, measurement of outcome is essential. [1] Indicators may provide insight in the structure and process aspects of care that are related to outcome. [2]

A quality indicator is a screening tool to identify potential suboptimal clinical care. [3] Quality indicators provide a measure of quality of structure, process, and outcome of care, [4] and can serve as instruments to improve healthcare. [5] Structure indicators are related to the resources and means to be able to give treatment and care. Process refers to the activities related to treatment and care. Outcome is defined as changes in the state of health of a patient that can be attributed to an intervention or to the absence of an intervention. The classification has been proven feasible and easy to apply in the clinical situation for both workers in the medical field as well as for research professionals and managers. [5] However, the condition of the patient at admission has to be considered separately, because of its great impact on patient outcome. [5] In this study, the focus is on internal indicators, which are used by professionals and managers of the intensive care units (ICUs) to monitor quality of care. [6] The focus is not on performance indicators to evaluate the hospital achievements for, for example, care consumers.

The ICU is an area in a hospital that constitutes substantial risk of morbidity and mortality. [7] The underlying disease of intensive care patients may partly determine outcome of care, but also treatment at the ICU will have an effect on outcome. To reduce the risks of iatrogenic and organizational adverse effects on patient outcome, quality management is important in the ICU. Indicators can provide insight in quality of care and guide improvement of care on ICUs. It is important that an indicator meets several criteria: reliability, validity, responsiveness, relevance, significance, and utility. [8]

The purpose of this study is to develop a comprehensive set of structure, process, and outcome indicators that measures aspects of all domains of the quality of care at ICUs and to evaluate the feasibility of the registration of these indicators.

METHODS

The whole process of defining a set of indicators was carried out by an expert panel, which included physicians and researchers. This expert panel defined the aim of the indicators and the procedure for selection. Indicators were selected based on several criteria: its relation with quality of care (valid), the reproducibility of the measurement (reliable), the responsiveness of the indicator (also including variability among hospitals), and the feasibility of the registration. These criteria were used in three steps: literature search, consensus procedure, and feasibility study.

Literature search

To obtain relevant literature about quality indicators for intensive care, a literature search was performed using Medline. The search strategy was based on a review of ICU quality indicators performed by Berenholtz et al.,[7] who included publications published from January 1965 to July 2000. The present study is an update from the literature search from Berenholtz et al.,[7] and we adopted this search strategy for articles published between July 2000 and July 2005. The Medical Subject Headings used were critical care, ICUs, mortality, morbidity, length of stay, quality indicators (healthcare), and quality of healthcare. The search was restricted to the English and the Dutch language and adult age category (18 years and older). The search was limited to meta-analyses, reviews and randomized controlled trials. To obtain observational studies, the Medical Subject Headings case-control studies and retrospective studies were added.

A limited set of additional articles was included, which was suggested by experts. [9-16] Also, the Cochrane Library Issue was searched by using the keywords intensive care, critical care, ICU, and quality of health care. [17] Studies were included that described a process or structure measure associated with improved outcome (morbidity, mortality, quality of life, or patient satisfaction) in a population of patients admitted to ICU hospital care.

Studies about paediatric or neonatal ICUs were excluded, because we focused on indicators for adult ICUs. Articles with a specific patient population, for instance, burn injury or HIV-infected patients, were excluded. Studies performed in non-Western societies were excluded.

Two researchers independently checked all articles on relevance. Relevant articles were subsequently discussed in an expert panel until consensus was reached.

Expert opinion

To select a balanced set of indicators meeting the criteria, experts were consulted. The Dutch National Society of Intensive Care Medicine (NVIC) established a multidisciplinary expert panel, aiming to develop a set of indicators that can be used to provide information for improvement of the care in the ICU. The expert panel included seven physicians with different backgrounds: internal medicine, anaesthesiology, and surgery. In addition, one ICU nurse and two scientific researchers took part in this panel. From February 2004 onwards, the expert panel met monthly to discuss the literature and select the indicators. First, the expert panel extracted structure, process, and outcome indicators from the selected articles. Second, additional indicators based on expert opinion were taken into account. The final step to select indicators was made by using a procedure similar to that used by the Agency for Healthcare Research and Quality (AHRQ). [3] A questionnaire using Likert scales was used to make a first selection of the indicators. [8] One ICU nurse and seven physicians from the expert panel completed the questionnaire. The questionnaire measured for each indicator on a 5-point scale the degree of the following: relevance for quality of care, the potential to use the indicator to guide improvement of quality of care, and the feasibility of the registration of the indicators. If there was no clear conclusion to either include or exclude the indicator, the decision was made on the basis of discussion until consensus was reached.

A further selection of remaining indicators was made through ranking. The expert panel was asked to rank the potential structure, process, and outcome indicators separately on their degree of recommendation for use. The final decision for the current set of indicators was made on the basis of consensus between panel members. This method is similar to the one used in the development of indicators for acute myocardial infarction care in Canada. [18] The set of indicators was constructed in a way that all quality domains as described by the Institute of Medicine were addressed. [19]

Feasibility study

A feasibility study was carried out to evaluate the use of the identified quality indicators. Intensive care units in the Netherlands were asked by the expert panel if they would be willing to participate in this study. Out of 97 hospitals, 33 initially agreed to participate. Clusters were made to get a balanced selection of categorical hospitals, teaching, and non-teaching hospitals. By random selection in each category of hospitals, eighteen hospitals were included in the study: one categorical hospital, seven teaching hospitals, and ten non-teaching hospitals. Physicians and nurses were trained to collect uniformly all data for the twelve indicators. A data dictionary was available with detailed definitions and examples. Data were collected for six months in collaboration with the National Intensive Care Evaluation (www.stichting-NICE.nl). In the Netherlands, approximately half of the ICUs provide monthly data for this database. ICUs that did not use this registration system either used another system or developed a special input module.

Site visits were done by researchers to support the data collection where necessary. To obtain information about the process of data collection, two representatives from each ICU (a nurse and an intensivist), responsible for the registration, were interviewed and filled in a questionnaire. In a semi-structured interview, data were collected on perceived validity and reliability of the indicators, possible improvements in definitions, and the local process of collecting and processing the data. The questionnaire included questions on the time investment for the registration (daily, <30 minutes, >30 to <60 minutes, and >60 minutes), a 4-point Likert scale on the acceptability of the time investment and on the desirability of future implementation of each indicator.

RESULTS

To achieve a limited and balanced set of quality indicators, a selection was made in several steps, resulting in a set of eleven indicators (Figure 1).

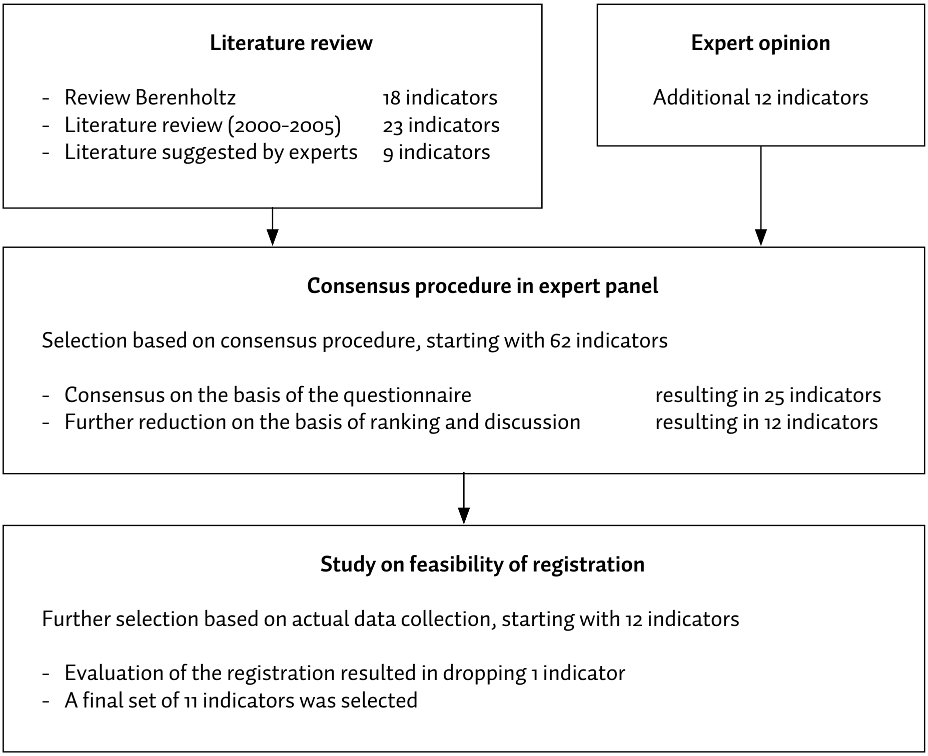

Figure 1 *– Flow diagram for selecting the indicators*

Literature search

In the current literature study, 647 articles from the search were identified. Of these, 594 (92%) articles were rejected after review of the abstract on relevance. Fifty-three relevant articles were selected, which reported on a variety of indicators that were associated with improved patient outcome. This resulted in the selection of twelve structure indicators, thirteen process indicators, and seven outcome indicators (Table 1). Berenholtz et al.[7] also performed a review to identify quality indicators for ICUs. From this publication, eighteen additional indicators were selected, consisting of five structure, nine process, and four outcome indicators (Table 1). Furthermore, a limited set of additional articles, as suggested by experts, was taken into account and indicators from these articles are presented in Table 1.[8-15] In addition to indicators extracted from the literature, we also included twelve indicators suggested by the experts in the panel (Table 2).

***Table 1** – Indicators found in literature and indicators identified by Berenholtz et al.*[7]

Structure	Process	Outcome
Physician staffing [20,21]	Non-invasive ventilation [22,23]	Ventilator associated pneumonia [24-27]
Patient-to-nurse-ratio [16,28-31]	SDD[32]	Deep venous thrombosis [33-35]
Mattresses of pressure-relieving beds [9]	TISS score by discharge [36]	Pulmonary embolism [33-35]
Daily sedation interruption policy [37]	Unplanned extubation [38-39]	Pressure ulcers [9]
Use of case management approach [40]	Continuous lateral rotational therapy [24,41,42]	Stress ulcer [43]
Computerized physician order entry [44]	Interclinical transport [45-47]	Quality of life [15]
Pharmacist participation during daily rounds [16]	Red cell concentrate transfusion [48,49]	Hospital mortality rate [32,50]
Weaning following a protocol [10]	Nutrition support [51-54]	
Protocol for admission and discharge [11]	Glucose regulation [55,56]	
Infection control participation [12]	Autopsy discussion [57-59]	
Organization form ICU [21,60]	Open vs closed suction system [61]	
QI program [13]	Daily rounds by an intensivist [14]	
	Number of patients with premature discharge [11]	
Berenholtz et al. [7]	**Berenholtz et al. [7]**	**Berenholtz et al. [7]**
Rate of delayed admissions	Effective assessment of pain	ICU mortality rate
Rate of delayed discharge	ICU LOS	Patient/family satisfaction
Cancelled operating room cases	Average days on mechanical ventilation	Rate of catheter-related blood stream infection
Emergency department bypass hours	Suboptimal management of pain	Rate of resistant infections
Rate of unplanned ICU readmission	Appropriate use of blood transfusions	
	Prevention of ventilator-associated pneumonia	
	Appropriate sedation	
	Appropriate peptic ulcer disease prophylaxis	
	Appropriate deep venous thrombosis prophylaxis	

Abbreviations: ICU, intensive care unit; QI, quality improvement; LOS, length of stay; SDD, selective decontamination of the digestive tract; TISS, Therapeutic Intervention Scoring System

Table 2 – Additional indicators based on expert opinion

Structure	Process
Policy to register outcome	Examination of post-ICU quality of life
Policy to prevent medication errors	Number of patient days with isolation for outbreak control
Education level IC staff	Number of refused ICU admissions
Registration of complications	Numbered of cancelled OK admissions
Registration of absenteeism among ICU personnel	Occupation rate
	Days of 100% occupation
	Number of discharged patients in out of office time

Abbreviations: ICU, intensive care unit

Indicator selection

From the indicators found in the literature and the indicators identified by experts in the field, a list of 62 indicators was made. These 62 indicators were reduced to 25 by using a questionnaire. Three criteria were used to select these 62 indicators: (1) at least six of eight available panel members completely or partly agreed on relevance for quality of care, (2) potential use of the indicator to guide improvement of quality of care, and (3) feasibility of the registration of the indicator.

These 25 indicators were reduced to a set of twelve indicators (Table 3): four structure indicators, five process indicators, and three outcome indicators. This selection was based on ranking and further discussion until consensus was reached. Arguments in the discussion were related to the level of evidence, the availability of the data, validity, and a balanced distribution of structure, process, and outcome indicators covering the six quality domains from the Institute of Medicine.[19] Furthermore, the panel was reluctant to include indicators of current medical knowledge as new scientific data are constantly released, resulting in increased time dependency of the indicator set. The only indicator that directly measures medical treatment concerns glucose regulation. Three of the selected indicators were similar to the indicators selected by Berenholtz et al..[7] ICU mortality, average ICU length of stay, and duration of mechanical ventilation.

For each indicator, a detailed description was made defining the quality target, definition, numerator and denominator, and type of the indicator. These descriptions were collected in a data dictionary available for all participants.

Table 3 – Selected indicators that were measures in the feasibility study

Indicator	
Structure	
Availability of intensivists (per hour)	The average couple of hours per day that an intensivist is available within 5 minutes at the ICU, including weekends
Patient-to-nurse ratio (measured 3 times daily)	Number of ICU patients present compared to the number of qualified ICU nurses that are available in day shift, evening shift, and night shift. Student nurses are not included
Strategy to prevent medication errors	Strategy to prevent medication errors measured by 10 items, yes or no
Measurement of patient/family satisfaction	Whether or not a registration of patient/family satisfaction is present
Process	
Length of ICU stay	Days of ICU stay in a particular period compared to the total number of discharged patients at the ICU in the same period
Duration of mechanical ventilation	Days of mechanical ventilation of the ICU patients compared to the total number of mechanical ventilated patients
Absolute number of interclinical transport	Total number of interclinical transported patients connected to capacity problems
Percent of days with all ICU beds occupied	Days of 100% bed occupation compared to the total number of days in the same period
Percent glucose measurements greater than 8 mmol/L or lower than 2.2 mmol/L	Number of measurements greater than 8.0 mmol/L or lower than 2.2 mmol/L compared to the total number of glucose measurements
Outcome	
Standardized mortality (APACHE II)	(A) Mortality rate in the ICU compared to the total number of ICU patients (B) Mortality rate in the hospital compared to the expected mortality rate based on average
Number of unplanned extubations	Number of unplanned extubations (per 100 ventilation days) in a period compared to the total days of mechanical ventilation in the same period
Incidence of pressure ulcers	Number of ICU patients with incidence of pressure ulcers, level 3 or 4 compared to the total number of treated patients in the same period

Abbreviations: ICU, intensive care unit

Feasibility study

To evaluate the registration of the twelve indicators, a feasibility study was done in eighteen ICUs. The pilot study covered 7682 admissions and 31 849 treatment days (of which 16 860 ventilated).

Seventeen percent of ICUs needed more than 60 minutes per day to collect the items. These ICUs did not routinely participate in the NICE registry. Thirty-seven percent of ICUs that routinely use the database needed 30 to 60 minutes per day to collect the items, and 46% less than 30 minutes per day.

More than 80% of respondents supported further implementation of ten indicators. "Interclinical transport" and "measurement of patient/family satisfaction" were supported by less than 80% of respondents. In addition to the lack of support for implementation, "interclinical transport" was also reported in the interviews to be very unreliable to register, and was therefore dropped for the final set of indicators. The indicator "patient/ family satisfaction" was consolidated in the final set because it was considered easy to register and important due to a growing interest in patient centeredness in care evaluation.

DISCUSSION

In the current study, a set of quality indicators for intensive care was defined, which after implementation in clinical practice may beneficially influence the quality of care at ICUs. The indicators identified on the basis of the literature study were evaluated, and additional indicators were selected by a panel of experts. This expert panel selected a set of twelve indicators on the basis of a questionnaire and consensus. A feasibility study was done to evaluate the registration of these indicators. Finally, a set of eleven indicators was identified.

The search strategy we used was based on a review of ICU quality indicators performed by Berenholtz et al.[7] In the current study, we found additional indicators. These additional indicators resulted from new reports after the publication year 2000, and from meta-analyses that were excluded by Berenholtz et al.[7] Another difference between the selections made in this study as compared to the set used by Berenholtz et al.[7] is that the panel also took operational, logistic, and national arguments into consideration. A process of selection was performed to limit the number of indicators to make the registration feasible and the set applicable.

The set of indicators should be dynamic; an indicator that does not seem to provide opportunities for improvement in time can be dropped, whereas other indicators that seem more favourable can be added. In addition, if an indicator does not show variability (anymore), the indicator can be exchanged for a new indicator.

Several studies showed that the use of indicators and quality programs significantly improve the quality of health care. [62,63] Monitoring indicators implies an administrative burden for physicians and should be worth the effort. Lagoe and Westert described the impact of the exchange of daily, weekly, and quarterly information among a full range of healthcare administrators and practitioners on the accessibility and efficiency of care. [62] These efforts resulted in increased accessibility of hospital emergency departments and greater efficiency of acute and long-term care. Another study developed and reported clinical indicators as measures of the quality of care received by patients with acute coronary syndromes or congestive heart failure. [63] The study showed that clinical indicators can be used by clinicians to monitor practice standards and to effectuate change in system of care and clinician behaviour. However, other studies showed that some indicators, frequently used as a measure of quality, have no relationship with quality, and that ranking of hospitals does not quantify the potential gains that could be achieved. [64-66]

The main goal is to use the indicators for internal comparison and internal use, by comparison within an ICU over time and by comparing with other ICUs on a national level. However, this benchmarking will be performed for a particular ICU compared to anonymous other ICUs and data will not be available for the public. Next to this internal use of indicators, some of the indicators may be suitable for external reporting. The Dutch Health Care Inspectorate (IGZ) has defined a hospital wide set of performance indicators in 2003. [67] Two indicators in the Dutch set match those used in this study: "duration of mechanical ventilation" and "availability of intensivists". Hospitals are asked to report about these indicators in 2004 over the past year. The IGZ uses these indicators as an instrument for their supervision and monitoring of healthcare.

The indicator set currently identified can be used both to measure and to improve quality of care delivered in ICUs. Feedback of information on the indicators aims to guide management of care. Feedback on the indicators and comparison with other sets in time may stimulate improvement in quality of care for doctors, nurses, and other health care workers. Comparison within an ICU over time will be more easy to interpret and less susceptible to bias and differences in case-mix. For comparison between ICUs, case-mix plays a major role. For example, a method to make differences in mortality rate easier to interpret is to correct for severity of illness by using standardized mortality ratios. With other indicators, case-mix should also be considered.

At present, analyses are being developed to relate the results of different indicators and to improve insight in the validity of the final set. The set of indicators gives a relatively quick view of the quality of care in ICUs. However, computerized assistance is necessary to limit the registration workload.

This study reflects the first step of a promising initiative to use quality indicators in improving the quality of care in Dutch ICUs. For effective monitoring of intensive care quality and to identify areas of improvement, we aim to implement this set of indicators in all Dutch ICUs. Because there is no legal obligation to register indicators in the ICUs, this registration should be highly supported in the field of ICUs to obtain maximal effect. This set is developed in close cooperation with the NVIC, which promotes support for further implementation of the set.

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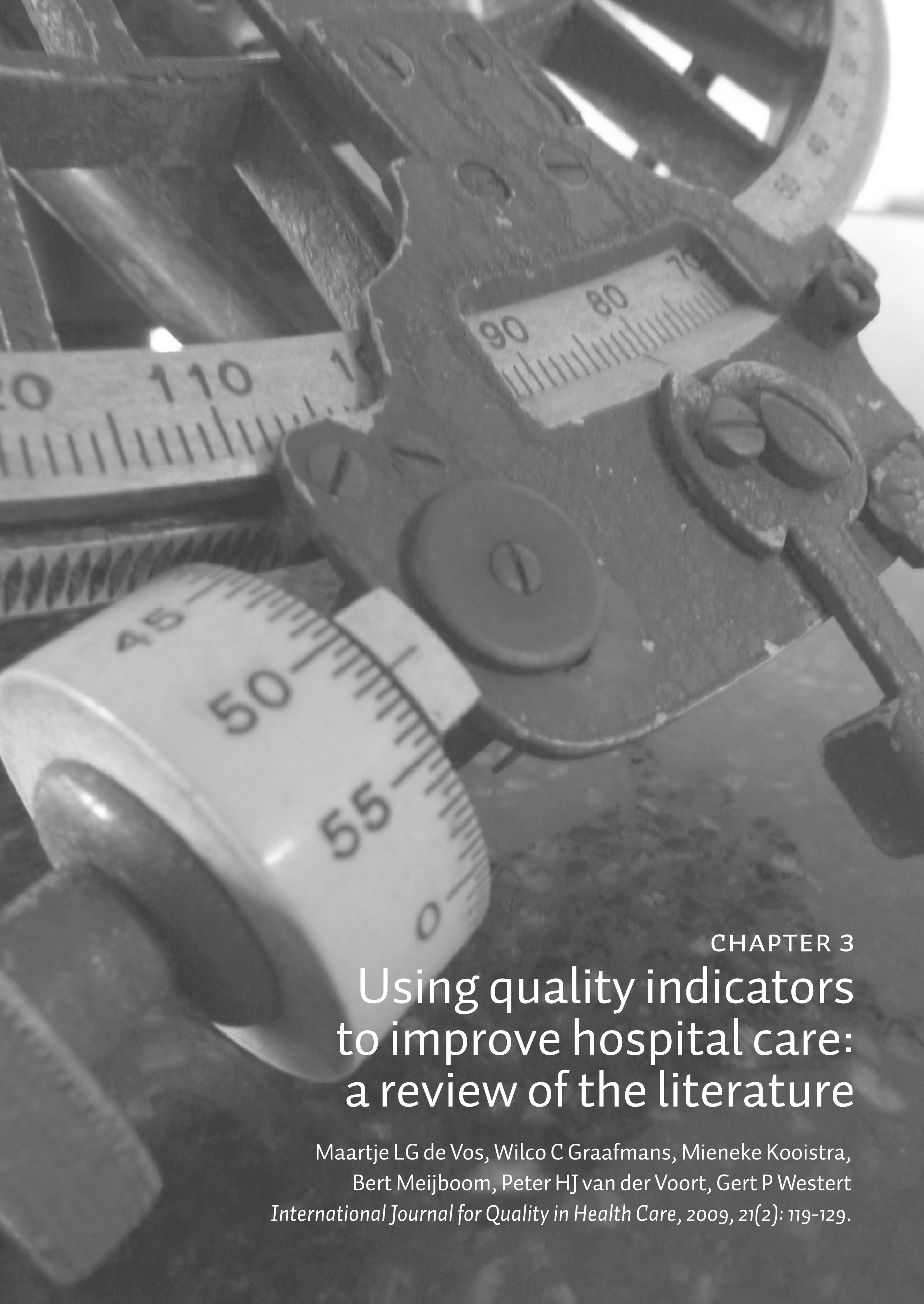

CHAPTER 3

Using quality indicators to improve hospital care: a review of the literature

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ABSTRACT

Purpose: To review the literature concerning strategies for implementing quality indicators in hospital care, and their effectiveness in improving the quality of care.

Data sources: A systematic literature study was carried out using MEDLINE and the Cochrane Library (January 1994 to January 2008).

Study selection: Hospital-based trials studying the effects of using quality indicators as a tool to improve quality of care.

Data extraction: Two reviewers independently assessed studies for inclusion, and extracted information from the studies included regarding the healthcare setting, type of implementation strategy and their effectiveness as a tool to improve quality of hospital care.

Results: A total of 21 studies were included. The most frequently used implementation strategies were audit and feedback. The majority of these studies focused on care processes rather than patient outcomes. Six studies evaluated the effects of the implementation of quality indicators on patient outcomes. In four studies, quality indicator implementation was found to be ineffective, in one partially effective and in one it was found to be effective. Twenty studies focused on care processes, and most reported significant improvement with respect to part of the measured process indicators. The implementation of quality indicators in hospitals is most effective if feedback reports are given in combination with an educational implementation strategy and/or the development of a quality improvement (QI) plan.

Conclusion: Effective strategies to implement quality indicators in daily practice in order to improve hospital care do exist, but there is considerable variation in the methods used and the level of change achieved. Feedback reports combined with another implementation strategy seem to be most effective.

INTRODUCTION

With increasing frequency, hospitals in various countries report and monitor indicator data in order to improve the quality of care. [1-4] Quality indicators aim to detect suboptimal care either in structure, process or outcome, and can be used as a tool to guide the process of quality improvement in healthcare. [5] Monitoring the healthcare quality makes hospital care more transparent for physicians, hospitals and patients. Furthermore, it provides information to target quality improvement initiatives. However, collection of indicator data also implies an administrative burden for physicians and hospitals; therefore, the use of this information should be optimized. It is unclear which implementation strategy for quality indicators is optimal, and what effects can be achieved when quality improvement (QI) is guided by indicator information.

The implementation of quality indicators as a tool to assist QI requires effective communication strategies and the removal of hindrances. [6] Evidence suggests that audit and feedback based on indicator data can be effective in changing healthcare professional practice. [7,8] Monitoring the indicator data may also help to target specific QI initiatives such as educational programs and development of protocols.

The effect of monitoring indicator data to promote QI, and ultimately patient care, has been demonstrated in specific situations. For example, in the Bradford Teaching Hospital in the United Kingdom, feedback of mortality rates resulted in the reduction of the standardized mortality rate from 0.95 to 0.75. [9]

At present, no clear overview is available about strategies for implementing indicators and the effects on quality of care in hospitals. Some reviews do address the issue of implementation of indicators, but do not focus on hospital care. [10,11] Another review of the literature has a limited focus on audit and feedback as implementation strategies. [8] With respect to the effectiveness of using indicators to promote QI, previous reviews have focused on specific diseases or medical disciplines, e.g. pneumonia or cardiac surgery. [12,13] In our review, we focus on hospital care in general, and take into account all possible implementation strategies described in the literature. The purpose of our study is firstly to review the literature concerning strategies for implementing quality indicators, and secondly to examine their effectiveness in improving the quality of hospital care.

METHODS

Data source

A systematic literature search was conducted in MEDLINE and the Cochrane Library for the period from January 1994 to January 2008. We searched all articles published in the English and Dutch languages. The search was limited to randomized controlled trials (RCTs), controlled clinical trials (CCTs) and controlled before–after studies (CBAs), as categorized in MEDLINE. A RCT is the most robust study design to show the effect of QI strategies. [14] However, as some strategies are not amenable to randomization, we also included non-randomized trials.

The search strategy in MEDLINE combined a truncated search for ‘quality indi*’ with the text words ‘hospital care’ or ‘quality improvement’. In addition, we searched the Cochrane Library, based on the Medical Subject Heading: ‘quality indicators, healthcare’. The reference lists of all retrieved articles were searched for additional relevant references.

Two reviewers independently assessed the studies for inclusion. In case of disagreement between the two researchers, a third researcher was consulted.

Study selection

Firstly, we selected studies based on the relevance of the focus of the study. Studies reporting the use of quality indicators as a tool to improve hospital care were included. Studies that measured care processes or patient outcomes were also included, if the focus was on inpatient care at the hospital level, ward, or individual specialist. Studies concerned with primary care, e.g. general practitioners, chronic health, mental health and dental care were excluded because the delivery of care may differ considerably in these care settings from the hospital care setting.

Secondly, we selected studies based on study design and quality of the study. Studies had to report a baseline and follow-up measurement, and include a control and an intervention group. The effects of the implementation strategy had to be quantified, and studies had to be carried out in two or more hospitals because of generalization of the results.

For those studies that met the inclusion criteria, we classified the implementation strategies in which the information on quality indicators was used directly into the following categories (Table 1): (1) educational meeting, (2) educational outreach, (3) audit and feedback, (4) development of a quality improvement plan and (5) financial incentives.

Implementation strategies that did not directly use the information on quality indicators, but support the implementation, were categorized in 'distribution of educational material', 'local opinion leaders' and 'quality improvement facilities' (Table 1). Educational meeting was regarded as a supporting activity if the meeting focused on quality improvement techniques instead of presenting feedback on quality indicators.

Common to all studies on which we focus in this review is the use of key information of structure, process and outcome of care, and the systematic use of this information to improve quality of care. Central to the use of quality indicators is the feedback of information. Therefore, in order to summarize the implementation strategies that were used, we categorized the contribution of feedback to the implementation strategy in 'receiving no feedback report', 'receiving a feedback report only' and 'receiving a feedback report combined with another strategy, which also used quality indicators as part of the implementation strategy.'

For the studies included, information was collected concerning the healthcare setting, methods used to implement quality indicators in hospitals, and their effectiveness in improving the quality of hospital care. The effectiveness of these strategies may be explained by the fact that they are capable of dealing with different barriers simultaneously.[15] We have summarized the barriers reported in some of the studies.

Table 1 – Classification of implementation strategies

Implementation strategies in which the information on quality indicators was directly used	
Educational meeting	Participation in conferences, seminars, lectures, workshops or training sessions. During these meetings, feedback of quality indicators was presented, and study participants discussed how to improve performance.
Educational outreach	A trained independent person or investigator who met with health professionals or managers in their practice setting to provide information (e.g. feedback of quality indicators).
Audit and feedback	Report including a summary of clinical performance over a specified period of time had to be given.
Development of a QI plan	A plan based on indicator data was used to improve the quality of care.
Financial incentive	Rewarding individual health professionals or institutions with higher payments when they improve performance.
Supporting activities	
Distribution of educational material	Distribution of educational material was used if published or printed recommendations for clinical care or QI were used.
Local opinion leader	Professionals named by their colleagues as influential with emphasis on acting as authority locally.
QI facilities	An implementation process organized by a QI team or organizations to improve the quality of care and implementing system support methods (support by phone or mail for QI).

Abbreviations: QI, quality improvement

RESULTS

Selection of articles

As a result of the search, 516 studies were identified (Figure 1). Of these, 465 were excluded, because these studies did not aim to measure the effect of the use of quality indicators. Four additional new articles were obtained from the reference lists. A total of 55 articles was evaluated by two reviewers, based on the quality of the studies. Finally, 21 studies were included.

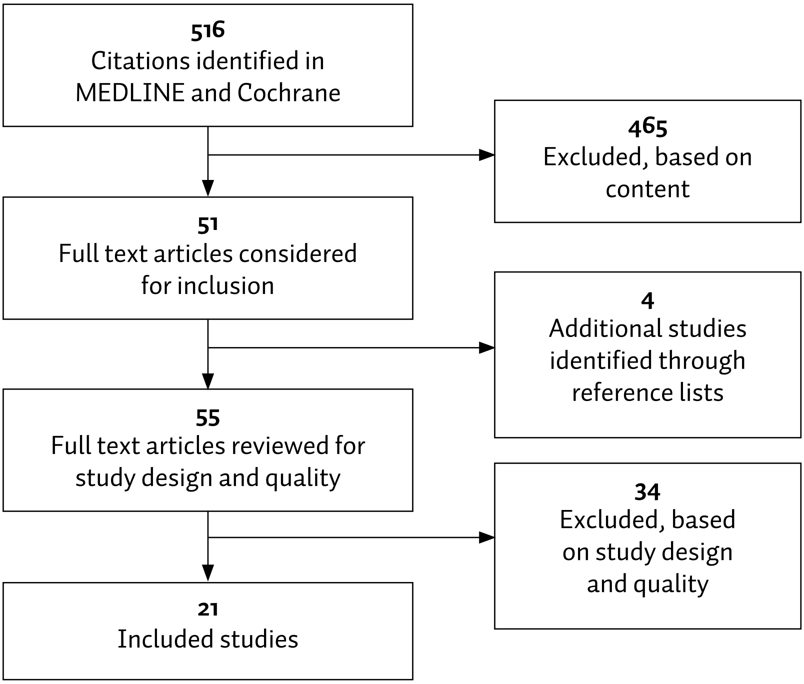

Figure 1 *– Flow chart of study selection process*

Study characteristics

We included nine RCTs, [16–24] two CCTs [25,26] and ten CBAs. [27–36] The majority of the trials were conducted in the United States (17 studies); the others were carried out in Canada, [17] Australia, [33] Sweden [16] and Laos. [21] Furthermore, quality indicators were in a wide range of medical disciplines within hospital care. The majority of studies focused on the use of quality indicators in cardiovascular care (67%). [16,17,19,20,22-24,27,29,32-36] Most studies (81%) aimed at improving quality of care in one specific medical discipline. The sample size showed great variation, from one to 379 hospitals in the intervention group (Table 2).

Table 2 – *Characteristics and results of the studies included*

First author; year	Study design	Clinical area	Methods to implement quality indicators	Effects on care processes	Effects on patient outcome
Pandey et al, 2006 [16]	CBA (CG=6, IG=7)	Cardiovascular care	Educational outreach and educ. meeting vs. chart audit only	No sign. improvement for 6 out of 7 process indicators, except for lipid screening (adj. OR 19.93; 90% CI 2.99-36.86)	Not measured
Carlhed et al, 2006 [17]	RCT (CG=19, IG=19)	Cardiovascular care	Real-time feedback report, educ. meetings and QI plan vs. no intervention *Supporting activities* (QI facilities, incl. QI team and ongoing support by phone and on request site visits)	Sign. improvement for 4 out of 5 process indicators: use of ACE inhibitor 1.4% vs. 12.6% (P= 0.002), use of lip. low. 2.3% vs. 7.2% (P= 0.065), use of heparin 5.3% vs. 16.3% (P= 0.010) and use of Cor-Angio 6.2% vs. 18.8% (P= 0.027)	Not measured
Grossbart et al, 2006 [18]	CBA (CG=6, IG=4)	Cardiovascular care, pneumonia, hip/ knee	Feedback report and rewarding hospitals with an incentive bonus vs. no intervention	Sign. improvement in composite process indicator scores of 6.7 % vs. 9.3% (P<0.001)	Not measured
Moscucci et al, 2006 [19]	CBA (CG=7, IG=5)	Cardiovascular care	Quarterly + annual feedback reports, educational outreach, educ. meeting, distribution educ. material and QI plan vs. no intervention	Sign. improvement on all 6 process indicators	Sign. improvement for 4 out of 6 outcome indicators; contrast nephropathy (adj. OR 0.59; 95% CI 0.44-0.77), emergency CABG (adj. OR 0.54; 95% CI 0.32-0.90), stroke (adj. OR 0.33; 95% CI 0.16-0.65) and death (adj. OR 0.57; 95% CI 0.40-0.82)

Table 2 (continued)

First author; year	Study design	Clinical area	Methods to implement quality indicators	Effects on care processes	Effects on patient outcome
Rosenthal et al, 2005 [20]	CBA *(CG=31, IG=134)*	Cancer screening, mammography, haemoglobin testing	Rewarding healthcare professionals with an incentive bonus vs. no intervention	No sign. improvement for 2 out of 3 process indicators, except for cervical cancer screening (3,6% improvement, $p= 0.02$)	Not measured
Beck et al, 2005 [21]	RCT *(CG=38, IG=38)*	Cardiovascular care	Rapid feedback report vs. delayed feedback report	No sign. improvement in any of 12 process indicators	No sign. improvement for mortality at 30 days after discharge (adj. OR 0.6; 95% CI -0.70-1.8)
Snyder et al, 2005 [22]	CBA *(CG=142, IG=199)*	Cardiovascular care, pneumonia	Feedback report vs. no intervention *Supporting activities* (distribution educ. material and QI facilities, incl. assisting implementing system change	No sign. improvement for 14 out of 15 process indicators, except for pneumonia immunization ($p= 0.005$)	Not measured
Landon et al, 2004 [23]	CCT *(CG=25, IG=44)*	HIV infection	Monthly feedback reports, educ. meetings and QI plan vs. no intervention *Supporting activities* (QI facilities, incl. QI team and monthly conference calls)	No sign. improvement for 7 out of 8 process indicators, except for screening and prophylaxis papanicolaou smear ($p= 0.06$)	Not measured
Horbar et al, 2004 [24]	RCT *(CG=57, IG=57)*	Surfactant preterm infants	Feedback report vs. no intervention *Supporting activities* (educ. meeting for QI techniques and QI facilities incl. ongoing support by quarterly conference calls and mail discussion list)	Sign. improvement in all 3 process indicators: proportion receiving surfactant in delivery room (adj. OR 5.38; 95% CI 2.84-10.20), proportion receiving first surfactant >2 hours after birth (adj. OR 0.35; 95% CI 0.24-0.53) and median time from birth to first dose surfactant ($P< 0.0001$)	No sign. improvement in rate of death before discharge

***Table 2** (continued)*

First author; year	Study design	Clinical area	Methods to implement quality indicators	Effects on care processes	Effects on patient outcome
Berner et al, 2003 [25]	RCT *(CG=6, IG1=8, IG2=7)*	Cardiovascular care	Educ. meeting and QI plan (IG1) vs. no intervention *Supporting activities* (distribution educ. material and IG2 added opinion leader)	No sign. improvement for 4 out of 5 process indicators, except for antiplatet medication within 24 hours for IG2 vs. CG (adj. OR 1.92; 95% CI 1.19-3.12) and antiplatet medication within 24 hours for IG1 vs. IG2 (adj. OR 1.79; 95% CI 1.09-2.94)	Not measured
Chu et al, 2003 [26]	CCT *(CG=16, (crossover) IG=20)*	Pneumonia	Feedback report, educ. outreach and QI plan *Supporting activities* (distribution educ. material and QI facilities incl. support QI training and site visits)	Sign. improvement for 2 out of 4 process indicators: antibiotics given emergency department (adj. OR 10.72; 95% CI 3.56-32.30) and blood culture obtained in 4 hours (adj. OR 2.48; 95% CI 1.17-5.25)	No sign. improvement in LOS and unadjusted mortality
Ferguson et al, 2003 [27]	RCT *(CG= 115, IG1=101, IG2=107)*	Cardiovascular care	Feedback report, QI plan and distribution educ. material (one arm received educ. beta blockade (IG1), other arm received educ. IMA grafting (IG2)) vs. no intervention *Supporting activities* (local opinion leader)	Sign. improvement of 1 out of 2 process indicators: use of preoperative beta-blockade (IG1 group vs. CG ($P< 0.001$)) and (IG2 vs. CG ($P = 0.02$))	Not measured
Wahlström et al, 2003 [28]	RCT *(CG=12, IG=12)*	Malaria, diarrhea and pneumonia	Educ. meetings vs. no intervention *Supporting activities* (educ. meeting incl. QI and QI facilities, incl. QI team)	Sign. improvement for overall mean process indicator scores for malaria, diarrhoea and pneumonia together (OR 0.63; 95% CI 0.16-1.112)	Not measured

Table 2 *(continued)*

First author; year	Study design	Clinical area	Methods to implement quality indicators	Effects on care processes	Effects on patient outcome
Hayes et al, 2002 [29]	RCT *(CG=16, IG=16)*	Cardiovascular care	Educ. outreach vs. feedback report and educ. material *Supporting activities* (opinion leader, educ. meeting)	No sign. improvement for 4 out of 5 process indicators, except for discharge counselling for daily weights (OR 2.63 ; 95% CI 1.14-6.07)	Not measured
Mehta et al, 2002 [30]	CBA *(CG=11, IG=10)*	Cardiovascular care	Educ. outreach, feedback report and QI plan vs. no intervention *Supporting activities* (opinion leader (outside hospital), distribution educ. material)	Sign. improvement for 4 out of 8 process indicators: use of aspirin on admission (81% vs. 87%; p= 0.02), use of beta-blockers on admission (65% vs. 74%; p= 0.04), use of aspirin after discharge (84% vs. 92%; p= 0.002) and smoking counselling at discharge (53% vs. 65%; p= 0.02)	Not measured
Scott et al, 2001 [31]	CBA *(CG=112, IG=1)*	Cardiovascular care	Feedback reports and educ. meeting vs. no intervention *Supporting activities* (distribution educ. material)	Not measured	Sign. improvement in inpatient mortality (adj. OR, 0.59; 95% CI 0.45-0.77)
Hayes et al, 2001 [32]	RCT *(CG=15, IG= 14)*	Cardiovascular care	Educ. meeting and QI plan vs. feedback report *Supporting activities* (opinion leader and distribution educ. material)	No sign. improvement in any of 5 process indicators	Not measured
Sauaia et al, 2000 [33]	CBA *(CG=9, IG=9)*	Cardiovascular care	Educ. outreach and QI plan vs. mailed feedback report *Supporting activities* (opinion leader)	No sign. improvement in any of 7 process indicators	Not measured

Table 2 *(continued)*

First author; year	Study design	Clinical area	Methods to implement quality indicators	Effects on care processes	Effects on patient outcome
Ellerbeck et al, 2000 [34]	CBA *(CG=73, IG=44)*	Cardiovascular care	QI plan based on feedback vs. no QI plan based on feedback	Sign. improvement for 3 out of 8 process indicators: aspirin during hospitalization (6% vs. 13%) and at discharge (6% vs. 15%) and use of beta-blockers (14% vs. 22%)	Not measured
Marciniak et al, 1998 [35]	CBA *(CG=not given, IG= 379)*	Cardiovascular care	Feedback report and QI plan vs. no intervention	Sign. improvement for 3 out of 7 process indicators: use of aspirin at discharge (OR, 5.6; 95% CI 2.6-8.7), use of beta-blockers (OR, 8.0; 95% CI 1.4-14.6) and smoking counselling (OR, 8.5; 95% CI 1.6-15.5)	No sign. improvement in hospital mortality
Soumerai et al, 1998 [36]	RCT *(CG=17, IG=20)*	Cardiovascular care	Educ. meeting vs. mailed feedback report *Supporting activities* (local opinion leader and distribution educ. material)	Sign. improvement for 2 out of 4 process indicators: use of oral aspirin ($p < 0.04$) and use of beta-blockers ($p < 0.02$)	Not measured

Abbreviations: RCT, randomized controlled trial; CCT, controlled clinical trial; CBA, controlled before-after study; CG, number of hospitals in control group; IG, number of hospitals intervention group; QI, quality improvement; OR, odds ratio; CI, confidence interval; sign., significant; adj., adjusted; incl., including; educ.,educational; ACE inhibitor, inhibitor of angiotensin-converting enzyme; lip.low, lipid lowering therapy; Cor-Angio, coronary angiography; CABG, coronary artery bypass surgery; IMA, internal mammary artery; LOS, length of stay

Types of implementation strategies

The methods used to implement quality indicators were classified into implementation strategies in which the information on quality indicators was used directly, or that did not use the information on quality indicators directly, but only supported the implementation, such as the involvement of a QI team.

Table 2 shows the implementation strategies used. The most frequently used implementation strategies in which the information on quality indicators was used directly were audit and feedback (12 studies), followed by the development of a QI plan based on quality indicator data (10 studies), 57% and 48%, respectively. The combination of these strategies was used in seven studies, and often supplemented by educational meetings and/or educational outreach.[16,25,26,29,32] The most frequently used supporting activity was distribution of educational material (9 studies). Other supporting activities were the use of a local opinion leader and the development of a QI team.

In most studies (86%), multiple implementation strategies were used. In 14 studies, implementation strategies that related directly to quality indicators were combined with supporting activities. In four studies, strategies that related directly to quality indicators alone were used.[27–29,36]

Three studies reported a single implementation strategy in which the information on quality indicators was used directly. The single implementation strategies described were as follows: providing external feedback with an incentive bonus,[30] providing immediate feedback[17] and using a QI plan.[35] Most follow-up measurements of process and outcome indicators were performed 6 months after the strategy was implemented.[16–18,20,21,23,25,32]

Effects of quality indicator use

Different designs, implementation strategies and outcome measurements to measure the effect of quality indicators were described. In Table 2, the results are summarized as per study.

Most studies measured several outcomes, e.g. the change in several process indicators. In an attempt to summarize the results of the studies, we divided them into three categories: effective, partly effective and ineffective. We categorized the studies as ‘effective’ if more than half of all the outcome measures improved significantly. Studies were considered ‘partly effective’ if approximately half of the outcomes improved significantly, and ‘ineffective’ if there was significant improvement in less than half of all the outcomes.

Nine RCTs, two CCTs and ten CBAs were included. There was no clear relationship between the study design used and the effectiveness. Four out of nine RCTs showed the implementation to be ineffective, [27,19,22,23] one CCT was ineffective[25] and four out of ten CBAs did not show clear positive effects. [27,30,31,34] The results of the studies included are reported in three different types of outcomes: overall composite score, patient outcomes and care processes, e.g. hospital mortality and prescribing medication.
In two studies, an overall indicator score was measured. These studies showed a statistically significant improvement in the composite process indicator score. [21,28] Five studies reported patient outcomes as well as care processes. [17,18,26,29,36] One study measured patient outcomes only. [33] In total, six studies evaluated whether or not quality indicator implementation improved patient outcomes. Four studies were found to be ineffective, one was partly effective and one was categorized as effective (Table 2). Five studies reported inpatient mortality as endpoint. Two studies found significant improvements in patient outcomes: reduction in inpatient mortality, [29,33] stroke or transient ischemic attack, [29] emergency coronary artery bypass graft (CABG) [29] and contrast nephropathy. [29]

In 20 studies, process indicators were used to measure care processes (Table 2). In each of these studies, more than one process indicator was measured. In three studies, there was no significant improvement in all the process indicators measured. [17,23,34] Two studies reported significant improvements in all process indicators. [18,29] Most studies reported significant improvements in part of the measured process indicators. Of these studies, seven studies seemed to be effective or partly effective. These studies reported mostly on higher rates of prescribing drugs: inhibitors of angiotensin-converting enzyme (ACE), [16] heparin, [16] antibiotics at emergency department, [26] beta-blockers [20,24,32] and aspirin. [24,32] In addition, these studies also reported on treatments given: lipid-lowering therapy, [16] coronary angiography, [16] blood culture obtained in 4 h[26] and higher rates of smoking counseling. [32]

Not all studies adjusted the analyses for differences in distributions of other determinants when comparing the effect in the intervention group with that of the control group. Fourteen of the studies reported adjusted outcome measurements at patient level (age, co-morbidity) and/or hospital level (teaching status/ volume). Of these studies eight were found to be ineffective, [17,19,22,23,25,27,31,34] four were partly effective [18,20,26,32] and only two were categorized as effective. [29,33] Looking at the studies using unadjusted outcome measurements, three studies were found to be effective, [16,21,28] three were partly effective [24,35,36] and one was ineffective. [30]

The follow-up measurement period varied from four months [27,35,36] to four years. [33] Studies with a follow-up measurement period of less than six months showed less significant improvement and functioning of the hospital outcome measures. [27,34-36]

Types of implementation strategies and their effects

In order to summarize the prevailing implementation strategies, we divided them into three categories: receiving no feedback report, a feedback report only and receiving a feedback report combined with another implementation strategy (Table 3). There seemed to be a relation between implementation strategies used and the effectiveness of the study (Kruskal–Wallis x2 ¼ 6,720, P ¼ 0.035).

Effective or partly effective studies appear to use feedback reports combined with other implementation strategies. For example, feedback reports in combination with education and the use of a QI plan seemed to be effective. [16,20,26,29,32] Studies that did not use feedback reports systematically seemed to be less effective. [19,22-24,27,30,34,35] Studies using a feedback report only also seemed to be less effective. [17,31]

From the studies describing an implementation strategy in which the information on quality indicators was used directly, eight studies reported a single implementation strategy, with additional supporting activities in five of these. Only one out of eight studies was effective. [21] This study used monthly educational meetings, including feedback and discussion on performance improvement. Thirteen studies used multifaceted implementation strategies, and of these four were effective. [16,28,29,33]

Table 3 *– Types of implementation strategies and their effects*

Implementation strategies in which indicator scores were directly used	Effective [a]	Partly effective [b]	Ineffective [c]
No feedback report	1	2	6
Feedback report only	0	1	2
Feedback report combined with another implementation strategy	4	4	1

[a] *Effective= if more than half of all outcomes improved significantly.*
[b] *Partly effective= if approximately half of the outcomes improved significantly.*
[c] *Ineffective= if less than half of all outcomes improved significantly.*

Reported barriers

Analyses of barriers to changing practice, such as a review of 76 studies on doctors, have shown that obstacles to change can arise at different levels at the healthcare system, such as at the level of the patient, the individual professional, the healthcare team, the healthcare organization, or the wider environment. [37]

In our study, we identified reported barriers to implementation. In seven of the studies included, perceived barriers to change were reported. In these studies, we also identified barriers at different levels of the healthcare system (Table 4): knowledge and cognitions (not convinced of the evidence) of the individual healthcare professional; interaction within the team (no mutual accountability and control, no leadership) and functioning of the hospital (facilities).

Four studies reported a lack of resources, e.g. time investment and lack of administrative support (Table 4). Several facilitating factors were reported, such as the availability of supportive/ collaborative management, administration support, using detailed and credible data feedback to evaluate effects and the ability of persons receiving feedback to act on it.

Table 4 *– Studies addressing the perceived barriers*

Barriers at level of	Focus of factors	Barriers	Study
Professional	Knowledge	Unawareness	(25)
	Cognitions	Lack of credible data	(21, 28)
Team or unit	Social influence and leadership	No support management/ physicians	(21, 29)
Hospital	Resources	Lack of resources	(20, 27, 29, 32)

DISCUSSION

The two main objectives of this review were to explore the best implementation strategy for quality indicators, and to quantify the effectiveness of using quality indicators as a tool to improve quality of hospital care. Our results show that the majority of the studies included reported combinations of implementation strategies in which audit and feedback were most frequently used. Few studies showed significant improvements in the outcomes measured. Most of them focused on process measures, and reported significant improvements in part of the measured process indicators. Only few studies focused on the improvement of patient outcomes.

We recognize that significant improvements in patient outcomes are difficult to achieve. In our review, studies with a follow-up measurement period of less than six months showed less significant improvements in outcome measures. Short follow-up on the effects of the implementation strategies may have contributed to the lack of effectiveness in some studies.

Looking at the type of implementation strategies used and their effects, there does seem to be a link between how quality indicators are used and the effectiveness of the study. Although this relationship was statistically significant (Kruskal–Wallis x2 ¼ 6,720, P ¼ 0.035), we should be cautious in interpreting this partly arbitrary data. Effective or partly effective studies appeared to use feedback reports combined with other implementation strategies. Receiving a feedback report combined with education and the use of a QI plan seemed to be effective. Less effective were those implementation strategies in which health care providers or managers did not receive a feedback report of quality indicator data. To improve patient outcomes or provider performance, healthcare providers should receive feedback on their performance in order to change practice and improve patient outcomes.

It has been suggested that multifaceted implementation strategies are more effective than single implementation strategies.[10,38] In this review, we also found combinations of implementation strategies to be most effective. However, we could not really confirm these results because only few studies involved single implementation strategies.

The prevailing view on implementation of strategies to improve quality of care is that they should be tailored to potential barriers.[39] Ideally, possible barriers should be analyzed before the quality improvement implementation strategies are developed in order to influence both type and content of the implementation strategy.[39] Remarkably, none of the studies included reported translation of a priori identified barriers into tailor-made implementation strategies, but only reported barriers after the strategy was implemented. This may have affected the effectiveness.

The studies included in this review showed a great diversity in outcomes measured. Therefore, in an attempt to summarize the results of these studies, we categorized studies as 'effective', 'partly effective' and 'ineffective'. However, the results of this aggregation have to be interpreted with caution. All outcomes were included on an equal basis, but outcomes may be valued differently for their relevance for quality of care. For example, one measure for patient outcome may be of more value than a process measure.

The implications of the findings reported in the present review must be considered within the context of the limits of the study. Firstly, we used strict selection criteria and as a result, the studies included are limited. Studies without a control group were excluded and, consequently, interrupted time series were excluded as well.

Due to our inclusion criteria, we report only on studies with primary quantitative outcome measurements. As a result, insights from qualitative studies fall outside the scope of this paper.

We noted the relatively narrow range of clinical areas studied. While cardiovascular care is an important clinical topic, other important areas, such as intensive care and obstetrics, were not covered in the studies. As a result, it is difficult to make generalized conclusions about hospital care as a whole.

Secondly, there is a great variation in quality of the studies. The availability of well-designed studies on this topic is limited. In the results section, we reported that adjustments for differences in distributions of other determinants varied when comparing the effects in the intervention group with the control group. Studies using unadjusted outcome measurements seemed to be more effective than studies using adjusted outcomes. In addition, most studies describe a combination of implementation strategies, which hampers a quantification of the effects of separate implementation strategies. Finally, implementation strategies used in the studies were often poorly described; therefore, we checked them against a standardized list of strategies.

In conclusion, there are many different implementation strategies in which the information on quality indicators was used directly, focusing on feedback, education, etc. Often, these strategies were combined with supporting activities. Receiving a feedback report, combined with education, and the development of a QI plan seemed to be most effective. Effective strategies to implement quality indicators in daily practice in order to improve hospital care do exist, but there is considerable variation in methods used and the level of change achieved. Based on the present review, receiving a feedback report combined with another implementation strategy is recommended. There is a need for thoroughly designed studies on the implementation of quality indicators to further guide future implementation.

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CHAPTER 4

Implementing quality indicators in intensive care units: exploring barriers to and facilitators of behaviour change

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ABSTRACT

Background: Quality indicators are increasingly used in healthcare but there are various barriers hindering their routine use. To promote the use of quality indicators, an exploration of the barriers to and facilitating factors for their implementation among healthcare professionals and managers of intensive care units (ICUs) is advocated.

Methods: All intensivists, ICU nurses, and managers ($n = 142$) working at 54 Dutch ICUs who participated in training sessions to support future implementation of quality indicators completed a questionnaire on perceived barriers and facilitators. Three types of barriers related to knowledge, attitude, and behaviour were assessed using a five-point Likert scale (1 = strongly disagree to 5 = strongly agree).

Results: Behaviour-related barriers such as time constraints were most prominent (Mean Score, MS = 3.21), followed by barriers related to knowledge and attitude (MS = 3.62; MS = 4.12, respectively). Type of profession, age, and type of hospital were related to knowledge and behaviour. The facilitating factor perceived as most important by intensivists was administrative support (MS = 4.3; $p = 0.02$); for nurses, it was education (MS = 4.0; $p = 0.01$), and for managers, it was receiving feedback (MS = 4.5; $p = 0.001$).

Conclusions: Our results demonstrate that healthcare professionals and managers are familiar with using quality indicators to improve care, and that they have positive attitudes towards the implementation of quality indicators. Despite these facts, it is necessary to lower the barriers related to behavioural factors. In addition, as the barriers and facilitating factors differ among professions, age groups, and settings, tailored strategies are needed to implement quality indicators in daily practice.

BACKGROUND

Quality indicators are increasingly being used in healthcare to support and guide improvements in quality of care. The purpose of implementing quality indicators as a tool to assist quality improvement is to periodically report and monitor indicator data in order to improve quality of care. In several countries, the development of indicators is emerging and examples of sets of indicators for quality of hospital care are available.[1,2] Although quality indicators are applied as a tool to guide the process of QI in healthcare, hospitals that adopt quality indicators are faced with problems concerning implementation.[3,4] Successful implementation, however, is critical to maximise the effect of quality indicators on the quality of care.[5]

Quality management is crucial in intensive care units (ICUs), and quality indicators can be used as a tool to assist quality improvement. Morbidity and mortality rates in ICUs vary widely among hospitals.[6] This variation is likely to be related to differences in ICU structure and care processes.[7,8] Understanding of these factors may reduce variation and ultimately improve patient care.

An evaluation of barriers to and facilitators for using quality indicators could inform strategies for their implementation in daily practice.[9] Cabana *et al.* assessed potential barriers at each stage of behavioural change for guideline implementation and placed them within a knowledge-attitude-behaviour framework.[10] Successful implementation depends upon three conditions. First, all healthcare professionals involved have to be familiar with and aware of quality indicators. Second, they need to have positive attitudes towards the use of quality indicators as a tool to improve the quality of care. Third, barriers related to behaviour, such as time and organizational constraints, need to be addressed.[9,10] Although behaviour can be changed without knowledge or attitude being affected, behaviour change based on improving knowledge and attitude is probably more sustainable than indirect manipulation of behaviour alone.[10]

In general, little is known about the knowledge, attitudes, and behaviour of physicians, nurses, and managers regarding the implementation of quality indicators in daily practice. Some studies have assessed the knowledge, attitude, and behaviour of ICU staff to specific practice guidelines or guidelines in general.[11–13] Relatively few studies have examined attitudes of physicians towards the use of quality indicators; we are aware of none that have addressed the intensive care setting.[14–17]

In 2006, the Dutch National Society of Intensive Care Medicine (NVIC) developed a set of quality indicators in order to evaluate and improve quality at Dutch ICUs.[18] This set of indicators is due to be implemented in all ICUs from 2008 onwards as part of the Dutch National Intensive Care Evaluation (NICE) registry. For each ICU, the implementation process of the indicators started with a course for ICU staff regarding the collection of data. This offered the possibility for the current study to explore barriers to knowledge, attitude, and behaviour that may affect implementation of quality indicators in Dutch ICUs, and to assess facilitators for the implementation of these indicators in daily practice.

METHODS

Study population

Included in this study were all intensivists, ICU nurses, and managers (n = 142) who participated in the NICE registry course regarding the collection of indicator data in the period from September 2007 to December 2008.[18] In this study, managers were people working in the ICU who were not engaged in direct patient care but carried the responsibility of making management decisions for the ICU based on the indicator scores. Participants completed the questionnaire at the start of the training sessions.

Questionnaire content

In close cooperation with the NVIC, we developed a questionnaire that was divided into three sections. The first part addressed professional as well as demographic characteristics such as gender, age, profession, year of graduation, and type of hospital. The second section contained statements concerning barriers at each stage of behaviour change that may affect the implementation of quality indicators in ICUs. We classified the barriers into three categories using Cabana's framework of barriers related to knowledge, attitude, and behaviour.[10] Knowledge-related barriers refer to lack of awareness or familiarity with the term quality indicator in general; barriers related to attitude refer to lack of motivation to implement and use quality indicators, or a lack of confidence in outcome. Behaviour-related barriers concern external factors such as lack of time and resources, or organizational constraints that restrict healthcare professionals' abilities to change their behaviour.

Analogous to this framework, we assessed eleven statements focusing on barriers related to knowledge, attitude, and behaviour. We used statements from a previously validated instrument designed to assess barriers to change across different innovations and healthcare settings.[19] The barriers to change in this instrument were based on a literature review and an expert panel consensus procedure with implementation experts. Studies have used this instrument successfully to identify barriers to the implementation of clinical practice guidelines.[19,20] We consulted four healthcare professionals (ICU nurses and intensivists with special interest in implementation) to check the relevance of each item on the questionnaire and whether there were any items missing that should be included. Several items in the questionnaire that were not relevant to the context of the ICU setting or to the implementation of indicators were removed. We performed an exploratory factor analysis based on current data regarding the eleven statements. This resulted in three factors, all with reasonably good reliability (Cronbach's alpha 0.73, 0.74 and 0.71).[21] Factor one comprised two items that addressed how respondents rated their knowledge regarding quality indicators with factor loadings 0.70 and 0.81. Factor two contained six statements about their attitude with factor loadings ranging from 0.32 to 0.68, and the three statements of factor three assessed their behaviour with factor loadings 0.48, 0.50, and 0.57 respectively.

The third section of the questionnaire included questions regarding perceived facilitating factors for healthcare professionals and managers. This was based on results from a review, including studies dealing with healthcare professionals' attitude to quality and QI.[22] These studies assessed healthcare professionals' enabling factors for QI in healthcare.

All statements and items used in the questionnaire were scored on a five-point Likert scale ranging from '1 =strongly disagree' to '5 = strongly agree.' An open-ended question was added for additional suggestions regarding facilitating factors that might enable the implementation of quality indicators in daily practice.

Data analysis

Descriptive statistics were used to characterize the study sample. The questionnaire contained both positively and negatively formulated statements. To calculate a mean score (MS), we recoded the response on the negatively formulated statements. A score of more than three on the five-point scale was indicated as positive, less than three as negative and a score of three was indicated as neutral. Data were excluded from analysis if there was a missing value on one or more of the items.

Multiple linear regression was used to explain the scores of the overall knowledge, attitude, and behaviour scales stratified by professional characteristics and settings. All independent variables were included into the model simultaneously, adjusting each variable in relation to the others. The scores of the overall knowledge, attitude, and behaviour scales were calculated based on the mean scores of the individual statements. The independent variables included in the model were gender, profession (healthcare professional or manager), and type of hospital (academic/teaching or non-teaching). For the purpose of analysis, respondents were divided into three age groups: <40 years, 40 to 49 years, and ≥ 50 years of age. In addition, MS of the reported facilitating factors among professions (intensivist, ICU nurse, and manager) were compared using analysis of variance (ANOVA) with statistical significance defined as $p \leq 0.05$. The presence of multicollinearity was tested by determining the variance inflation factor (VIF) and tolerance value per variable. Cut-off values were a VIF >4 and tolerance <0.25.[23]

RESULTS

Study population

All 142 professionals attending the training sessions (82 intensivists, 40 ICU nurses, and 20 managers coming from 54 ICUs in 51 hospitals out of the total of 94 Dutch ICUs) completed the questionnaire (response rate 100%). The group of participating ICUs included 36 teaching hospitals, of which six were academic hospitals (affiliated to a university), and 15 were non- teaching hospitals. The characteristics of the respondents are shown in Table 1. The majority of the 142 respondents were male (66%), 71% graduated after 1990, 50% were between 40 and 50 years of age, and 76% were affiliated to teaching or academic hospitals.

Table 1 – Study population (n=142)

Demographics and professional characteristics	n	(%) [a]
Gender		
Male	93	(65.5)
Female	49	(34.5)
Age (years)		
<40	42	(29.6)
40 to 49	72	(50.7)
>49	28	(19.7)
Profession		
Intensivist	82	(57.7)
ICU nurse	40	(28.2)
Management	20	(14.1)
Hospital type		
Academic hospital	12	(8.5)
Teaching hospital	96	(67.6)
Non-teaching hospital	34	(23.9)
Year of graduation		
1971 to 1990	41	(29.1)
>1990	100	(70.9)

Abbreviations: ICU, intensive care unit

[a] *Numbers may not add up to 142 and percentages may not add up to 100% due to missing values*

Barriers regarding knowledge, attitude, and behaviour

Figure 1 shows the response to each of the eleven statements. Seventy-seven percent of the respondents were familiar with the use of quality indicators as a tool to improve quality of care, and 41% knew about the Dutch set of ICU quality indicators (statements one and two).

Scores on attitudes varied between 55% of the respondents agreeing that monitoring of quality indicators leads to reliable benchmark data for ICUs, up to 95% of the respondents agreeing that receiving feedback on quality indicators stimulated them to adjust their practice (statements three through eight). More than 90% reported understanding the importance of using quality indicators and were willing to implement quality indicators in daily practice. Approximately 80% agreed with the statement that they would not resist working with indicators in the near future and agreed that monitoring of quality indicators stimulates QI.

As shown in Figure 1, 59% percent of all respondents agreed that monitoring of quality indicators fits into the daily routines in the hospital setting, 28% agreed that monitoring does not take too much time, and 30% agreed that monitoring of quality indicators could be done without huge investments (statements nine through eleven).

Facilitating factors

In regard to the perceived facilitating factors, respondents reported receiving feedback on quality indicator data (92% of the respondents), administrative support (89%), and education (87%) as important facilitating factors (Figure 2). Factors related to the intrinsic motivation of healthcare professionals and managers for improvement (90%) and possibilities to improve care (91%) were also considered as important facilitators. The least perceived as facilitating factors were those related to external motivation, such as social pressure from hospital management (14%), pay for performance (57%), social demand for transparency (58%), and the designation of an opinion leader (41%).

Of the 142 respondents, 77 reported additional suggestions regarding facilitating factors for the implementation of quality indicators. Most of the responses revealed factors relating to the availability of resources such as the implementation of a patient data management system (PDMS) coupled with a hospital information system (20% of 77 respondents) and user-friendly software to register the indicators (9%). Other suggestions regarding resources are the appointment of one person responsible for the coordination and registration of the indicators (for example, a secretary) (8%), additional staff members for administrative support (10%), additional hours for non-patient related work such as the registration of the indicators (9%), the establishment of a QI team (5%), support from management (4%), and the appointment of a quality manager at the ICU (3%). In addition, respondents offered some suggestions regarding education. Most respondents reported the importance of well-trained personnel for the indicator registration (14%), availability of information about the purpose and importance of using indicators (8%), and education in QI principles (7%). Regarding feedback, some respondents suggested that the frequency of the feedback should be quarterly and be provided by mail (7%), and should also give alerts when one exceeded predefined targets (3%). With respect to the content of the feedback, respondents reported that feedback should be confidential, independent, and positive (4%). In addition, the content of the feedback should include results at ward level with comparison to the national benchmark and to similar units (3%). Finally, respondents state that it is important that the recipients of the feedback include ICU management and healthcare professionals (2%).

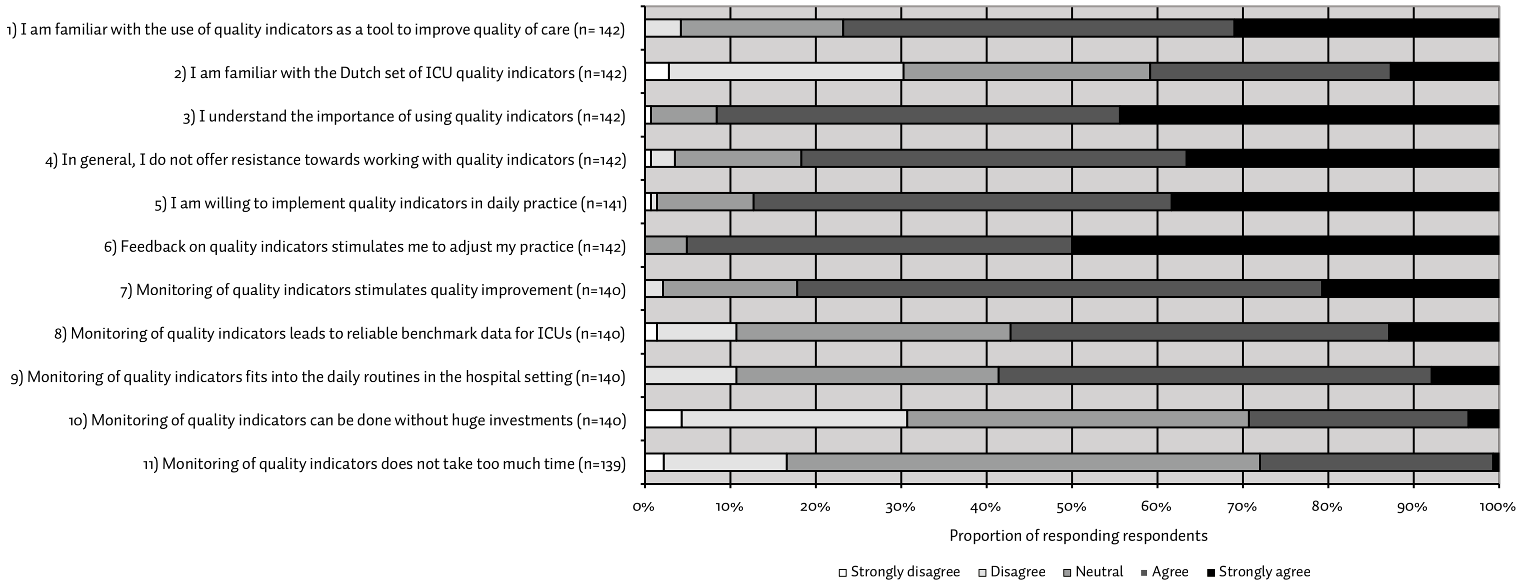

Figure 1 *– Response to eleven statements regarding perceived barriers towards implementation of quality indicators*

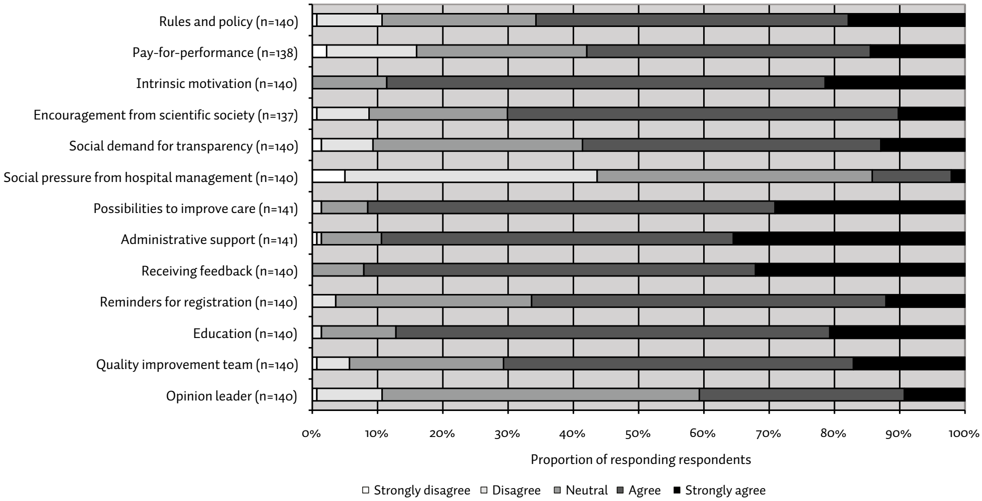

Figure 2 *– Response to several items about factors that may facilitate the implementation of quality indicators*

Determinants of knowledge, attitude, and behaviour

Collinearity statistics did not show any variables with a VIF > 4 or a tolerance < 0.25. Therefore, all previously described independent variables were included in the multiple linear regressions. Table 2 illustrates the determinants of self-reported scores on overall knowledge, attitude, and behaviour determined from regression analyses. The multiple linear regression showed that being a manager ($\beta = 0.58$; $p = 0.00$) and being between 40 and 49 years old ($\beta = 0.35$; $p = 0.03$) were related to a higher level of overall knowledge. Managers had a higher level of knowledge compared to healthcare professionals (MS = 4.1 versus MS = 3.5; $p = 0.004$). Within the group of healthcare professionals, ICU nurses had a lower level of knowledge than intensivists (MS = 3.1 versus MS = 3.7; $p = 0.01$). In addition, working in a non-teaching hospital was associated negatively with overall knowledge ($\beta = -0.32$; $p = 0.05$) (Table 2). Healthcare professionals and managers working in non-teaching hospitals had a lower level of knowledge compared to those working in academic or teaching hospitals ($p = 0.01$).

None of the characteristics was statistically significant related to overall attitude (Table 2). The multiple linear regression revealed that being older than 49 years (as compared to colleagues under 40 years of age) positively affected overall behaviour ($\beta = 0.36$; $p = 0.01$), whereas working in a non-teaching hospital was negatively associated with high scores on the overall behaviour scale ($p = 0.01$).

Table 2 – Determinants of scores on overall knowledge, attitude, and behaviour scale

	Overall knowledge [a]		Overall attitude [a]		Overall behaviour [a]	
	Beta	P-value	Beta	P-value	Beta	P-value
Constant	3.37	0.00	4.06	0.00	3.18	0.00
Manager (versus healthcare professional)	0.58	0.00	0.20	0.10	0.07	0.63
Female (versus male)	0.04	0.79	0.05	0.61	-0.03	0.81
Aged between 40 and 49 years (versus aged <40 years)	0.35	0.03	0.01	0.88	0.05	0.65
Aged >49 years (versus aged <40 years)	0.31	0.13	0.16	0.20	0.36	0.01
Non-teaching hospital (versus academic or teaching)	-0.32	0.05	-0.09	0.35	-0.29	0.01

Mean values and P-values were obtained by multiple linear regression (n = 142), involving all variables simultaneously
[a] *Overall = all statements combined*

Determinants of facilitating factors

The perceived facilitating factors differed among the various types of professions. Intensivists reported administrative support as the strongest facilitating factor (MS = 4.3; p = 0.02), ICU nurses reported education as being the most important (MS = 4.0; p = 0.01), and managers indicated receiving feedback (MS = 4.5; p = 0.001) and opportunities to improve care (MS = 4.5; p = 0.003) as the most important facilitating factors. Intensivists, nurses, and managers perceived social pressure from hospital management as the least facilitating factor (MS = 2.6; 2.8 and 2.8, respectively).

DISCUSSION

We conducted an exploratory study of self-reported barriers to and facilitators for the implementation of quality indicators in Dutch ICUs. Our results show that, in general, healthcare professionals and managers are familiar with the concept of using quality indicators to improve care. Although they have positive attitudes regarding the implementation of quality indicators, many are less than confident that these indicators can be fully implemented in their daily practice. These findings in the ICU setting are in line with previous results outside the ICU, which indicate that even if healthcare professionals are familiar with indicators and have overall positive attitudes regarding quality indicators, there is no guarantee that they will change their daily practice.[24,25] Lack of time and resources can be considered as the most important barriers to the implementation of quality indicators in Dutch ICUs.

The facilitating factors most frequently mentioned in this study were related to the availability of resources such as a PDMS interfaced with a hospital information system and user-friendly software to register the indicators. Other important factors were the designation of well-trained persons to carry out the indicator data registration. These results are similar to the findings of other international studies.[20,22]

Our results show that respondents' profession, age, and type of hospital were associated with certain aspects of knowledge and behaviour. Familiarity with the use of quality indicators as a tool to improve the quality of care was higher among intensivists and managers, compared to nurses. Nurses were also less familiar with the Dutch set of ICU quality indicators. In order to become more familiar with the set of ICU quality indicators, it may be necessary to provide them with additional training, including handbooks and instructions on how to collect data. Healthcare professionals and managers between 40 and 49 years old and working in academic or teaching hospitals had a higher overall knowledge level, compared to those younger than 40 and those working in non-teaching hospitals. This finding is consistent with a recently conducted study that reported that older healthcare professionals working in the ICU had more knowledge of guidelines compared to younger healthcare workers.[12] None of the characteristics included in our analyses was a significant predictor of overall attitude.

Regarding behaviour-related barriers, higher age and working at academic or teaching hospitals were significant predictors. Healthcare professionals and managers working at ICUs in academic and teaching hospitals tend to be more prepared to change behaviour and to actively work towards implementation compared to healthcare professionals and managers working in ICUs in non-teaching hospitals.

In our sample, non-teaching hospitals are slightly underrepresented compared to the overall proportion of non-teaching hospitals nationwide in the Netherlands. This may indicate that the results are somewhat more positive, because these hospitals showed lower scores on knowledge and behaviour in our study. However, generalizability to all Dutch ICUs is not the main objective of the current study. The study aims to identify barriers as perceived by healthcare professionals who already work with indicators. In addition, the proportion of non-teaching hospitals in our study is similar to the proportion of non-teaching hospitals participating in the Dutch NICE registry, which may indicate that non-teaching hospitals are less motivated to implement quality indicators in daily practice. Haagen et al. also found that working in a non-teaching hospital is related to barriers regarding motivation.[26]

Several factors can be of importance in facilitating the implementation of quality indicators. Our study showed that intrinsic motivation and possibilities to improve care are considered as very important facilitating factors. Consistent with results from other studies, factors such as administrative support and receiving feedback were also considered as important facilitators.[18,27] Intensivists, nurses, and managers appear to have different ideas concerning the perceived facilitating factors. Nurses were less familiar with quality indicators and reported that they would like to have some training in the registration of the indicators. Managers prefer to receive feedback on indicator scores, and intensivists reported administrative support as the most important facilitating factor. These findings imply that in order to implement quality indicators successfully in the ICUs, different strategies for different types of professionals are needed.

This study was a first exploration of barriers to and facilitators for the implementation of quality indicators in ICUs. The sample of respondents represented healthcare professionals who volunteered to attend training sessions aiming to implement quality indicators at their ICU. Therefore, the results might give a somewhat more positive picture than is the case elsewhere because these respondents may be more motivated compared to the total population of ICU professionals. In addition, because the 54 ICUs represented in our sample represent 57% of Dutch ICUs, results may not be generalizable to all ICUs. However, it serves as a valuable first attempt to evaluate attitudes of healthcare professionals and managers towards implementation of quality indicators in daily practice. Whether these results can be extrapolated to other countries can only be a matter of speculation. However, we cannot think of obvious reasons why other developed countries would yield different results.

This study relies on self-reported perceived knowledge, attitude, and behaviour. Inevitably there is a risk of social desirability bias (individuals may wish to present themselves or their organization in a favourable way). Nevertheless, these data provide evidence of the barriers and facilitators that exist in regard to the implementation of quality indicators in ICUs and provide useful suggestions for the implementation. Administrative support, additional education, and effective feedback of indicator scores may be effective strategies to lower the barriers. In addition, special attention needs to be paid to healthcare professionals working in ICUs in non-teaching hospitals in order to motivate them to implement quality indicators, and to the education in QI concepts for both those working in ICUs in non-teaching hospitals and nurses. This difference in focus should be taken into account when developing implementation strategies. Tailored strategies have to be developed for each profession or type of hospital.

Because no validated questionnaires were available on this subject, we developed our own questionnaire. In this, we used the well-known framework of Cabana evaluating the stages of behaviour change. We reformulated the statements regarding barriers to guideline adherence because we used the classification within the framework of identifying barriers to implementing indicators in daily practice. Although the value of the questionnaire needs to be confirmed, inspection of the factor loadings and internal consistency suggests that it could be a useful tool for future studies.

Summary

In conclusion, the results of this study suggest that even in a situation in which knowledge and attitude towards implementation are generally positive, barriers related to behaviour need to be addressed before healthcare professionals and managers would be willing to work actively towards implementation.

Despite the increased interest in using quality indicators in daily practice in order to improve the quality of care, hospitals often struggle with its implementation.[3,5,28] The present exploratory study is the first study with a structured method to identify important barriers and facilitators that might inform the process of implementation. It could serve as a starting point for professionals and organizations to identify local barriers in more detail and to develop tailored strategies for the implementation of quality indicators in their organization. Moreover, we have used these findings as a part of the development of a tailored strategy to address these barriers in order to improve the implementation of quality indicators in clinical practice.

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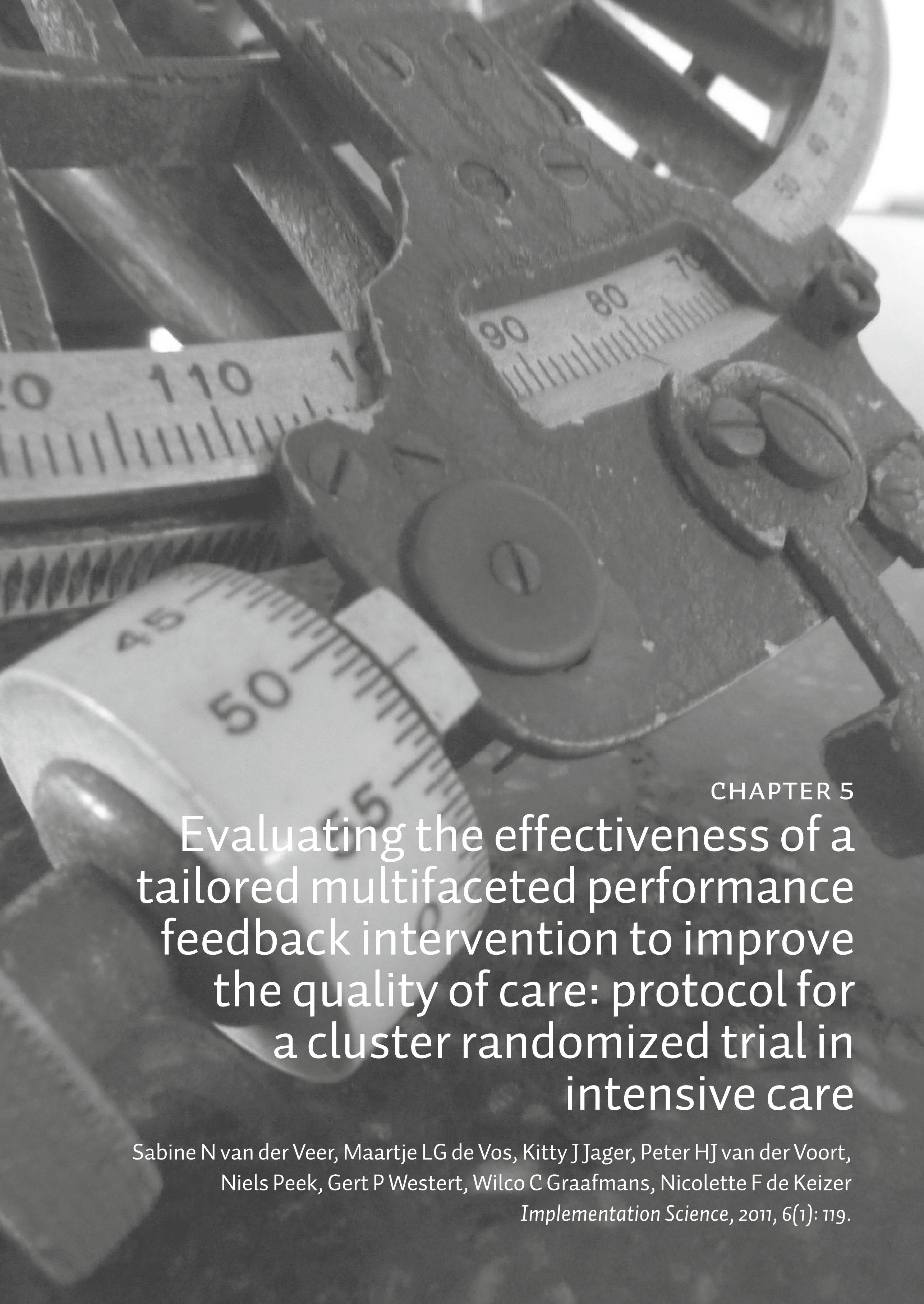

CHAPTER 5

Evaluating the effectiveness of a tailored multifaceted performance feedback intervention to improve the quality of care: protocol for a cluster randomized trial in intensive care

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ABSTRACT

Background: Feedback is potentially effective in improving the quality of care. However, merely sending reports is no guarantee that performance data are used as input for systematic quality improvement (QI). Therefore, we developed a multifaceted intervention tailored to prospectively analyzed barriers to using indicators: the Information Feedback on Quality Indicators (InFoQI) program. This program aims to promote the use of performance indicator data as input for local systematic QI. We will conduct a study to assess the impact of the InFoQI program on patient outcome and organizational process measures of care, and to gain insight into barriers and success factors that affected the program's impact. The study will be executed in the context of intensive care. This paper presents the study's protocol.

Methods/design: We will conduct a cluster randomized controlled trial with intensive care units (ICUs) in the Netherlands. We will include ICUs that submit indicator data to the Dutch National Intensive Care Evaluation (NICE) quality registry and that agree to allocate at least one intensivist and one ICU nurse for implementation of the intervention. Eligible ICUs (clusters) will be randomized to receive basic NICE registry feedback (control arm) or to participate in the InFoQI program (intervention arm). The InFoQI program consists of comprehensive feedback, establishing a local, multidisciplinary QI team, and educational outreach visits. The primary outcome measures will be length of ICU stay and the proportion of shifts with a bed occupancy rate above 80%. We will also conduct a process evaluation involving ICUs in the intervention arm to investigate their actual exposure to and experiences with the InFoQI program.

Discussion: The results of this study will inform those involved in providing ICU care on the feasibility of a tailored multifaceted performance feedback intervention and its ability to accelerate systematic and local QI. Although our study will be conducted within the domain of intensive care, we believe our conclusions will be generalizable to other settings that have a quality registry including an indicator set available.

BACKGROUND

To systematically monitor the quality of care and develop and evaluate successful improvement interventions, data on clinical performance are essential. [1,2] These performance data are often based on a set of quality indicators, ideally combining measures of structure, process, and outcomes of care. [3,4]

Also within the domain of intensive care, several indicator sets have been developed, [5-9] and numerous quality registries have been established worldwide to routinely have indicator data available on the performance of intensive care units (ICUs). [10-13] In the Netherlands, the National Intensive Care Evaluation (NICE) registry was founded in 1996 by the Dutch intensive care profession with the aim to systematically and continuously monitor, assess, and compare ICU performance, and to improve the quality of ICU care based on the outcome indicators case-mix adjusted hospital mortality and length of ICU stay. [13] In 2006, this limited core data set of outcome indicators was extended to a total of eleven structure, process, and outcome indicators, adding items such as nurse-to-patient ratio, glucose regulation, duration of mechanical ventilation, and incidence of severe pressure ulcers. The extended set was developed by the Netherlands Society for Intensive Care (NVIC) in close collaboration with the NICE foundation. [7]

Besides facilitating data collection and analyses, NICE-like most quality registries-also sends participants periodical feedback reports on their performance over time and in comparison with other groups of ICUs. Although feedback is potentially effective in improving the quality of care, [14-16] merely sending feedback reports is no guarantee that performance data are used as input for systematic quality improvement (QI).

Problem: barriers perceived by healthcare professionals to using performance feedback for systematic quality improvement

Previous systematic reviews reported potential barriers at different levels to using performance data for systematic improvement of healthcare, e.g., insufficient data quality, no acknowledgement of the room for improvement in current practice, or lack of resources to implement quality interventions. [15,16] The results of a validated questionnaire completed by 142 healthcare professionals working at 54 Dutch ICUs confirmed that such barriers also exist within the context of intensive care. [17] As suggested by others, [18,19] we translated these prospectively identified barriers into a multifaceted QI intervention using input from future users, expert knowledge, and evidence from literature. The table in 'Appendix 1' contains all barriers identified and how they are targeted by the intervention. We named the resulting QI program InFoQI (Information Feedback on Quality Indicators). InFoQI was developed and will be evaluated within the context of intensive care and the Dutch NICE registry. By targeting the potential barriers to using performance feedback as input for systematic QI activities at ICUs, the InFoQI program ultimately aims to improve the quality of intensive care.

Study objectives

The study as proposed in this protocol aims to evaluate the effect of the tailored multifaceted feedback intervention on the use of performance indicator data for systematic QI at ICUs. Specific objectives include:

1. To assess the impact of the InFoQI program on patient outcome and organizational process measures of ICU care.
2. To gain insight into the barriers and success factors that affected the program's impact.
3. The InFoQI program was designed to overcome the previously identified barriers to using performance indicator data as input for local QI activities. Based on this assumption we hypothesize that ICUs participating in the InFoQI program will improve the quality of their care significantly more than ICUs receiving basic feedback from the NICE registry.

The results of this study will inform those involved in providing ICU care on the feasibility of the InFoQI program and its ability to accelerate systematic, local QI at ICUs. More in general, we believe that our results might be of interest to clinicians and organizations in any setting that use a quality registry including performance indicators to continuously monitor and improve the quality of care.

METHODS

Study design

We will execute a cluster randomized controlled trial to compare facilities participating in the InFoQI program (intervention arm) to facilities receiving basic feedback from the NICE registry (control arm). Because the InFoQI program will be implemented at the facility rather than individual level, a cluster randomized trial is the preferred design for the evaluation of the program's effectiveness. [20] Like most trials aimed at evaluating organizational interventions, our study is pragmatic. [21] To apply to current standards, the study has been designed and will be reported in accordance with the CONSORT statement [22] and the appropriate extensions. [23,24]

Setting

The setting of our study is Dutch intensive care. In the Netherlands, virtually all 94 ICUs are mixed medical-surgical closed-format units, i.e., units with the intensivist as the patient's primary attending physician. The units are a mixture of academic, teaching, and non-teaching settings in urban and non-urban hospitals. In 2005, 8.4 adult ICU beds per 100,000 population were available, and 466 patients per 100,000 population were admitted to the ICU that year. [25] Currently, a representative sample of 80 ICUs-covering 85% of all Dutch ICUs-voluntarily submit the limited core data set to the NICE registry, and 46 of them collect the complete, extended quality indicator data set.

At the NICE coordination centre, dedicated data managers, software engineers, and a coordinator are responsible for routine processing, storing, checking, and reporting of the data. Also, for the duration of the study, two researchers will be available to provide the InFoQI program to ICUs in the intervention arm. The availability of these resources is essential for the feasibility of our study.

Selection of participants

All 46 ICUs that participate in NICE and (are preparing to) submit data to the registry on the extended quality indicator set will be invited to participate in our study. They should be willing and able to allocate at least two staff members for an average of four hours per month to be involved in the study. The medical manager of the ICU must sign a consent form to formalize the organization's commitment.

All patients admitted to participating ICUs during the study period will be included in the analyses. However, when evaluating the impact on patient outcomes, we will exclude admissions based on the Acute Physiology and Chronic Health Evaluation (APACHE) IV exclusion criteria, [26] as well as admissions following cardiac surgery, patients who were dead on admission, and admissions with any of the case-mix variables missing.

Control arm: basic feedback from the NICE registry

The ICUs allocated to the control arm will be treated as 'regular' NICE participants. This implies they will receive basic quarterly and annual feedback reports on the registry's core outcome indicators case-mix adjusted hospital mortality and length of ICU stay. In addition, they will be sent similar, but separate, basic quarterly and annual feedback reports containing data on the extended indicator set. Also, support by the NICE data managers is available and includes data quality audits, support with data collection, and additional data analyses on request. Furthermore, they are invited to a yearly discussion meeting where they can share experiences with other NICE participants.

Intervention arm: the InFoQI program

ICUs assigned to the intervention arm, i.e., participating in the InFoQI program, will receive the same intervention as the control arm, but extended with more frequent and more comprehensive feedback, a local, multidisciplinary QI team, and two educational outreach visits (Table 1).

From the prospective barriers analysis, it appeared that many barriers concerned the basic NICE feedback reports. To target the lack of case-mix correction and lack of information to initiate QI actions, the basic quarterly report will be replaced by an extended, comprehensive quarterly report that facilitates comparison of an ICU's performance with that of other ICUs, e.g., by providing the median length of ICU stay for elective surgery admissions in similar-sized ICUs as a benchmark. To increase the timeliness and intensity of reporting, we also developed a monthly report focusing on monitoring an ICUs' own performance over time to facilitate local evaluation of QI initiatives, e.g., by providing Statistical Process Control (SPC) charts.[27] To decrease the level of data aggregation, both the monthly and quarterly reports contain data at the level of individual patients, e.g., a list of unexpected non-survivors (i.e., patients who died despite their low risk of mortality). The table in 'Appendix 2' summarizes the content of the reports.

ICUs in the intervention arm will establish a local QI team, creating a formal infrastructure at their department for systematic QI. This team must consist of at least one intensivist and one nurse; a management representative and a data manager are suggested as additional members. To target the lack of motivation to change, team members should be selected based on their affinity and experience with measuring and improving quality of care and their capability to convince their colleagues to be involved in QI activities. The team's main tasks are described in a protocol and include formulating a QI action plan, monitoring of performance using the feedback reports, and initiating and evaluating QI activities (Table 1). We estimate the minimum time investment per team member to be four hours on average per month. This estimation takes into account all activities prescribed by the InFoQI program except for the execution of the QI plan. The actual time spent will depend on the type and number of QI actions in the plan.

Each ICU will receive two on-site educational outreach visits that are aimed at increasing trust in data quality, supporting the QI team members with interpreting their performance data, identifying opportunities for improvement, and translating them into a QI action plan. The structure of the visits will be equal for all intervention ICUs and the template for the action plan will be standardized. All visits will be facilitated by the same investigators who have a non-medical background; they have been involved in the development of the extended NVIC indicator set and have several years of experience with optimization of organizational processes at the ICU. Having non-clinicians supporting the QI team will make the intervention less intrusive, and therefore less threatening to participating units. It also increases the feasibility of the study, because clinical human resources are scarce in intensive care.

Table 1 *– Elements of the InFoQI program (intervention arm)*

Element	Description
Feedback reports	• monthly report for monitoring ICU's performance over time • comprehensive quarterly report for benchmarking ICU's performance to other groups of ICUs • sent to and discussed by QI team members
Local QI team	• multidisciplinary • responsible for formulating and executing a QI action plan • monthly monitoring and discussing of performance using feedback reports • sharing main findings with rest of ICU staff
Educational outreach visits	• on-site (1) at start of study period and (2) after six months • all QI team members are present; visits guided by principal investigators • promoting use of Plan-Do-Study-Act cycle for systematic quality improvement • formulating and evaluating QI action plan based on performance data

Abbreviations: ICU, intensive care unit; QI, quality improvement

Outcome measures

We used previously collected NICE data (regarding the year 2008) to select outcome measures from the extended quality indicator set to evaluate the effectiveness of our intervention. To decrease the probability of finding positive results by chance as a result of multiple hypotheses testing,[28] we limited our primary endpoints to a combination of one patient outcome and one organizational process measure. We selected the indicators that showed the largest room for improvement, i.e., the largest difference between the average of top-performing centres and the average of the remaining centres.[29]

Primary outcome measures will be:

1. Length of ICU stay (ICU LOS); this will be calculated as the difference in days between the time of ICU discharge and time of ICU admission. To account for patients being discharged too early, the length of stay of the first ICU admission will be prolonged with the length of stay of subsequent ICU readmissions within the same hospital admission.
2. Proportion of shifts with a bed occupancy rate above 80%; this threshold is set by the NVIC in their national organizational guideline for ICUs.[30] We will calculate the bed occupancy rate as the maximum number of patients admitted simultaneously during an eight-hour nursing shift divided by the number of operational beds in that same shift. A bed will be defined as 'operational' when it is fitted with monitoring and ventilation equipment and scheduled nursing staff.

Secondary outcome measures will be all-cause, in-hospital mortality of ICU patients, duration of mechanical ventilation, proportion of glucose measurements outside the range of 2.2 to 8.0 mmol/L, and the proportion of shifts with a nurse-to-patient ratio below 0.5.

Data collection

We will use the existing data collection methods as currently applied by the NICE registry.[31] Most ICUs participating in NICE combine manual entry of data using dedicated software with automated data extractions from electronic patient records available in, e.g., their patient data management system. Each month, participants upload their data from the local, electronic database to the central, electronic registry database. ICUs in the intervention arm that have not submitted their data at the end of a month will be reminded by phone, and assisted if necessary. Quarterly reports are provided within ten weeks after the end of a period, and monthly reports within six weeks.

The NICE registry uses a framework for data quality assurance,[32] including elements like periodical on-site data quality audits and automated data range and consistency checks. For each ICU, additional data checks for completeness and accuracy will be performed before, during, and after the study period using descriptive statistics.

Sample size calculations

The minimally required number of ICUs participating in the trial was based on analysis of the NICE registry 2008 data. First, ICUs were ranked by average ICU LOS of their patients. The anticipated improvement was defined as the difference in average ICU LOS of the 33% top ranked ICUs (1.28 days) and average ICU LOS among the remaining ICUs (2.11 days), and amounted to a reduction of 0.58 days per patient. A senior intensivist confirmed that this reduction is considered clinically relevant. Assuming an average number of 343 admissions per ICU per year, calculations based on the normal distribution showed that we will need at least 26 ICUs completing the trial to detect this difference with 80% power at a type I error risk (a) of 5%, taking an estimated intra-cluster correlation of 0.036 into account. With this number of ICUs, the study will also be sufficiently powered to detect a reduction in mechanical ventilation duration of 0.75 days per patient (from 2.96 to 1.75 days). We do not expect to be able to detect an effect of the intervention on ICU or hospital mortality.

To determine the required sample size for bed occupancy, shifts with an occupancy exceeding 80% were counted. This occurred in 44% of all shifts in 2008. Following the same ranking procedure as described above, a reduction of 24% was anticipated, and considered clinically relevant. Power calculations based on the binomial distribution showed that we will need a minimum of 16 ICUs completing the trial to detect this difference, taking an estimated intra-cluster correlation of 0.278 into account.

Randomization

We will randomly allocate ICUs (clusters) to one of both study arms, stratified by the number of ventilated, non-cardiac surgery admissions (less than the national median versus more than the national median), and involvement in a previous pilot study to evaluate feasibility of data collection of the NVIC indicator set (involved versus not involved).[7] Each stratum will consist of blocks with a randomly assigned size of either two or four ICUs (Figure 1). A researcher-not involved in the study and blinded to the identity of the units-will use dedicated software to generate a randomization scheme with an equal number of interventions and controls for each block. The size and the randomization scheme of the blocks will be concealed to the investigators enrolling and assigning the ICUs. In an email to the ICU confirming the arm to which they have been allocated, the researcher that executed the randomization process will be sent this information in copy as an additional check on the assignment process. Due to the character of the intervention, it will not be possible to blind participants or the investigators providing the InFoQI program.

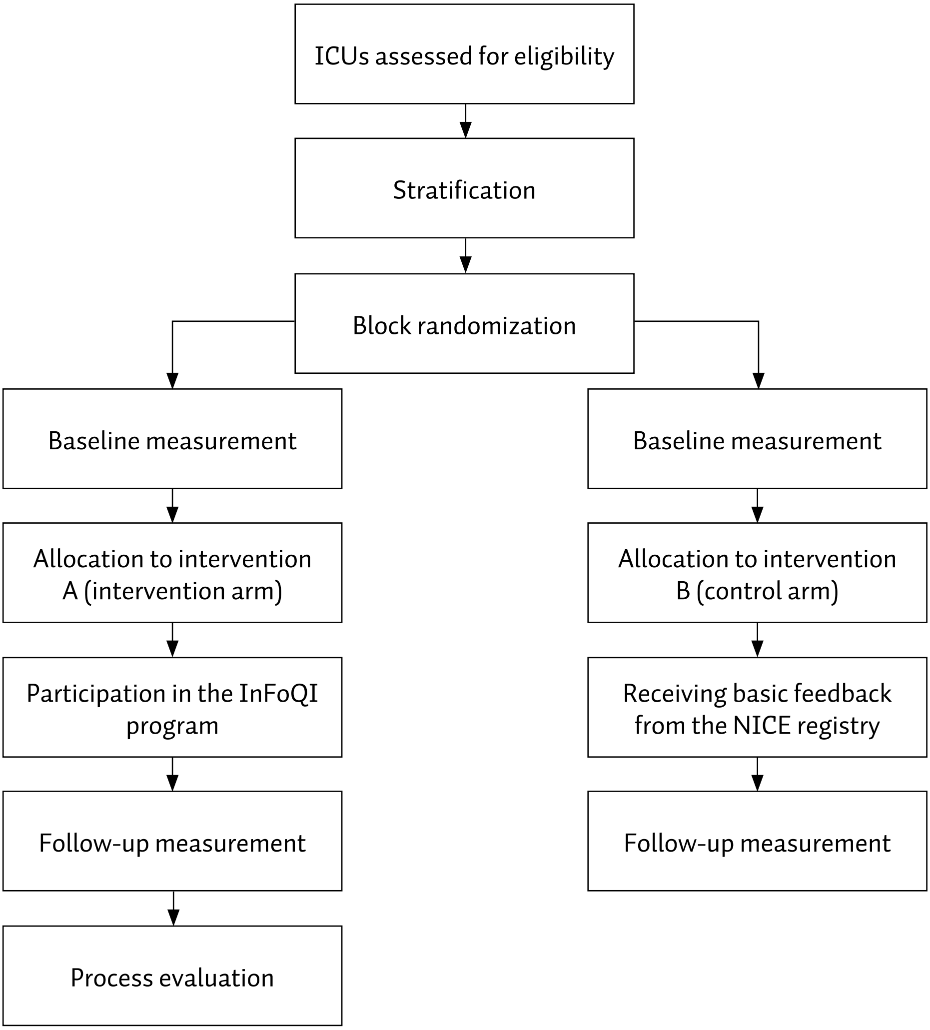

Figure 1 *– Study flow*

** Stratification was based on size (more/less than the national median number of ventilated, non-cardiac surgery admissions) and involvement (yes/no) in a pilot to evaluate feasibility of indicator data collection*

Statistical analysis

For ICUs in the intervention group, the time from randomization to the first outreach visit-with an expected duration of six to eight weeks-will be regarded as a baseline period. Follow-up will end three months after the last report has been sent, assuming this is the average time required for an ICU to read, discuss, and act on a feedback report. The expected duration for intervention ICUs will therefore be approximately fourteen months. Control ICUs will have a fixed baseline period of two months, and a follow-up of fourteen months.

To assess the effect of the InFoQI program, the outcome values measured during the follow-up period will be compared between both study arms. To assess the effect of the program on length of stay, we will perform a survival analysis of time to alive ICU discharge with dying at the ICU as a competing risk,[33] and adjusting for patient demographics, severity of illness during first 24 hours of admission, and admission type. To account for potential correlation of outcomes within ICUs, we will use generalized estimation equations with exchangeable correlation.[34-36] The same procedure will be used to analyze duration of mechanical ventilation. For all-cause mortality, logistic regression analysis will be used, adjusting for severity of illness at ICU admission by using the APACHE IV risk prediction model.[26]

To assess the effect of the intervention on the proportion of shifts with a bed occupancy rate above 80%, shift-level occupancy data (0 for an occupancy rate below or equal to 80%, 1 for a rate above 80%) will be analyzed with logistic regression analysis. In this case, generalized estimation equations with an autoregressive correlation structure will be used to account for the longitudinal nature of shift occupancy observations. The same procedure will be followed to analyze the proportion of shifts with a nurse-to-patient ratio below 0.5.

To assess the effect on the proportion of out-of-range glucose measurements, multi-level logistic regression analysis will be performed where subsequent glucose measurements on the same patient are treated as time series data, and both patient-level and ICU-level intercept estimates are used to account for potential correlation of measurements within patients and within ICUs.

Process evaluation

We will complement the quantitative trial results with the results from a process evaluation to gain insight into the barriers and success factors that affected the program's impact.[37] We will determine the actual exposure to the InFoQI program by asking all members of the local QI teams to record the time they have invested in the different study activities. We will also investigate the experiences of those exposed, and evaluate which of the barriers identified before the start of the program were actually solved, and if any other unknown barriers affected the program's impact; this might include barriers at the facility level as well as at the individual level. Data will be collected by sending an electronic questionnaire to all QI team members at the end of the study period. They will be asked to rate on a 5-point Likert scale to what extent they perceived certain barriers to using the InFoQI program for quality improvement at their ICU. In addition, we will invite delegates of the local QI teams for a focus group to discuss in more detail their experiences with the InFoQI program and the barriers they perceived.

Ethics

The Institutional Review Board (IRB) of the Academic Medical Center (Amsterdam, the Netherlands) informed us that formal IRB approval and patient consent was not deemed necessary due to the focus of the InFoQI program on improving organizational processes; individual patients will not be directly involved. Additionally, in the Netherlands there is no need to obtain consent to use data from registries that do not contain patient-identifying information, as is the case in the NICE registry. The NICE foundation is officially registered according to the Dutch Personal Data Protection Act.

DISCUSSION

This paper describes the protocol of a cluster randomized trial to evaluate the effect of the InFoQI program on the quality of ICU care and a qualitative process evaluation to gain insight into the barriers and success factors that affected the program's impact. The program-tailored to prospectively identified barriers and facilitators-consists of comprehensive feedback reports, establishing a local, multidisciplinary QI team, and educational outreach visits. We expect that this multifaceted intervention will improve the quality of ICU care by enabling ICUs to overcome known barriers to using performance data as input for local QI activities.

Strengths and weaknesses of the study design

In our study, we used the previously developed NVIC extended indicator set as the basis for our feedback intervention. Although the NVIC is the national organization representing the Dutch intensive care profession, some ICUs may still disagree with the relevancy of some of the indicators in the set. This would hinder the use of the feedback as input for local QI activities, potentially decreasing the effectiveness of the intervention. However, disagreement with the content of the indicator set was not identified as a barrier in our prospective barriers analysis. We will reassess this during the process evaluation.

Building on an existing indicator set also results in a clear strength of our study, because we are able to use the data collection methods as currently applied by the NICE registry. This will increase the feasibility of the InFoQI program, because eligible ICUs already routinely collect the necessary data items as a result of their participation in NICE; participation in the InFoQI program does not require additional data collection activities. Furthermore, the data quality assurance framework as applied by NICE increases the reliability of the data,[31,38] and all recommended data quality control methods for QI projects[39] are being accounted for in our study. This will minimize the probability of missing and erroneous data.

Unfortunately, the design of the study will not allow us to quantitatively evaluate the relative effectiveness of the individual components of the InFoQI program. We considered a factorial design[40] for a separate evaluation of the impact of the comprehensive feedback reports and the outreach visits. However, the strong interconnectedness between the two elements made this difficult. Furthermore, the program aims to successfully overcome known barriers to using performance feedback for improving practice. During the development process of the InFoQI program, it became apparent that in order to achieve this a combination of strategies would be required. Also, previous reviews of the literature reported that multifaceted interventions seem to be more effective than single interventions.[15,16,41] Therefore, we will primarily focus on evaluating the effectiveness of the program as a whole; yet, the process evaluation will provide us with qualitative information on how and to what extent each program element might have contributed to this effectiveness.

As for the participants in our study, only ICUs that participate in the NICE registry, are capable of submitting indicator data, and agree to allocate resources to establish a local QI team will be eligible for inclusion. These criteria may lead to the selection of a non-representative sample of ICUs, because eligible facilities are less likely to be understaffed and more likely to have information technology (IT) support to facilitate routine collection of NICE data. This will not affect the internal validity of our results, because both study arms will consist of these early adopters. Moreover, the 'earliest adopters'-i.e., the ICUs involved in the indicator pilot study[7] -should be equally distributed between intervention and control group as a result of our stratification method. However, the generalizability of our findings will be limited to ICUs that are motivated and equipped to systematically monitor and improve the quality of the care they deliver. Nevertheless, as the number of ICUs participating in NICE is rapidly increasing, IT in hospitals is expanding, and applying QI principles is becoming more common in healthcare, we believe that this requirement will not reduce the relevancy of our results for future ICU practice.

Relation to other studies

The effectiveness of feedback as a QI strategy has often been evaluated, as indicated by the large number of included studies in systematic reviews on this subject. [14,15] However, the number of studies comparing the effect of feedback alone with the effect of feedback combined with other strategies was limited and relatively few evaluations regarded the ICU domain. [14,42]

Previous before-after studies found a moderate effect of performance feedback[43] and of multidisciplinary QI teams[44] on the quality and costs of ICU care. However, many have advocated the need for rigorous evaluations using an external control group to evaluate the effect of QI initiatives, [45-47] with the cluster randomized trial usually being the preferred method. [48,49] There have been cluster RCTs in the ICU domain that evaluated a multifaceted intervention with audit and feedback as a basic element. [50-52] Some of them were highly successful in increasing adherence to a specific evidence-based treatment, such as the delivery of surfactant therapy to neonates [51] and semi-recumbent positioning to prevent ventilator-associated pneumonia. [50]

Our study will adopt a similar approach, combining feedback with other strategies to establish change. Nevertheless, the InFoQI program will not focus on promoting the uptake of one specific type of practice. Instead, we assume that: an ICU will be prompted to modify practice when they receive feedback on their performance being low or inconsistent with that of other ICUs; the members of the QI team are capable-with support of the facilitators-to formulate effective actions based on this feedback; and the resulting customized QI plan will contain QI activities that are considered important and feasible within the local context of the ICU. With the process evaluation, we will learn if these assumptions were correct.

Expected meaning of the study

The results of this study will inform ICU care providers and managers on the feasibility of a tailored multifaceted performance feedback intervention and its ability to accelerate systematic, local QI activities. However, the results will also be of interest to other settings where national quality registries including performance indicators are used for continuous monitoring and improving care. Furthermore, the quantitative effect measurement together with the qualitative data from the process evaluation will contribute to the knowledge on existing barriers to using indicators for improving the quality of care and how they can be effectively overcome.

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Appendix 1: *Barriers to using performance data and how they are targeted*

Barrier identified	Statement (from future users or literature) to illustrate the barrier	How the barrier is targeted by the feedback intervention
Lack of knowledge on how to interpret the data	'Another obstacle is that people are not being taught how to handle the results, how to interpret them.'	During educational outreach visits the facilitators support the QI team in interpreting their performance data in the reports and in formulating a QI action plan.
Lack of information to initiate QI actions	'You want to improve the quality, but you don't know where to start or where the real problems lie....The current set of [outcome] indicators doesn't give enough information.'	The feedback reports contain extended information on six of the indicators; During educational outreach visits the facilitators support the QI team in further exploration of data in the NICE registry.
Lack of trust in data	'The data are often regarded as unreliable. If you put rubbish in, you will only get rubbish out. Trust in the data is essential.' 'Monitoring of quality indicators does not lead to reliable benchmark data for ICUs.'	During educational outreach visits the facilitators discuss with the QI team completeness and correctness of the data sent to the NICE registry and -if necessary- support them in formulating actions to improve their data quality.
Lack of statistical power for small ICUs	'If your ICU is small, how reliable can your data ever get?'	Not targeted by the intervention.
Lack of case-mix correction	'...what are the characteristics of my ventilated population? That can be a cause of prolonged ventilation duration.' 'the 'my patients are sicker' syndrome.'	Besides already available case-mix corrected hospital mortality data, data are stratified based on admission type or on APACHE IV diagnosis. During educational outreach visits the facilitators support the QI team in formulating additional case-mix related analyses on data in the NICE registry.
Level of aggregation too high	'For partnership practices, the [care providers] were shown prescribing data at practice level, not at the level of the individual prescriber.'	Besides data aggregated on ICU level, the feedback reports contain data on patient or shift level for six of the indicators.

***Appendix 1** (continued)*

Insufficient timeliness	'…the information might not have been presented close enough to the time of decision making.'	As the monthly reports do not contain comparisons with other ICUs, it is possible to decrease the time between the end of a period and reporting data on this period from ten (for quarterly reports) to six weeks (for monthly reports).
Lack of intensity	'…the [care providers] received prescriber feedback letters only once.'	In addition to the quarterly reports, the QI team receives monthly feedback reports containing their performance data presented in a different way.
Lack of outcome expectancy	'…the current rates were not considered a problem.'	During educational outreach visits the facilitators discuss with the QI team the opportunities for improvement.
Lack of trust in QI principles	'It is difficult to convince staff to use continuous quality improvement principles.'	The facilitators discuss with the QI team members the principles of systematic QI during the educational outreach visits.
Lack of dissemination of information	'…inadequate dissemination within the hospitals.'	Each QI team member receives the feedback reports by e-mail. During educational outreach visits and in monthly reminders they are encouraged to share their findings with the rest of the staff.
Lack of motivation	'As the intervention was unsolicited, the participants had not agreed to review their practice.'	The members of the QI team should be selected based on their affinity and experience with measuring and improving quality of care and their capability to convince staff to be involved in QI activities.

Appendix 1 *(continued)*

Organizational constraints	'Monitoring of quality indicators does not fit into the daily routines in the hospital setting.' 'Patient care is the main task and [QI activities are] just an extra' 'You will need a change of organizational culture…That will take some time to achieve.' 'Most of the participating [care] facilities did not have well-developed quality improvement programs with systems to support implementing changes needed in care delivery.'	The QI team forms the organizational basis for monitoring performance and initiating QI activities. One of their tasks is formulating a QI action plan corresponding with the opportunities for improvement within their own organization. They are also asked to discuss their performance during monthly QI team meetings, using the available reports and their QI plan as a basis. They are encouraged to report their findings during regular existing staff meetings.
Lack of resources	'Monitoring of quality indicators takes too much time.' 'Money is a huge obstacle. Hospitals are forced to seriously cut back their expenses in the coming few years.'	Not targeted by the intervention.
External barriers	'…there is [a lack of] public awareness now of the need to [improve the quality of care]'	Not targeted by the intervention.

Appendix 2: *Content of the feedback reports*

Indicator [a]	Presented as
QUARTERLY INFOQI REPORT	
• Patient-to-nurse ratio • Bed occupancy	Box plots displaying three months of data, with one-week periods on x-axis. Boxes based on aggregated data from ICUs with similar number of admissions are provided as benchmark. Target value as set by NVIC [b] is made visible in plot. Separate plots for day-, evening- and night shifts and for all shifts together. Bar charts displaying the ICU's mean benchmarked against means of ICUs with similar number of admissions and of same and other levels.
• Length of ICU stay [c] • Mechanical ventilation duration [c] • Glucose regulation	Text or tables with ICU's mean or median [d] benchmarked against mean or median of ICUs with similar number of admissions and national mean or median. Table with ICU's own top five APACHE IV diagnoses, based on the highest value of the indicator [e]. Benchmarked against ICUs with similar number of admissions and national value. Table with national top ten of most frequent APACHE IV admission diagnoses. For each diagnosis the value for the indicator is presented [e]. Benchmarked against ICUs with similar number of admissions and national value.
• Length of ICU stay [c] • Mechanical ventilation duration [c]	Bar charts displaying ICU's median benchmarked against median of ICUs of same and other levels. Tables with ICU's percentage of outliers benchmarked against mean percentage of ICUs with similar number of admissions and national mean. Tables with patient-specific information. No benchmarks presented. *E.g.*, admissions with an ICU length of stay longer than national 90th percentile. [f]
• Number of unplanned extubations • Incidence of decubitus	Text or tables with ICU's incidence of events and incidence of events relative to total number of admissions or ventilation days benchmarked against national mean, *e.g.*, the number of unplanned extubations per 100 ventilation days.
• Availability of intensivist (on week days and in weekends) • Strategy to prevent medication errors • Measurement of patient/ family satisfaction	Text or table displaying the values that ICUs submit quarterly to NICE; benchmarked against national mean, *e.g.*, the number of hours per week day that an intensivist was present at the ICU.

Appendix 2 *(continued)*

Indicator [a]	Presented as
MONTHLY INFOQI REPORT	
· Nurse-to-patient ratio · Bed occupancy	Run charts displaying one month of data, with days of the month on x-axis. Target value as set by NVIC [b] is made visible in chart. Separate charts for day-, evening- and night shifts and for all shifts together. Table with monthly top 10 of shifts with lowest nurse-to-patient ratio (at least below 0.5) or highest bed occupancy (at least above 80%).
· Length of ICU stay · Mechanical ventilation duration · Glucose regulation	Statistical Process Control (SPC) charts displaying one year of data, with two-week periods on x-axis. Any identified special cause variation[g] is shown in an accompanying table. For length of ICU stay and mechanical ventilation duration there are separate charts for different types of admissions (e.g., cardiac surgery, elective non-cardiac surgery, emergency non-cardiac surgery, non-surgical, etc). Glucose regulation is expressed in four separate charts, displaying the mean glucose value, time between two subsequent glucose measurements and the number of hypo- and hyperglycaemic events.
· Glucose regulation · Mortality	Tables with patient-specific information, such as · all patients that were admitted with a APACHE IV adjusted mortality risk <20%, but died · all hypoglycaemic events [d]

[a] *Information on case-mix corrected hospital mortality and additional bar charts on length of ICU stay are fed back in separate, already existing quarterly reports, available to intervention ICUs as well as ICUs in the control group*

[b] *For nurse-to-patient ratio the target value is between 0.5 to 1.0 (i.e., minimum of one and maximum of two patients per nurse); For bed occupancy the target value is 80%*

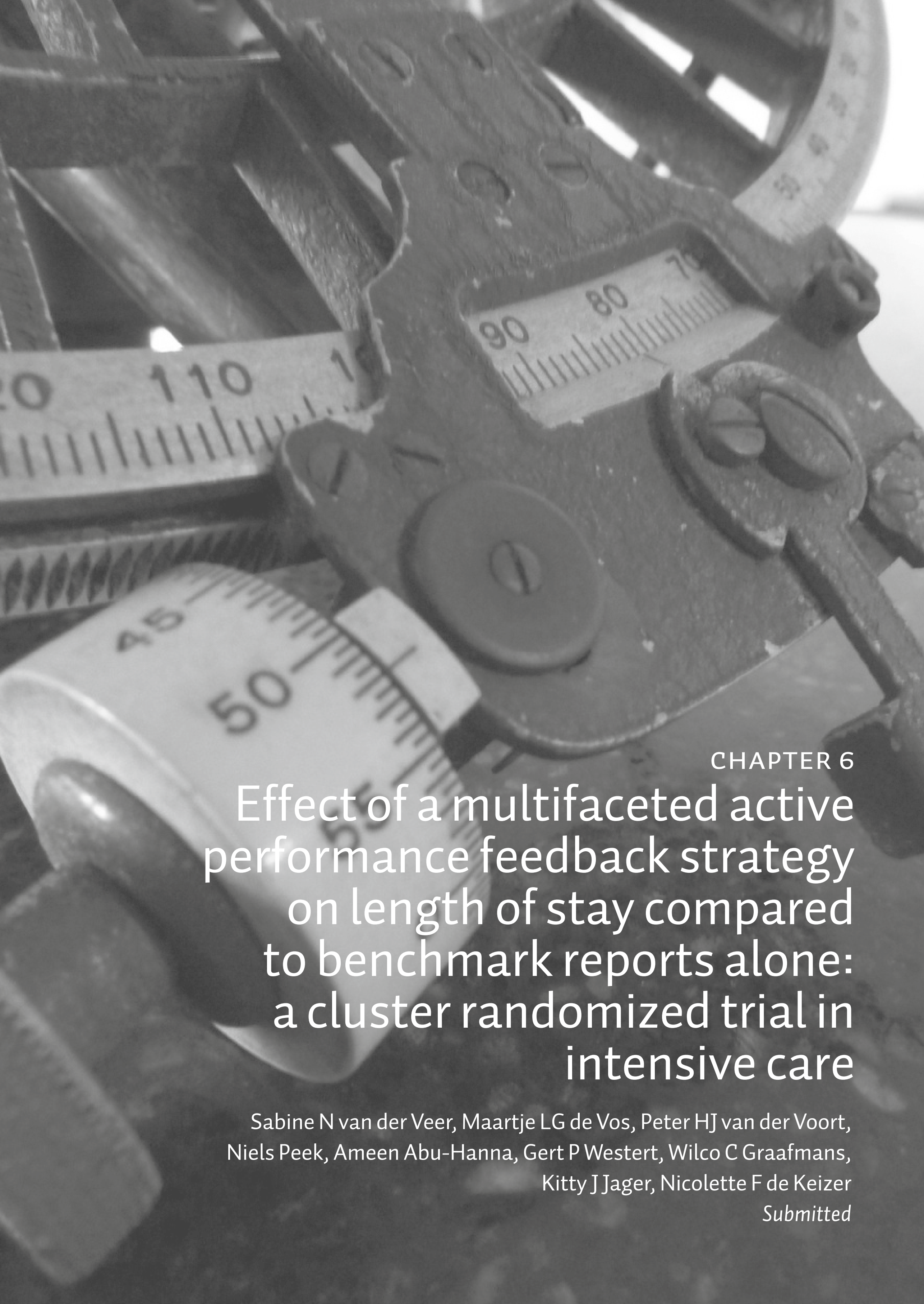
[c] *Most data on length of stay and ventilation duration are reported separately for different types of admissions (e.g., cardiac surgery, elective non-cardiac surgery, emergency non-cardiac surgery, non-surgical, et al.)*

[d] *Glucose regulation is expressed using mean glucose value, median time between two subsequent measurements and median duration of hypo- and hyperglycaemic events (i.e., one or more subsequent measurements with a value <2.2. mmol/l or >8.0 mmol/l resp.)*

[e] *For glucose regulation both the percentage of measurements with a value <2.2. mmol/l and the percentage of measurements with a value of >8.0 mmol/l relative to the total number of glucose measurements are used as values*

[f] *The national 90th percentile is calculated using all data of the previous year of all ICUs in the NICE registry*

[g] *Special cause variation in SPC charts expresses a significant change in the process*



CHAPTER 6

Effect of a multifaceted active performance feedback strategy on length of stay compared to benchmark reports alone: a cluster randomized trial in intensive care

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Submitted

Abstract

Objective: To assess the impact of applying a multifaceted active performance feedback strategy on intensive care patient outcomes compared to passively receiving benchmark reports.

Design, Setting, and Participants: The InFoQI (Information Feedback on Quality Indicators) study was a cluster randomized trial from February 2009 to May 2011 among 30 Dutch closed-format intensive care units (ICUs) that participated in the national registry; all completed the study. Study duration per ICU was sixteen months. Cardiac surgery admissions were excluded. Finally, we analyzed data on 26077 admissions.

Intervention: The intervention aimed to formalize local responsibility for acting on performance feedback, and to support ICUs with increasing the impact of their improvement efforts. Therefore, intervention ICUs established a local, multidisciplinary quality improvement (QI) team. During one year, this team received two educational outreach visits, monthly reports to monitor performance over time, and extended, quarterly benchmark reports. Control ICUs only received four standard quarterly benchmark reports.

Outcome measures and results: The extent to which the intervention was implemented in daily practice varied considerably between intervention ICUs: the average monthly time investment per QI team member was 4.1 hours (standard deviation (SD), 2.3; range, 0.6 to 8.1); the average number of reports reviewed per team was 10.6 (SD, 2.8; range, 3 to 16); the average number of monthly QI team meetings to discuss the reports was 5.7 (SD, 1.4; range, 0 to 12). In adjusted analyses, ICU Length of stay (LOS) did not reduce significantly after one year in intervention units compared to controls (hazard ratio [HR], 1.03; 95% confidence interval [CI], 0.94 to 1.14). The strategy also had no statistically significant impact on any of the secondary measures (duration of mechanical ventilation, proportion of out-of-range glucose measurements, and all-cause hospital mortality).

Conclusions: Applying a multifaceted active performance feedback strategy did not lead to better ICU patient outcomes than passively receiving periodical registry reports. Our study underlines the difficulty of further improving ICU performance with this type of intervention within the context of well organized healthcare systems, where levels of care are already high.

INTRODUCTION

Intensive care units (ICUs) provide complex multidisciplinary and expensive care to a heterogeneous patient population with relatively high mortality and morbidity rates. In the field of intensive care medicine, performance monitoring and systematic quality improvement (QI) have become increasingly common tools. [1-5] These tools rely on indicator sets [6-9] and collection of indicator data in national registries. [10-14] ICUs that –often voluntarily– participate in such registries substantially invest scarce healthcare resources. As input for local QI initiatives, they receive periodical feedback reports on a broad range of performance indicators, benchmarked against their own historical performance or that of other units. The underlying assumption is that inferior or inconsistent care presented in these reports prompts providers to change their practice. [15]

However, the previous Cochrane review by Jamtvedt and colleagues [16] suggested that only sending reports may be a suboptimal strategy to improve healthcare quality. They stated that the impact of performance feedback might be larger, when care providers would be actively involved in and have formal responsibility for implementing change, instead of just being passive feedback recipients. [16] Yet, only one of the 118 included randomized studies in the systematic review pertained to adult intensive care, [17] and since contextual factors are known to influence the success of QI interventions, [18] it was not self-evident that the results of this review could be extrapolated to the intensive care setting. This indicated paucity in high-level evidence on the effect of active performance feedback interventions on the quality of ICU care. More recently, three randomized studies showed that such interventions may positively affect ICU practice, [19-21] but their contexts did not specifically resemble that of ICUs worldwide already participating in registries and receiving benchmark reports to monitor and improve their care.

To augment the body of knowledge on effectiveness of active feedback interventions within the specific registry context, we conducted the cluster randomized InFoQI (Information Feedback on Quality Indicators) trial among ICUs that participated in the Dutch national intensive care registry. [13] In this trial, we evaluated the impact of applying for one year a newly developed active feedback strategy on ICU length of stay (ICU LOS), mechanical ventilation duration, glucose regulation and mortality, compared to passively receiving standard quarterly registry reports. The active strategy aimed to formalize local responsibility for acting on the feedback, and to support ICUs with increasing the impact of their QI efforts.

METHODS

The National Intensive Care Evaluation registry

The Dutch National Intensive Care Evaluation (NICE) registry aims to systematically and continuously monitor and improve ICU performance by reporting and benchmarking quality indicators. They started in 1996 with the outcome indicators case-mix adjusted hospital mortality and ICU LOS, [13] at the time of the current study, a sample of 80 ICUs –covering 85% of all Dutch ICUs– voluntarily submitted these core data to the NICE registry. Recently, the core set was extended to a total of eleven structure-, process- and outcome indicators. [6] Regular NICE services include standard quarterly benchmark reports on both the core set, and the extended indicator set. NICE does not actively support participants with interpreting their performance data or putting the feedback into QI actions.

Study design

We randomized ICUs (i.e. clusters), because the intervention was targeted at the facility rather than patient level. [22] Our study was also pragmatic. [23] A detailed description of our methods was published elsewhere. [24]

Participating ICUs

All ICUs in the Netherlands are closed-format, [25] and the large majority has an intensivist on call around the clock. We regarded the intensivists being responsible for the clinical process a facilitator for systematic, local QI activities. [26] ICUs were eligible for the study if they participated in the NICE registry and were preparing to submit data to the registry on the extended indicator set. They had to be able to allocate at least two staff members for a minimum of four hours per month for study activities. All patients admitted to the participating ICUs during the study period were included in the analysis, except for admissions following cardiac surgery, and patients admitted to prepare for organ donation.

Active performance feedback strategy

We tailored the active feedback strategy to previously identified barriers to using performance feedback for QI activities, e.g., lack of trust in data quality, and having difficulties to interpret the feedback. [27–29] Furthermore, the Cochrane review on audit and feedback concluded that the effects of feedback are more likely to be larger when recipients have an active and formalized role in achieving improvement; and when the feedback is provided more intensively. [16] Another systematic review on using indicators to improve hospital care suggested that performance feedback reports combined with an educational component and the development of a QI plan may positively affect care. [29]

So, for ICUs assigned to the intervention arm, we extended the regular NICE services with the establishment of a local, multidisciplinary QI team. The team had to consist of at least one intensivist and one nurse, and had the specific responsibility of implementing changes at the local level based on the feedback. Their main tasks were: formulating a QI action plan; monthly monitoring and discussing of performance using the feedback reports; initiating QI activities. In addition, the investigators actively supported the QI team with interpreting performance data and identifying opportunities for improvement during two educational outreach visits. Lastly, intervention ICUs received more frequent and more extensive feedback reports: twelve monthly reports focusing on monitoring local performance over time, and four quarterly benchmark reports to facilitate comparison with other ICUs. The reports contained extended feedback on six of the eleven indicators. Standard feedback was given on the remaining five indicators. A detailed description of the active strategy was published elsewhere. [24] Units allocated to the control arm received standard quarterly benchmark reports only (i.e., regular NICE services). Table 1 shows the main elements of the feedback strategies in both arms.

Table 1: *- Elements of the active feedback strategy (intervention arm) vs. regular NICE services (control arm)*

	Intervention	**Control**
Local, multidisciplinary QI team	Yes	no
Formalized QI action plan	Yes	no
Monthly QI team meetings	Yes	no
Two educational outreach visits	yes	no
Monthly feedback on 6 of the 11 indicators [a]	yes	no
Quarterly feedback on 6 of the 11 indicators [a]	extended	standard
Quarterly feedback on the 5 remaining indicators [b]	standard	standard

Abbreviations: QI, Quality improvement

[a] *Mortality, ICU length of stay, mechanical ventilation duration, glucose regulation, nurse-to-patient ratio, bed occupancy*

[b] *Availability of intensivists, strategy to prevent medication errors, measurement of patient/family satisfaction, unplanned extubations, decubitus*

Outcome measures

In the study as reported here, we focused on the impact of the intervention on the patient-related indicators, with ICU LOS as the primary endpoint. Firstly, because we expected successful QI actions aimed at other indicators to contribute to an improvement of ICU LOS. Secondly, NICE data from 2008 showed that ICU LOS was the indicator showing the largest variation among ICUs, when corrected for admission type. The indicators mechanical ventilation duration, proportion of glucose measurements outside the range of 40 to 144 mg/dl, and all-cause hospital mortality were selected as secondary endpoints. The impact of the intervention on organizational indicators (bed occupancy; nurse-to-patient ratio) will be analyzed and reported separately.

Cluster randomization and allocation

Randomization of ICUs was stratified by size (more/less than the national median number of ventilated, non-cardiac surgery admissions) and involvement (yes/no) in a previous indicator development pilot to evaluate feasibility of data collection. [6] Per stratum, we generated a randomization scheme with variable block sizes using dedicated software. This scheme was concealed to those enrolling and assigning ICUs. Due to the character of the intervention, it was not possible to blind participants or those involved in providing the strategy.

Data collection and validation

We used the available information infrastructure of the NICE registry, [30] in which participants either manually entered data using dedicated software, or automatically extracted data from electronic patient records. They uploaded their local data monthly to the central NICE registry database. The registry's infrastructure routinely provides data quality assurance. [30,31] To evaluate the extent to which the intervention was implemented as planned we asked individual QI team members twice during the study period to record their activities, including the estimated time they invested.

Statistical analysis

The total study period for intervention ICUs lasted sixteen months, starting at randomization and ending three months after the last report was sent. The period between randomization and the first outreach visit was approximately two months and marked as pre-InFoQI, directly followed by the InFoQI period. The pre-InFoQI period for control ICUs was defined as the first two months after randomization, followed by a fixed InFoQI period of fourteen months (Figure 1).

In all analyses, we tested for the effect of arm (intervention versus control), time since start InFoQI period (with value '0' for all admissions during the pre-InFoQI period), and the time x arm interaction. We focused on the interaction term to assess the difference in change at the end of the InFoQI period between the two arms –i.e., the effect of the intervention– because we expected intervention ICUs to improve gradually.

For ICU LOS we performed a Cox proportional hazard regression analysis to the subdistribution hazard [32] of the time to ICU discharge, with ICU death as competing risk. [33,34] The length of stay of the first ICU admission was prolonged with the length of stay of subsequent ICU readmissions within the same hospital admission. Furthermore, we analyzed the time to ICU death, with ICU discharge as the competing risk. For duration of mechanical ventilation, we applied the same procedure analyzing the time to extubation, with death within six hours after extubation as the competing event. To analyze the proportion of out-of-range glucose measurements we used binomial regression with a logistic link function, including only admissions with an ICU LOS >72 hours because we expected the benefit of improved glucose regulation to be most pronounced in this group. [35] Logistic regression analyses were used to verify that the intervention did not increase all-cause hospital mortality or readmission rates.

To adjust for differences in case-mix between the study arms, we used four patient-level variables (age; sex; Acute Physiology and Chronic Health Evaluation (APACHE) IV score; admission type) and two ICU-level variables (academic/teaching or non-teaching unit; participation in indicator development pilot) as covariates in each regression analysis. We used natural splines to model non-linear effects of continuous variables (age, APACHE IV score). We chose a marginal modelling approach in all analyses to account for potential correlation of outcomes within ICUs, [36] in the Cox regression we followed the method of Lin and Wei, [37] while in the binomial and logistic regression analyses we used generalized estimating equations, with exchangeable working correlation. [38]

To further explore the impact of our intervention, we conducted a post-hoc as-treated analysis of ICU LOS, comparing all ICUs from the original control arm to the intervention ICUs that invested at least the required monthly minimum of four hours per QI team member as estimated beforehand.

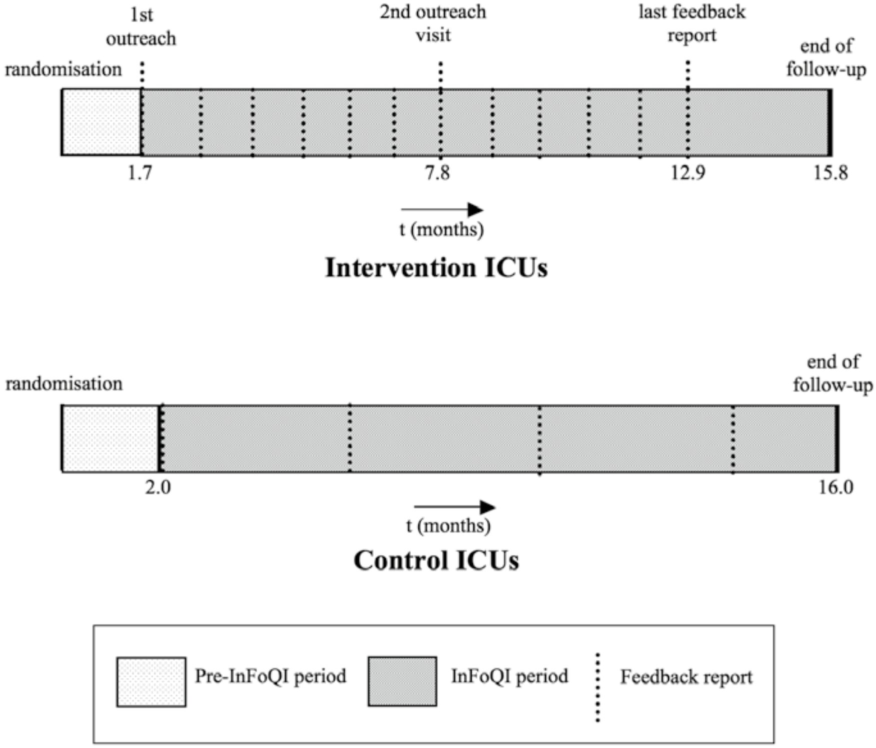

Figure 1 *- The pre-study and study period for intervention and control ICUs*

** The duration of the pre-InFoQI and InFoQI period in the intervention arm varied between units because this depended on, for example, how soon the first outreach visit could be scheduled so that all QI team members were able to attend. The months in the upper panel, therefore, reflect the mean values of all intervention ICUs. For units in the control arm the duration of both periods was fixed*

Sample size calculations

The minimally required number of ICUs participating in the trial was based on analysis of NICE registry data from 2008. First, we ranked ICUs by average ICU LOS of their patients. To determine what would be an achievable improvement, we calculated the difference in average ICU LOS of the 33% top ranked ICUs and the average ICU LOS among all units. This amounted to an absolute reduction of 0.58 days per admission, corresponding to a relative reduction of 27%. Assuming an average number of 343 admissions per ICU per year, calculations based on the Normal distribution showed that we needed 26 ICUs participating in the trial to detect this difference with 80%

power at a type I error risk (α) of 5%. We took into account an intra-cluster correlation of 0.036, which we estimated based on the 2008 NICE data.
We used R version 2.13.1 for statistical analyses.

RESULTS

Participants

Of the 80 ICUs submitting core data to NICE, 46 were preparing data collection on the extended indicator set; 30 accepted our invitation to participate in the trial (Figure 2). The main reason to refuse was a lack of resources to establish a local QI team (n=7). Fifteen units were assigned to the intervention arm, and an equal number to the control arm; all completed the study. ICUs were enrolled in the study between February and December 2009. All were mixed medical-surgical units. In total, there were 35196 admissions during the study period. We excluded 4996 admissions following cardiac surgery (14.2%), and 24 admissions for organ donation (<0.1%). We also excluded 3460 admissions for which –according to the APACHE IV criteria [39]– we could not calculate a severity of illness score (9.8%), and 639 admissions with one of the other case-mix variables missing (1.8%). Finally, we included 30 ICUs and 26077 admissions in our analysis. Table 2 displays the baseline characteristics of both arms at the level of ICUs and admissions.

For glucose regulation, four intervention ICUs failed to submit data due to technical problems with their local laboratory system interface, and were excluded from this part of the analysis.

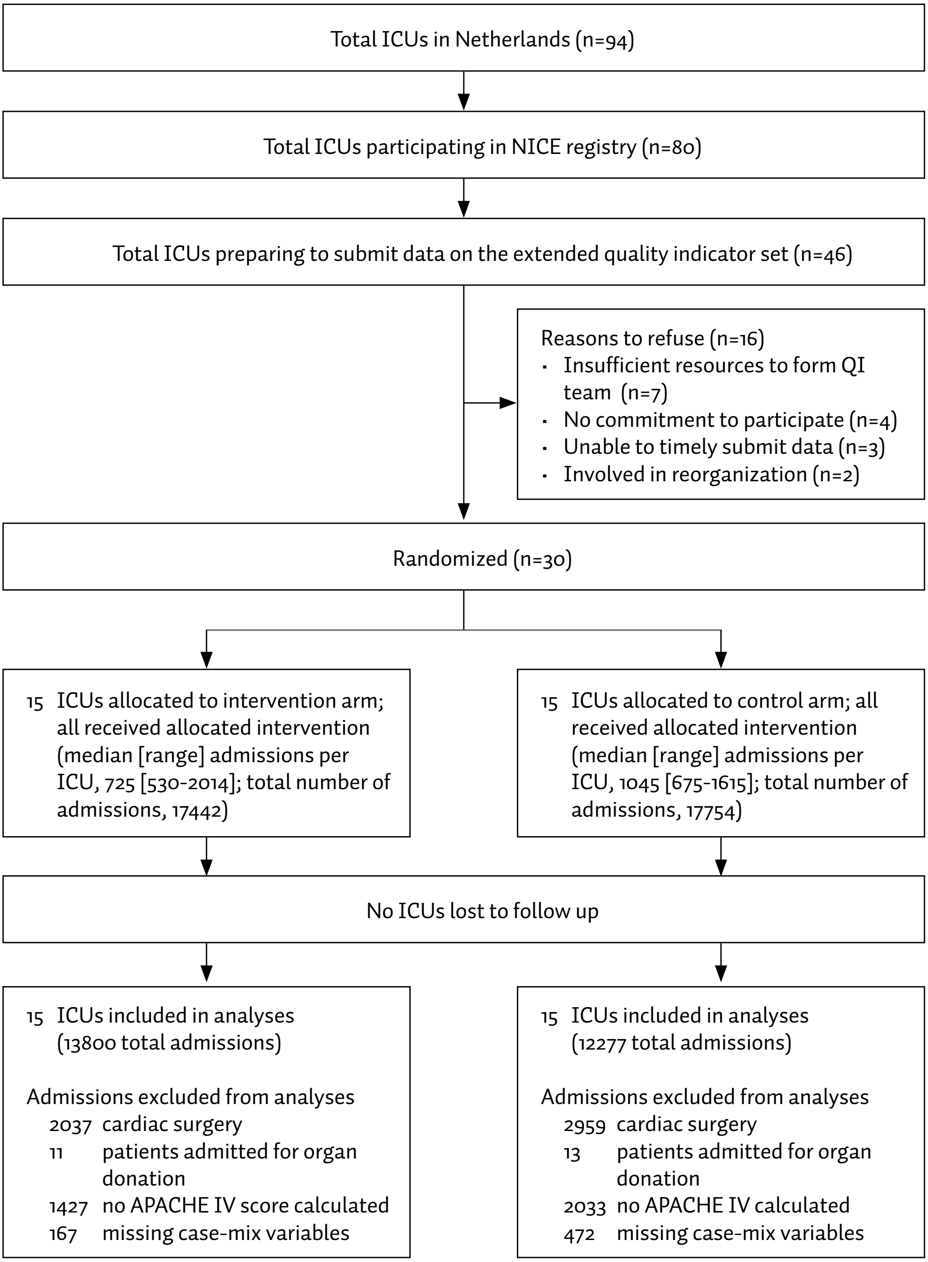

***Figure 2**- Flow diagram of ICUs and patients through the trial*

__Table 2__- Baseline characteristics of participating ICUs (clusters) and admissions. Values are numbers (percentages), unless indicated otherwise

	Intervention	Control
ICU level characteristics		
No. included in analysis	15	15
Median (IQR) number of admissions	725 (530-2014)	1045 (675-1615)
Academic or teaching hospital	9	7
> 150 ventilated, non-surgical admissions per year	8	9
Participated in indicator development pilot[a]	6	4
Admission level characteristics		
No. included in analysis	13800	12277
Mean (SD) age (years)	61.2 (16.8)	62.3 (17.1)
Male sex	7763 (56.3)	6856 (55.8)
Admission type		
Medical	6573 (47.6)	6167 (50.2)
Elective surgery	5177 (37.5)	3641 (29.7)
Emergency surgery	2050 (14.9)	2469 (20.1)
Mechanical ventilation	5745 (41.6)	5791 (47.2)
Mean (SD) APACHE IV score	57.4 (31.5)	59.8 (33.2)

Abbreviations: APACHE, Acute Physiology and Chronic Health Evaluation; ICU, Intensive Care Unit; IQR, Interquartile range; SD, Standard deviation

[a] Previous pilot to evaluate the feasibility of indicator data collection[6]

Implementation of the active feedback strategy in daily practice

All 15 intervention units established a local QI team in which intensivists and ICU nurses were represented. The median number of team members was 4 (range, 2 to 7); 13 ICUs complemented this team with other representatives, e.g. an operational manager. All ICUs received both educational outreach visits. The average monthly time investment per member was 4.1 hours (standard deviation (SD), 2.3; range, 0.6 to 8.1). As planned, all intervention ICUs received 4 quarterly and 12 monthly reports. The average number of reports reviewed by at least one team member was 10.6 (SD, 2.8; range, 3 to 16), while the average number of monthly QI team meetings to discuss the reports was 5.7 (SD, 1.4; range, 0 to 12). For units that spent at least 4 hours per month per team member (n=8) this was 13.2 reports (SD, 2.8; range, 8 to 16), and 9.1 meetings (SD, 2.3; range, 5 to 12). None of the ICUs were able to review and discuss all reports.

Table 3- *Examples of planned QI actions as formulated during outreach visits*

Type of action	ICU LOS	Duration of mechanical ventilation	Out-of-range glucose measurements	Hospital mortality
Investigate low performance for patient subgroups	investigate effect of delayed ICU discharge of surgery patients due to unavailability of ward beds	investigate effect of case- mix of ventilated surgical patients using a group of similar ICUs as comparison	analyze high % hyperglycaemi [a] in patients admitted after 'surgery for cranial neoplasm'	analyze standardized mortality ratio >1 for medical admissions
Investigate individual cases within QI team	discuss patients who were admitted / ventilated longer than the national 90th percentile		review episodes of hypoglycaemi [a]	investigate records of patients who died despite a low mortality risk
Share QI team findings in ICU staff meetings [c]	organize 6-weekly multidisciplinary meetings to discuss individual admissions with long ICU LOS / duration of mechanical ventilation		organize monthly meetings with ICU nurses to discuss causes of episodes of hypoglycaemi [a]	organize monthly mortality conferences with intensivists and anesthesiologists
Education	-	organize sessions to refresh knowledge on sedation protocol	formalize instructions on glucose regulation for temporary ICU nurses	-
Adjust protocols or care processes	appoint lead nurse for admissions with expected ICU LOS >7 days	develop wean protocol	clarify glucose protocol with regards to regulation of values exceeding 216 mg/dl	-

Abbreviations: ICU, Intensive Care Unit; LOS, length of stay; QI, Quality improvement

[a] *value below 40 mg/dl*

[b] *value exceeding 144 mg/dl*

[c] *includes newly established as well as existing meetings*

The QI action plans formulated during the outreach visits consisted of a mean of 12.2 planned actions (SD, 3.5; range, 6 to 17). Of all quality indicators, glucose regulation was the most actionable with an average of 2.5 actions (SD, 1.5; range, 1 to 5). Table 3 contains the type of actions and examples for each outcome measure.

Effect of the intervention

Our study did not show that ICUs applying the active feedback strategy improved their patient outcome measures more than ICUs passively receiving standard registry reports (Table 4). In adjusted analyses, ICU LOS did not reduce significantly after one year in intervention units compared to controls (hazard ratio [HR], 1.03; 95% confidence interval [CI], 0.94 to 1.14) (Figure 3). We also found no impact of the intervention on time to ICU death (HR, 1.03; 95% CI, 0.75 to 1.40). The risk of dying in the hospital in the intervention arm compared to controls did not decrease significantly after receiving the intervention for one year (odds ratio [OR], 0.96; 95% CI, 0.75 to 1.22). This was also true for the risk of having a glucose measurement outside the range of 40 to 144 mg/dl (OR, 0.89; 95% CI, 0.67 to 1.19). Lastly, the duration of mechanical ventilation did not change significantly in intervention ICUs compared to controls (HR, 0.96; 95% CI, 0.78 to 1.18), nor did the readmission rate (OR, 0.87; 95% CI, 0.66 to 1.13).

The results of the post-hoc as-treated analysis resembled those of our primary analysis: after receiving the intervention for one year, the reduction in ICU LOS in as-treated units did not reach statistical significance compared to controls (HR, 1.04, 95% CI, 0.95 to 1.14).

Table 4- *Results of primary analyses of effect over time of the intervention on primary and secondary outcome measures*

Variable	**No of clusters / admissions included in analysis**		**Crude outcome (median (IQR), unless indicated otherwise)**		**Crude difference in change over time between arms**		**Adjusted [a] difference in change over time between arms**		**ICC**
	Intervention	Control	Intervention	Control	Main effect (95% CI)	P Value	Main effect (95% CI)	P Value	
ICU Length of stay (days)	15 / 13800	15 / 12277	1.1 (0.8-3.5)	1.5 (0.8-4.2)	1.03 (0.96-1.11) [b]	.36	1.03 (0.94-1.14) [b]	.49	0.021
Duration of mechanical ventilation (days)	15 / 5745	15 / 5791	1.6 (0.4-5.7)	1.8 (0.5-6.0)	0.94 (0.84-1.04) [b]	.23	0.96 (0.78-1.18) [b]	.67	0.032
Proportion of out-of-range [c] glucose measurements [d]	11 / 2608	15 / 3807	0.29 (0.15-0.46)	0.30 (0.17-0.45)	0.86 (0.64-1.15) [e]	.31	0.89 (0.67-1.19) [e]	.44	0.072
All-cause hospital mortality	15 / 13800	15 / 12277	2021 (14.6) [f]	2128 (17.3) [f]	0.95 (0.80-1.14) [e]	.61	0.96 (0.75-1.22) [e]	.73	0.003

Abbreviations: CI, Confidence Interval; ICC, Intracluster correlation coefficient; ICU, Intensive Care Unit; IQR, Interquartile range

[a] *Adjusted for age, sex, APACHE IV score, admission type, academic/teaching or non-teaching unit, and participation in previous indicator development pilot*

[b] *Hazard ratio for the interaction term between arm and time, reflecting the difference in change between the two arms after one year of exposure to the intervention; a value >1 means that patients in the intervention arm reached the event of interest (e.g. alive ICU discharge) sooner than controls (i.e. had a shorter ICU length of stay)*

[c] *Values below 40 mg/dl or exceeding 144 mg/dl*

[d] *Only admissions with ICU length of stay > 72 hours were originally included in the analysis (n=7617); of these, we excluded admissions (number, percentage) (i) with missing glucose measurements due to technical problems with the automated laboratory system interface (1148; 15.1); this implied excluding four intervention ICUs from the analysis, and (ii) without any glucose measurements (54; 0.7)*

[e] *Odds ratio for the interaction term between arm and time, reflecting the difference in change between the two arms after one year of exposure to the intervention*

[f] *Values are numbers (percentage)*

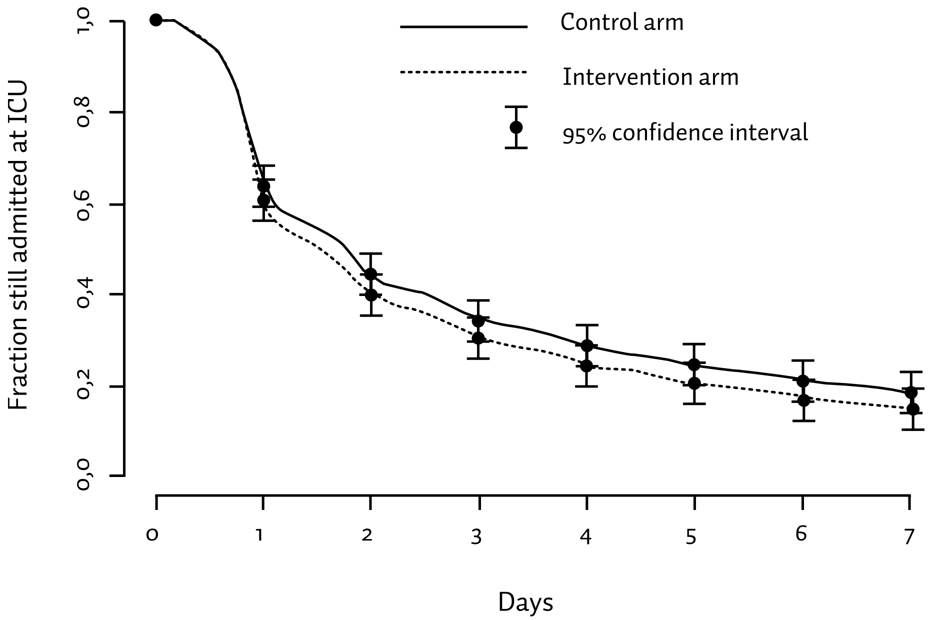

Figure 3 *- Time to alive discharge from the ICU in both arms after one year of receiving the intervention*

DISCUSSION

We evaluated the effect on patient outcome measures of applying an active performance feedback strategy –including local, multidisciplinary QI teams, and educational outreach visits– compared to passively receiving standard quarterly registry reports. We randomized 30 closed-format ICUs that participated in the Dutch national registry, and analyzed data on over 26000 admissions, which –to our knowledge– is the largest number of patients included in a randomized trial evaluating a QI strategy in intensive care so far. The extent to which the strategy was implemented in daily practice varied substantially between ICUs in the intervention arm. The strategy had no impact on ICU LOS nor on any of the secondary outcome measures.

Strengths and limitations

A strength of our study was that we built on the established infrastructure of the Dutch national registry which enabled ICUs participating in the study to rely on routine registry procedures without requiring any additional data collection activities.

This decreased the risk of demotivated control ICUs –potentially leading to a Hawthorne effect [40]– or control units discontinuing their participation due to an increased workload without the advantage of receiving the intervention. Also, the registry's quality assurance framework [31] accounted for all recommended data quality control methods for evaluating QI programmes, [41] which increased the completeness and reliability of our data. [42]

Our analysis strategy formed another strength as it prevented us from falsely interpreting a decrease in ICU LOS as a positive effect of the intervention, while in fact this may have been caused by more ICU deaths, and more premature discharges leading to readmissions.

The study was designed to detect a relative reduction of 27% in ICU LOS. We considered this an ambitious but feasible improvement since one third of the ICUs were already achieving this level of performance before the start of the study. Repeating the power analysis using trial data showed that 23 centres would have been sufficient to detect this pre-defined reduction in ICU LOS. Also, the actual intra-cluster correlation coefficient of 0.021 was lower than anticipated. This implies that the study was not underpowered.

A limitation was that the strategy aimed to intervene at the organizational level, where it might take longer to effectuate change than at the individual physician or patient level. [43] For example, an intervention ICU that identified the hospital ward responsible for the majority of the delayed discharges, and thus for increasing ICU LOS, was still working on a solution with the ward's management at the end of the study period. Hence, it is possible that prolonging the study period would have increased the probability of finding a statistically significant effect of the strategy.

Another limitation is that we had mainly outcome of care measures available as the basis for our feedback. Indicators like hospital mortality and ICU LOS are influenced by several providers and practices, and factors other than ICU care. This impedes feedback interpretation, assignment of accountability, and identification of effective actions. By contrast, process of care measures directly assess provider action, making them more 'actionable. [44,45] This was confirmed by our finding that the proportion of out-of-range glucose measurements was the indicator with most QI actions.

Relation to other studies

Other cluster randomized trials within the ICU domain evaluated the effect of a multifaceted QI intervention including performance feedback. [19-21] In contrast to our study, the control ICUs in these trials received no feedback, increasing the difference between both arms. Moreover, they focused on improving a specific part of ICU care, e.g. preventing accidental extubations. [21] All were successful in increasing adherence to best practice, but only few also evaluated the effect of their intervention on outcome of care measures. One study that improved adherence to feeding guidelines, reported a non-significant impact on ICU LOS. [20] Likewise, a non-randomized study that reported a decrease in catheter-related bloodstream infections and a reduction in hospital mortality in ICU patients, did not show a significant difference in hospital LOS. [43,46] This illustrates the difficulty to define QI interventions with a sufficiently strong link to and detectable impact on length of stay.

Meaning of the study

All ICUs in our study were Dutch closed-format units, with an infrastructure to routinely submit data to a national registry, and sufficient, motivated staff and supportive management to establish a QI team. Although this optimized the environment for successful implementation of the active feedback strategy, the feasibility of the intervention in daily practice appeared not to be self-evident. A possible explanation is an underestimation of the required time investment for team members resulting in an unanticipated lack of local resources to perform study activities and execute the QI action plan.

Although ICUs that invested more time achieved a more complete implementation of the strategy, our as-treated analysis suggested that this is not the only ingredient for success. We expect opportunities to lie in providing teams with additional tools to translate feedback into potentially more effective, evidence-based QI actions. For example, cause-and-effect diagrams for systematic analysis of local barriers, [47] or evidence-based input on how to change daily practice in order to improve performance, e.g., using a daily goals form during patient care rounds. [48]

The generalizability of our findings is limited to high-level healthcare systems, in which a national registry has been available for some time, and ICUs are willing and able to allocate staff to QI activities. These contextual factors are likely to have contributed to ICU patient outcomes steadily improving over the last decade, [49] increasing levels of care, and possibly causing a ceiling effect. Nevertheless, areas of intensive care that are optimized in the Dutch situation might still show room for improvement elsewhere. Our intervention could, therefore, be effective in the context of less well organized systems, or in countries that only recently established a national registry to monitor ICU performance. Yet, in such contexts we expect the issue of feasibility to be even more tenacious.

Our study underlines the difficulty of showing benefits to patient outcomes even with motivated participants and an active feedback strategy. Based on our results, national ICU registries and their participants should give careful consideration to the trade-off between the required investments and the expected benefits of establishing and actively supporting local QI teams. To enforce the active feedback strategy as evaluated in this study, we suggest expanding the feedback with actionable process measures linked to patient outcomes, and providing additional tools to support the translation of feedback into effective actions.

Future research

We tailored the active feedback strategy to overcome barriers to using performance data for local QI activities. In a future qualitative study, we will evaluate which prospectively identified barriers remained untargeted, and if any other factors affected the impact, in order to find a more detailed explanation for the strategy's ineffectiveness.

Future research might aim to identify actionable process of care measures. Besides a solid evidence-base link between the measures and ICU patient outcome, routine collection of reliable data on the process measures should be feasible. Lastly, more knowledge is needed on effective and useful tools to facilitate ICU clinicians to translate performance feedback into QI actions.

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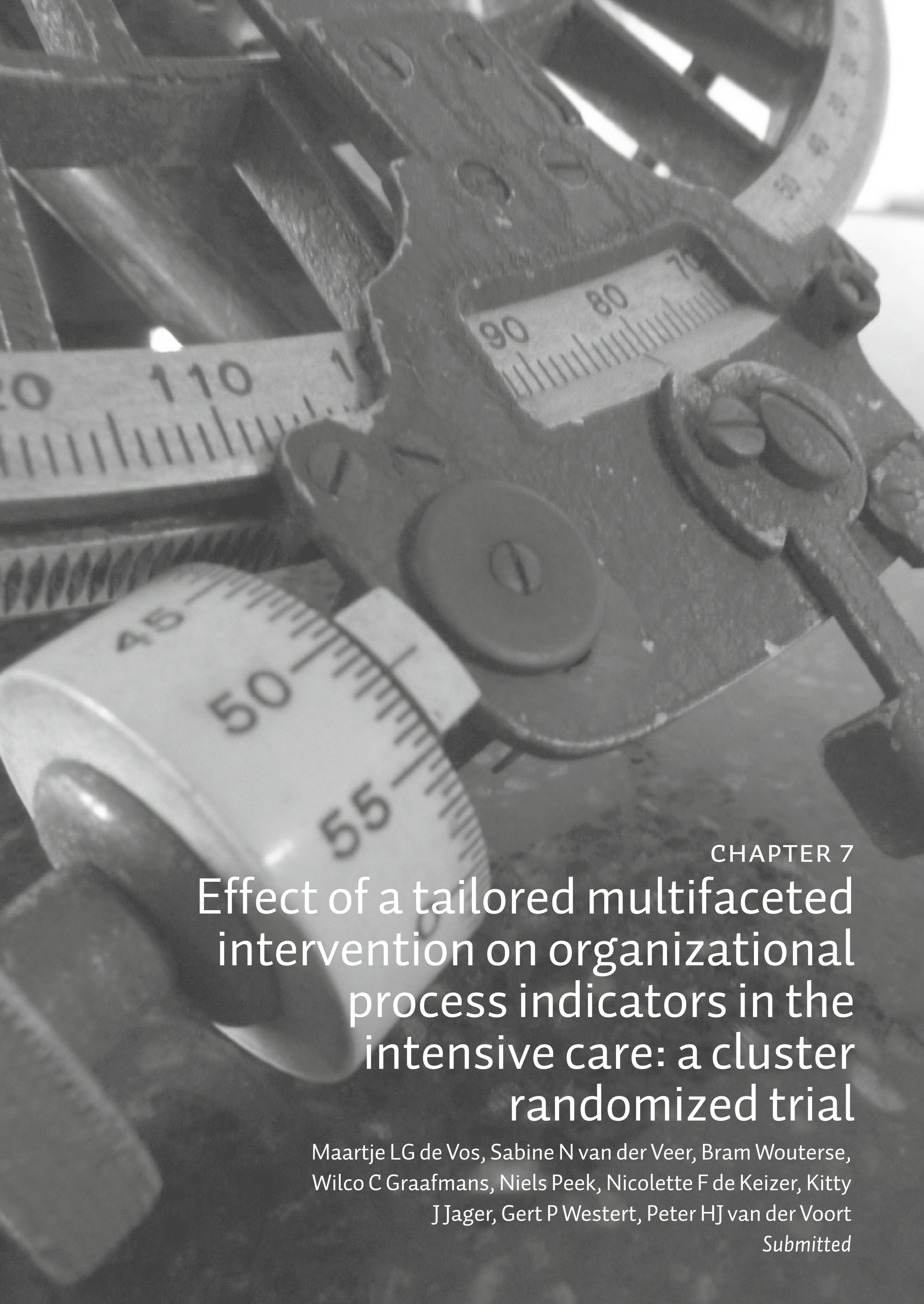

CHAPTER 7

Effect of a tailored multifaceted intervention on organizational process indicators in the intensive care: a cluster randomized trial

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Submitted

ABSTRACT

Purpose: Optimizing organizational processes in Intensive Care Units (ICUs) can potentially be guided by feedback of indicator data about these processes. In this study, we evaluated the effect of a multifaceted intervention with tailored feedback of benchmarked data on organizational ICU processes.

Methods: We conducted a one year cluster randomized controlled trial (RCT) among 30 Dutch ICUs participating in the national quality registry. Fifteen ICUs were assigned to the intervention group. They received more frequent and comprehensive feedback reports of benchmarked data on bed occupancy rate and nurse-to-patient ratio, they established a local multidisciplinary quality improvement (QI) team and received two educational outreach visits. Fifteen ICUs were assigned to the control group and they received standard quarterly feedback reports of benchmarked data only. The study targeted a bed occupancy rate below 80% and a nurse-to-patient ratio above 0.5 according to current guidelines.

Results: Two intervention and four control ICUs were excluded from analyses because they failed to provide (valid) data. Data from thirteen ICUs in the intervention and eleven control ICUs were analyzed, including 67237 nursing shifts. ICUs receiving the multifaceted feedback intervention showed no difference in the proportion of shifts with a bed occupancy rate below 80% (Odds Ratio (OR), 0.63; 95% Confidence Interval (CI), 0.37-1.09; p=.10) or of shifts with a nurse-to-patient ratio above 0.5 (OR, 0.65; 95% CI, 0.35-1.19; p=.43).

Conclusions: This multifaceted feedback intervention had no effect on bed occupancy rate and nurse-to-patient ratio compared to feedback reports alone. Our study suggests that the way feedback of indicator data affect care processes is complex and improvements may be difficult to achieve in the short term.

INTRODUCTION

In intensive care, systematic monitoring of quality of care using quality indicators is increasing. [1–4] Various indicators are used to measure the quality of care in intensive care units (ICUs). [2–7] Often these indicators are related to structure, process, and outcome measures that provide a useful framework for understanding and improving the quality of healthcare. Structure indicators focus on the physical aspects of the ICU: biomedical equipment (beds, monitors, ventilators and other devices) and the qualification of personnel. [8] Process indicators refer to what is actually done in giving and receiving care such as use of protocols and care bundles, and optimization of capacity.[8] Outcome indicators are related to the health status of the ICU patient, e.g. mortality, and nosocomial infections.

Outcome measures are frequently used and represent intuitively important targets for clinicians, but they are often less responsive to improvement efforts and more prone to bias than process measures .[9–12] Process indicators preferably have an evidence-based link with patient outcomes [7,13,14] and can also be useful for management of resources. [15]

Organizational process measures such as ICU capacity and staffing levels are important for assuring quality of care. [16–20] Iapichino et al. 2005 showed that an occupancy rate above 80% was associated with higher mortality. [19] In addition, ICUs with an occupancy rate of 80% or more have a high risk of refusing patients. [22] Therefore, an average occupancy rate of 80% is regarded as the international standard for ICU bed occupancy. [23] Regarding the staffing levels, studies showed that a nurse caring simultaneously for more than two patients (n:p ratio below 0.5) is associated with worse outcomes. [16,24–26]

In 2006, the Dutch Society for Intensive Care (NVIC) developed a guideline containing a number of recommendations to support the organization of daily practice in Dutch ICUs including bed occupancy rate and nurse-to-patient ratio (n:p ratio).[21] These items were included in the indicator set for continuously monitoring and benchmarking in order to improve the efficiency of ICU resource use and ultimately improve the quality of intensive care. [3]

To study how indicators can best be used to improve daily care, we developed a tailored multifaceted performance feedback intervention, called the InFoQI (Information Feedback on Quality Indicators) program.[27] Previous reviews showed that sending feedback reports alone is no guarantee for improving quality of care. [28,29] However, feedback reports as part of a multifaceted intervention were found to be more successful in inducing change. [28,30] Several studies examined the impact of a multifaceted feedback intervention on clinical measures of critically ill patients [31–34] but data on the effects of multifaceted interventions on organizational process indicators in the ICU setting are lacking.

In the present study, we evaluated the effect of a multifaceted intervention on the organizational indicators bed occupancy rate and n:p ratio. Therefore, we conducted a cluster randomized trial (RCT) among Dutch ICUs to test the hypothesis that ICUs receiving the InFoQI program would significantly perform better on the two process indicators than ICUs receiving standard feedback reports only.

METHODS

Study design

We conducted a multi-centre RCT in which Dutch ICUs were randomized using a stratified protocol. [27] The study was approved by the Institutional Review Board (IRB) of the Academic Medical Centre (Amsterdam, the Netherlands) following Dutch and European legislation. The trial was registered with the controlled-trails.com (ISRCTN50542146) and results are reported according the CONSORT statements for cluster-randomized trials. [35]

Participating ICUs

ICUs were eligible to participate in the study if they were able to systematically submit indicator data to the Dutch National Intensive Care Evaluation (NICE) registry. This registry was founded by the Dutch intensive care profession in order to systematically and continuously monitor, assess and benchmark ICU performance and finally to improve the quality of ICU care. [36] Currently, 80 ICUs (90% of all Dutch ICUs) voluntarily submit outcome data containing case-mix adjusted hospital mortality and ICU length of stay. In 2006, the registry was extended with the NVIC set of eleven indicators including bed occupancy rate and n:p ratio. [3] To participate in the InFoQI study, ICUs also had to be able to establish a multidisciplinary quality improvement (QI) team with at least two staff members who were able to make time available for study activities (minimum of four hours per month).

Multifaceted feedback intervention: InFoQI program

Each intervention ICU received the InFoQI program during one year including (1) monthly and quarterly feedback reports, (2) establishment of a multidisciplinary

QI team and (3) two educational outreach visits. [27] The monthly report focused on ICUs' own performance over time, e.g. run charts with occupancy rates per nursing shift daily. The quarterly report focused mainly on comparing performance with other ICUs, e.g. box plots per nursing shift weekly. All feedback reports were sent to the members of the QI teams, together with a reminder to discuss the reports in a monthly QI team meeting and to share their findings with the rest of the ICU staff.

Besides the feedback reports, intervention ICUs were asked to establish a multidisciplinary QI team including at least one intensivist and one nurse. A representative of the ICU management or a data manager was suggested as additional member. The team's main tasks were formulating a QI action plan, monthly monitoring of performance using the feedback reports and initiating and evaluating QI activities. They were encouraged to share their main findings with the rest of the staff during existing regular meetings.

Finally, each intervention ICU received two educational outreach visits by two study investigators (SvdV, MdV) for increasing trust in data quality, the interpretation of the run charts and box plots presented in the feedback reports, translating these data into QI initiatives, and identifying opportunities for improvement. ICUs in the control group received quarterly standard feedback reports only. The provision of the standard feedback was anticipated to have limited effect on changing practice. A more detailed description of the intervention was published elsewhere. [27]

Study endpoints

The hypothesis was that the ICUs receiving the InFoQI program would make significantly more improvement on the two organizational process indicators than ICUs receiving standard feedback reports only. The first process indicator in our study was the proportion of shifts with a bed occupancy rate below 80%. In this study, the bed occupancy rate is calculated as the maximum number of patients simultaneously present during an 8-hour nursing shift divided by the number of operational beds in that same shift. A bed is defined as 'operational' when monitoring and ventilation equipment as well as nursing staff is available. The intervention is aimed at increasing the proportion of shifts with a bed occupancy rate below 80%.

The second process indicator is the proportion of shifts with a n:p ratio above 0.5. N:p ratio was based upon the maximum number of patients simultaneously present during an 8-hour nursing shift divided by the number of registered qualified ICU nurses in that same shift. Student nurses are not included. The intervention is aimed at increasing the proportion of shifts with a n:p ratio above 0.5.

Data collection

Data regarding the process indicators was gathered locally by each participating ICU and uploaded monthly to the central NICE database. Participating ICUs submitted the number of operational beds and qualified nurses in each shift to the NICE database which automatically calculated the bed occupancy rate and n:p ratio per shift. The quality of the data submitted to the NICE registry was guaranteed by periodical on-site data quality audits and automated data range and consistency checks. [37,38]

Randomization and blinding

Allocation was based on a stratified randomization with a blocking size of four. ICUs were stratified by size (more/less than the national median number of ventilated, non-cardiac surgery admissions) and participation (yes/no) in a pilot study to evaluate feasibility of indicator data collection, [3] which may have influenced a priori knowledge. An independent researcher- blinded to group assignment- generated the allocation list using a computer-generated randomization scheme. Due to the character of the intervention, intervention ICUs and those involved in providing the InFoQI program were aware of group assignment. ICUs in the control group remained unaware of intervention contents.

Statistical analyses

The individual nursing shifts are the unit of analysis in this trial. We used an intention-to-treat approach to analyze the process indicator data.

The total study period for intervention ICUs lasted sixteen months, starting at randomization and ending three months after the last report was sent. The baseline period, approximately two months, was the period between randomization and the first outreach visit, directly followed by fourteen months follow-up. The baseline period for control ICUs was defined as the first two months after randomization, followed by a follow-up period of fourteen months.

The effect of the intervention on the proportion of shifts with a bed occupancy rate below 80% was analyzed with logistic regression analyses. We used generalized estimation equations with an autoregressive correlation structure to account for clustering of shift occupancy observations within ICUs. The same procedure was followed to analyze the proportion of shifts with a n:p ratio above 0.5. The change in proportions was analyzed by testing for the effects of group (intervention versus control), study period (baseline versus follow-up), and the interaction between group and study period.

For both process indicators, the odds ratio (OR) for improvements in follow-up versus baseline for control and intervention ICUs were calculated separately. In addition, the ratio of these ORs for improvement in follow-up (OR intervention/OR control) were calculated. [31,39] This ratio of ORs can be seen as the OR of changes in follow-up in the intervention group controlled for changes in follow-up in the control group. A ratio of ORs > 1 signifies that improvement in follow-up is larger in the intervention group than in the control group.

In all analyses, we adjusted for type of shift (day, evening and night) and seasonal fluctuation in admission levels by including calendar month dummies for both indicators. In addition, to adjust for difference in organizational structure between the study arms we used three ICU-level variables (availability emergency bed; cardiac surgery centre or non-cardiac surgery centre; and academic/teaching or non-teaching hospital) as covariates in the analyses for the bed occupancy rate. For n:p ratio, we added the ratio of newly admitted mechanical ventilated patients and academic/teaching or non-teaching hospital as covariates.

Since the intensity of InFoQI activities differed markedly, we conducted subgroup analyses, intervention ICUs that reported a monthly time investment more than four hours per QI team member and intervention ICUs reporting less than four hours per QI team member.

Our sample size calculation showed that we needed minimum of 23 ICUs completing the trial to detect a reduction in bed occupancy rate of 20% taking an estimated intra-cluster correlation of 0.278 into account. We used SPSS version 16.0 for all statistical analyses.

RESULTS

Participating ICUs

From the 80 ICUs submitting data to the NICE registry, we invited 46 ICUs that were preparing to collect the process indicators. Of these, 30 ICUs agreed to participate in the study of which fifteen units were assigned to the intervention arm and an equal number to the control arm (Figure 1). The first participating ICU was included in January 2009 and the last ICU started in November 2009.

In our analyses, we had to exclude two ICUs in the intervention group and four ICUs in the control group because they failed to provide data throughout the study period or were not able to provide valid data. Finally, 24 ICUs were included in the analyses, with a total of 33582 nursing shifts for bed occupancy and 33655 shifts for n:p ratio. Table 1 presents the baseline characteristics of the 24 ICUs and the included shifts.

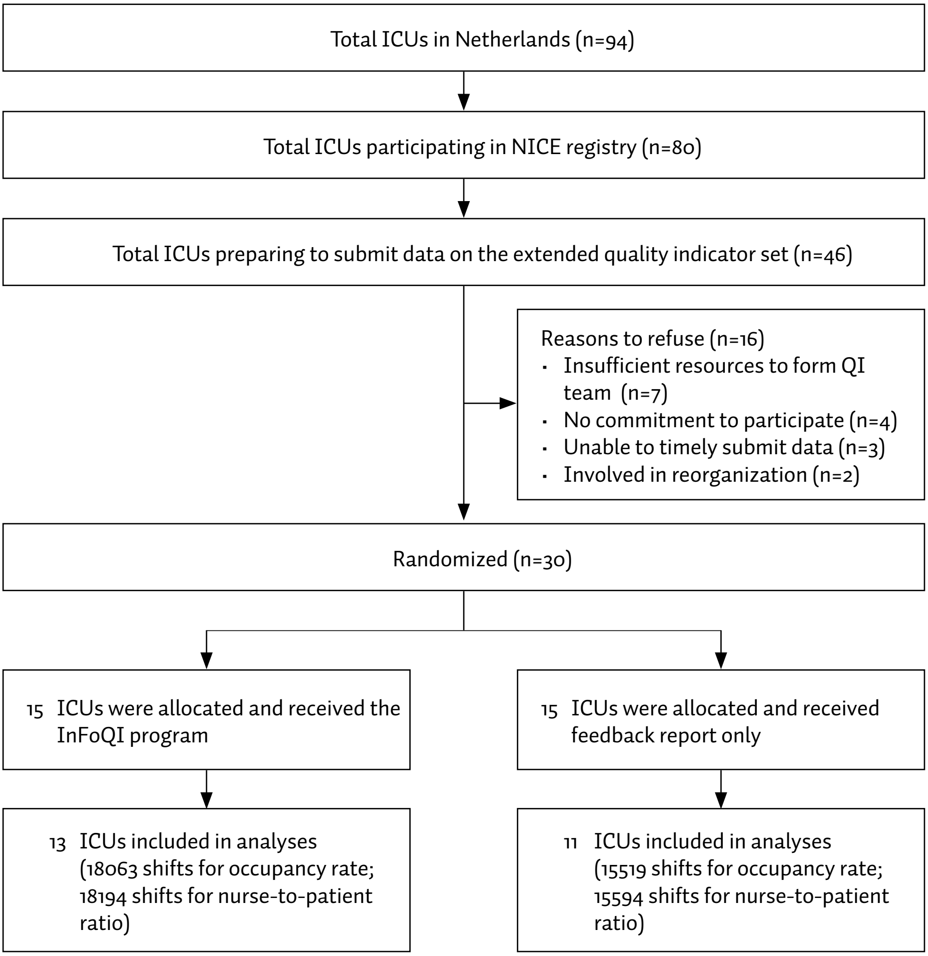

Figure 1 *- Flow diagram*

Table 1 - Baseline characteristics of participating ICUs and included shifts in the InFoQI program

	Intervention	Control
ICU level characteristics		
No. included in analysis	13	11
Academic or teaching hospital	9	5
Cardiac surgery centre	2	2
Emergency bed available	8	8
No. of qualified nurses[a]	7.1 (4.5)	6.6 (5.5)
Nurse-to-patient ratio[a]	0.72 (0.3)	0.69 (0.3)
No. of operational beds[a]	13.6 (8.1)	12.98 (7.7)
Bed occupancy rate[a]	75.6 (2.0)	79.5 (2.2)
Proportion of shifts with bed occupancy rate below 80%	50%	43%
Proportion of shifts with nurse-to-patient ratio above 0.5	76%	74%
Participated in indicator development pilot study	5	3
No. of shifts included in analysis		
Bed occupancy	18063	15519
Nurse-to-patient ratio	18061	15594

Abbreviations: ICU, intensive care unit; No., number
[a] *Values are mean of day, evening and night shifts together ± SD*

Effect of the InFoQI program

During the study period, ICUs receiving the multifaceted feedback intervention showed no significant improvements in either organizational process indicators compared to ICUs receiving feedback reports alone. Table 2 shows a (non-significant) decline in the proportion of shifts with a bed occupancy rate below 80% during follow-up for the intervention ICUs (OR, 0.85; 95% Confidence Interval (CI), 0.60 - 1.22). The proportion of shifts with a bed occupancy rate below 80% is slightly higher in follow-up compared to baseline for the control ICUs, but ratio of change during follow-up between intervention and control ICUs is not significant (ratio of ORs, 0.63; 95% CI, 0.37-1.09; p=.10).

Table 2 *- Results of InFoQI program on organizational process indicators*

	Crude outcome [a]		**Crude change in follow-up during intervention [b]**		**Adjusted[c] change in follow-up during intervention**		**Crude difference in change [d]**		**Adjusted [c,d] difference in change**	
Organizational indicators	Intervention	Control	Main effect (95% CI)	P Value	Main effect (95% CI)	P value	Main effect (95% CI)	P value	Main effect (95% CI)	P value
Proportion of shifts with bed occupancy rate below 80%	48%	51%	0.94 (0.68-1.29)	0.69	0.85 (0.60-1.22)	0.39	0.68 (0.41-1.20)	0.14	0.63 (0.37-1.09)	0.10
Proportion of shifts with nurse-to-patient ratio above 0.5	70%	75%	0.75 (0.44-1.30)	0.30	0.72 (0.41-1.26)	0.24	0.70 (0.38-1.28)	0.25	0.65 (0.35-1.19)	0.43

Abbreviations: CI, Confidence Interval

[a] *Percentages of shifts in follow-up that adhere to the guideline recommendations for each indicators*

[b] *Odds ratio for improvement in follow-up period for the intervention group compared to baseline period*

[c] *Bed occupancy rate adjusted for type of shift, month of the year, availability emergency bed, cardiac surgery centre or non-cardiac centre and academic/teaching or non-teaching unit. Nurse-to-patient ratio adjusted for type of shift, month of the year, ratio newly admitted mechanical ventilated patients in a shift and academic/ teaching or non-teaching unit*

[d] *Ratio of odds ratios for improvement in follow-up between groups, calculated as odds ratio of the intervention divided by the odds ratio of the control group*

The proportion of shifts with a n:p ratio below 0.5 did not show a significant reduction during follow-up compared to baseline for intervention ICUs (OR, 0.72; 95% CI, 0.41-1.26). The ratio of change in the proportion of shifts with a n:p ratio above 0.5 between intervention and control ICUs was not significant (ratio of ORs, 0.65; 95% CI, 0.35-1.19; p=.43).

The results of the subgroup analyses concerning time investment, showed no significant results for either process indicators.

Implementation process of InFoQI program

All intervention ICUs established a QI team and received two educational outreach visits. Variation existed between ICUs in the implementation of this intervention in daily practice. None of the ICUs were able to review and discuss all feedback reports. Moreover, there was variation in the number of initiated QI actions during the outreach visits, ranging from 0-4 actions for bed occupancy rate and 0-10 for n:p ratio. Examples of QI actions at the ward level were: weekly consultation with surgeons and anaesthesiologists about changes in the operating room program, improving communication between nurses and intensivists about admission and discharge policy and attracting more nurses with flexible working hours. However, most QI actions were aimed at understanding the data and the underlying processes rather than directly influencing or changing these processes.

DISCUSSION

To our knowledge this is the first study that evaluated the effect of a multifaceted feedback intervention on organizational process indicators in the ICU. Our results show that the InFoQI program with extended feedback reports, QI teams and educational outreach had no effect on improving bed occupancy rate and n:p ratio compared to standard feedback reports alone. Why did we not observe any effect on the primary outcome measures? One potential explanation is that it may have been difficult to translate feedback of organizational process indicators into effective actions even if they are thought to be responsive to improvement efforts. Most bedside professionals have limited experience in QI and needed time to gain insight in organizational processes. The initiatives were mostly aimed at improving data quality instead of changing daily practice. Trust in indicator data quality is one of the basic conditions required to using indicators as a tool for systematic QI. [40,41] In addition, the number and type of QI actions differed substantially between the QI teams.

Secondly, it takes time to achieve organizational changes based on feedback. Therefore, a 14- month follow-up period may not have been long enough to achieve meaningful improvements at the organizational level. A third explanation for the lack of effect could be the limited face validity of the indicators and "conflicting interests". The process indicators used in this study are based on evidence-based standards, but conflicting interests may have influenced the interpretation of the data and initiated QI activities. Economic targets and quality targets may be contradictory. For example, bed occupancy rates over 80% can be economically beneficial, but can have negative effects for the quality of care delivery. Finally, another explanation for the observed outcomes could be that the ICUs in the intervention group showed better results at baseline compared to the control group resulting in limited room for improvement in the follow-up period or due to regression to the mean.

Strengths of our study are that we used a cluster randomized design and that the included ICUs were already familiar with routinely data collection. This increased the feasibility of the InFoQI program. However, a clinical trial design in this complex intervention setting also has several limitations. First, our trial could not be double blinded, due to the nature of the intervention. However, we do not believe that this potential bias affected the results because the ICUs in the control group remained unaware of the contents of the intervention. In addition, we invited ICUs that already collected indictor data and these ICUs may be more motivated and successful in implementing changes. Therefore, the contrast between the intervention and the control treatment may have been limited. Another limitation was the absence of a control group without any feedback of process indicators at all. Having such a control group was not feasible because ICUs were used to feedback from their data submitted to the registry. The fourth limitation is that we had to exclude relatively many ICUs from our analysis because of absent or incomplete data even if they were familiar with data collection. This is caused by the time-consuming registration of organizational process indicators, three times daily, which most ICUs had to do manually. Nevertheless, we believe that the effect is limited because looking at the power analysis we included sufficient ICUs in our analyses.

Future research could evaluate the impact of a multifaceted feedback intervention compared to ICUs receiving no feedback on organizational process indicators. In addition, the feedback reports in the intervention group should be enriched with suggestions for potentially effective actions. Suggestions can be derived from guidelines, policies, evidence based strategies and best practices employed by high performing ICUs. As it is unclear which of the three components of the intervention contributed most or less to the final effects, a future process evaluation may reach into the 'black box' of the intervention to evaluate which components have been more or less effective. In addition, future research on the effects on organizational process indicators should take into account a longer follow-up period. The indicators have to be easy to register, based on consensus and outcomes of these indicators have to provide possibilities for translating feedback into effective actions ('actionability').

The results of this study inform those involved in providing ICU care and management on the feasibility of a tailored multifaceted feedback intervention and suggest several ways in which the implementation and use of organizational process indicators can be improved. Although our study has been conducted within the domain of intensive care, our conclusions may be used in other settings that have an existing quality registry including an indicator set available.

In conclusion, our study demonstrates no effect of a tailored multifaceted feedback intervention on organizational process indicators, including bed occupancy rate and nurse-to-patient ratio. Furthermore, this study suggests that efforts to improve quality of care will require more actionable and consensus based indicators and a longer follow-up. In addition, further refinements of the intervention are suggested aiming at more additional tools to support changing practice.

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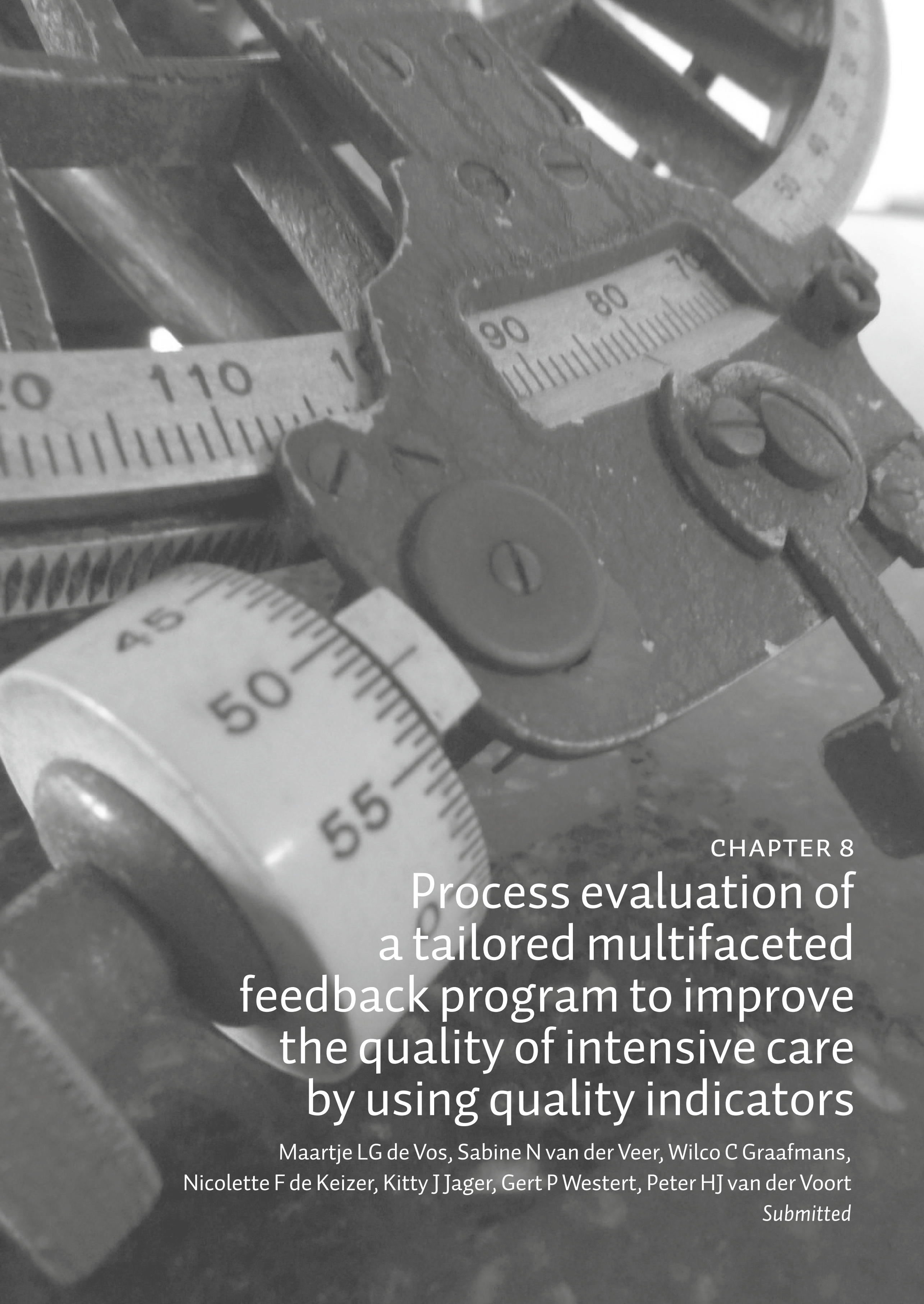

CHAPTER 8

Process evaluation of a tailored multifaceted feedback program to improve the quality of intensive care by using quality indicators

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ABSTRACT

Background: In multi-site trials evaluating a complex quality improvement (QI) strategy the 'same' intervention may be implemented and adopted in different ways. Therefore in this study we investigate the exposure to and experiences with a multifaceted performance feedback program, and explore potential explanations for why the intervention was effective or not.

Methods: We conducted a process evaluation as part of a cluster randomized trial investigating the effect of the feedback program on the quality of intensive care. Data were collected among participants receiving the intervention, which consisted of periodical feedback reports, establishment of a local QI team, and educational outreach visits. We used standardized forms to record time investment, and a questionnaire and focus group to collect data on perceived barriers and satisfaction.

Results: The monthly time invested per QI team member ranged from 0.6 to 8.1 hours. Persistent problems (in order of importance) were: not sharing feedback with other staff; lack of normative standards and benchmarks; inadequate case-mix adjustment; lack of knowledge on how to apply the intervention for QI; and insufficient allocated time and staff. The feedback intervention effectively targeted the lack of trust in data quality, and was reported to motivate participants to use quality indicators for QI activities. With regard to each of the elements of the feedback program, at least half of the respondents reported to have a satisfactory experience.

Conclusions: Time and resource constraints, difficulties to translate feedback into effective actions, and insufficient involvement of other staff members hampered the impact of the intervention. However, our study suggests that a tailored multifaceted feedback program stimulates clinicians to use quality indicators as input for quality improvement, and is a potential first step to integrating systematic QI in daily care.

BACKGROUND

In healthcare, there is a large variety of initiatives developing and reporting performance indicators. [1-3] By providing care providers insight into their performance, these initiatives ultimately aim to improve patient outcomes. However, it is still much debated how to use indicators in order to achieve this. [4-7]

In 2006, the Dutch National Society of Intensive Care Medicine (NVIC) developed a set of quality indicators in order to evaluate and improve the quality at Dutch Intensive Care Units (ICUs). [8] The Dutch National Intensive Care Evaluation (NICE) registry facilitates the indicator data collection and analyses. As a regular NICE service, participants of the registry receive standard quarterly feedback reports on these indicators. Although structured feedback on analyzed healthcare data is potentially effective in improving the quality of care, [9-11] studies showed that multifaceted interventions are usually more effective than those consisting of a single element, in this case sending feedback reports only. [9,11] Furthermore, interventions tailored to prospectively identified barriers are more likely to improve professional practice as compared to non-tailored interventions. [12-15] Therefore, a barriers analysis was performed in Dutch ICUs with regard to the standard NICE feedback reports. This analysis showed that Dutch ICU healthcare professionals perceived several barriers to using performance data for systematically quality improvement (QI). [16,17] Based on these results, we developed the Information Feedback on Quality Indicators (InFoQI) program, which is described in the Methods section. The effectiveness of this program was evaluated in a cluster randomized trial. [16]

In multi-site trials evaluating a complex QI strategy the 'same' intervention may be implemented and adopted in different ways, and the exposure to this intervention may vary considerably. Process evaluations can then be used to provide insights into to what extent the trial intervention was actually implemented and how it was experienced by the study participants. [18,19] Such insights facilitate the interpretation of quantitative results of trials, and may be crucial in explaining why a QI strategy was effective or not. In addition, a process evaluation assesses the feasibility of the intervention in daily practice, and increases its reproducibility. [19,20] However, publications on the results of formal process evaluations have been scarce. [19,21,22]

Therefore, besides assessing the effectiveness of the InFoQI program, we conducted a process evaluation as a fundamental part of our trial. With the current study we aimed to contribute to a better understanding of the implementation process of a multifaceted indicator feedback intervention, and its impact on the quality of ICU care.

METHODS

The InFoQI program

The InFoQI program is a multifaceted intervention for the ICU setting, tailored to barriers identified prospectively, and developed using evidence from literature, input by future users, and expert knowledge. [16] InFoQI aimed to promote the use of quality indicator data for systematic QI at ICUs. The main components of the InFoQI program included a) provision of comprehensive monthly and quarterly feedback reports, b) establishment of a local multidisciplinary QI team, and c) two educational outreach visits (Table 1). During these visits, the QI team was supported with formulating a QI action plan based on the performance data presented in the feedback reports. The main tasks of the QI team were to discuss their performance in monthly meetings and to communicate the main finding to the rest of the ICU staff.

To evaluate the impact of the InFoQI program on the quality of ICU care, we conducted a cluster randomized trial in the Netherlands from January 2009 until January 2011. [16] ICUs were eligible for InFoQI if they participated in the NICE registry (n=80), were preparing to submit performance indicator data to the registry (n=46), and were able to allocate at least two staff members to form the QI team. We estimated that the average time investment per QI team member would be four hours per month for implementing the intervention only, i.e. excluding the time needed for executing QI initiatives. Finally, 30 ICUs fulfilled the inclusion criteria and gave informed consent. Fifteen ICUs were randomly assigned to the control arm receiving basic quarterly feedback reports, and fifteen were allocated to participating in the InFoQI program. The trial did not show a significant effect of the InFoQI program on the endpoints, which were nurse-to-patient ratio, bed occupancy rate, ICU length of stay, duration of mechanical ventilation, glucose regulation, and hospital mortality.

Table 1 - Main components of the InFoQI program according to protocol

Component	Description
Feedback reports	• 12 monthly report for monitoring ICU's performance over time • 4 extensive quarterly report for benchmarking ICU's performance to other ICUs • sent to and monthly discussed by QI team members
Local QI team	• multidisciplinary; minimum of 2 members (intensivist and ICU nurse) • responsible for formulating and executing a QI action plan • 12 monthly QI meetings in order to monitor their performance using feedback reports • sharing main findings with rest of ICU staff
Educational outreach visits	• on-site (1) at start of study period and (2) after six months • all QI team members are present; visits guided by principal investigators • promoting use of Plan-Do-Study-Act cycle for systematic quality improvement • formulating and evaluating QI action plan based on performance data

Abbreviations used: ICU, intensive care unit; QI, quality improvement

Measurement and variables

We used the process evaluation framework described by Hulscher et al. [18] to evaluate 'the actual exposure to' and 'the experience with' the InFoQI program. The information presented in this paper was collected among those exposed, i.e., members of the multidisciplinary QI teams in the intervention ICUs. Both qualitative and quantitative methods were used.

Actual exposure to the InFoQI program

During the study period, all QI team members were asked to record the estimated time they invested in the various study activities. Each member received a time registration form –at six and twelve months after inclusion– for recording the time spent per activity, e.g., reviewing and discussing a specific quarterly report. We distinguished hours invested in implementing the InFoQI program (e.g. reviewing reports, local QI meetings) from hours spent on executing QI initiatives from the local QI plan.

Experience with the InFoQI program

In this paper, the experience with the InFoQI program refers to the barriers perceived by those exposed, as well as their satisfaction with the program. Between April 2010 and June 2011, electronic questionnaires were sent to all QI team members at the end of their follow-up period. The first part of the questionnaire addressed perceived barriers to using the InFoQI program for systematic quality improvement at their ICU. We formulated 47 statements based on barriers identified beforehand, [16] and based on factors influencing QI success mentioned in other studies. [17,23,24] The majority of the statements asked for the respondent's opinion (e.g., the definitions of the indicators are clear); some statements enquired after more factual circumstances (e.g., at our ICU, someone is responsible for collecting and submitting the indicator data).

Based on the framework of Fleuren at al., [23] the barriers were grouped into four categories: characteristics of the indicators, characteristics of professionals, characteristics of the environment, and characteristics of the intervention. The second part of the questionnaire consisted of nine statements concerning satisfaction with the different components of the InFoQI program. Answers to all statements could be given on a 5-point Likert scale ranging from '1= strongly disagree' to '5= strongly agree'. The questionnaire was pilot-tested by one ICU nurse and two intensivists with special interest in implementation to check the questionnaire for relevance and completeness.

In addition, we invited delegates of the local QI teams to a two-hour focus group session in December 2010, to elaborate on the preliminary results of the questionnaire. Five intensivists, two ICU nurses, and two managers from eight different ICUs participated; five worked in teaching or academic hospitals. The session was chaired and co-chaired by two health services researchers (MdV and SvdV). A topic guide with open-ended questions was used to structure the discussion. The session was audiotaped and transcribed verbatim by an independent research assistant.

Data analysis

We used descriptive analysis to analyze the data regarding time investment, and the response to the questionnaire. Responses to negatively formulated statements in the questionnaire were recoded to match those positively formulated. A score of more than three on the 5-point scale was indicated as positive, less than three as negative, and a score of three was indicated as neutral. We considered a statement to reflect a barrier if less than 50% of the respondents scored the statement as positive.

Regarding the analysis of the focus group session, two researchers (MdV and SvdV) independently studied the transcripts, identified all barriers, and classified them into one of the four abovementioned barrier categories. Results were compared, and discrepancies were discussed until consensus was reached.

RESULTS

Actual exposure to the InFoQI program

Table 2 shows the frequencies and time investments regarding the main components of the InFoQI program: monthly and quarterly feedback reports, the local multidisciplinary QI team, and the educational outreach visits.

Feedback reports

As planned, all intervention ICUs received four quarterly and twelve monthly feedback reports. The average number of monthly reports monitored per team was 8.3 (±3.7; range, 3 to 12), and the average number of quarterly reports was 2.6 (±1.4; range, 0 to 4). For ICUs that spent at least four hours per month per team member (n=8) this was 10.4 (±2.3; range, 6 to 12) monthly, and 3.5 (±0.8; range, 2 to 4) quarterly reports. The average time spent to review one monthly report per team member was 1.0 hour (±0.6; range, 0.4 to 2.5), and for a quarterly report this was 1.1 (±0.7; range, 0 to 1.9).

Multidisciplinary QI team

As prescribed by the InFoQI program, all fifteen ICUs established a QI team with a minimum of two and a maximum of seven members. Most of the teams (53%) consisted of four members, including at least one intensivist and one ICU nurse. Most of these teams (n=11) added a (quality) manager as an additional member. The total average monthly time investment per team member for the study was 4.1 hours (±2.3; range 0.6 to 8.1). On average, QI teams spent 62% of their time on activities pertaining to the InFoQI intervention itself (e.g. reviewing feedback reports, QI team meetings, etc.) (2.5 ± 1.3 hours; range, 0.6 to 4.8), and 38% on the execution of the QI initiatives as formulated in the local QI plan (1.6 ± 1.5 hours; range, 0 to 5.6). The average number of monthly QI team meetings was 5.7 (± 1.4; range, 0 to12). Only one ICU organized the maximum number of twelve monthly meetings; three ICUs did not organize any QI meeting.

Educational outreach visits

All ICUs received both educational outreach visits. Most of the visits (87%) were attended by all the members of the QI team. The average duration of the first outreach visit was three hours, and for the second outreach visit this was two hours.

***Table 2** - Exposure to the InFoQI program; frequencies and time investment regarding the main components of the intervention*

Components of the InFoQI program	Mean (SD)	Range
Multidisciplinary QI team		
• Number of members per QI team	4 (1.2)	2-7
• Time spent per team member per month (hours)		
- Total	4.1 (2.3)	0.6- 8.1
- Activities pertaining to the InFoQI intervention (hours)	2.5 (1.3)	0.6-4.8
- Execution of QI initiatives from the local QI plan (hours)	1.6 (1.5)	0-5.6
• QI meetings		
- Number of meetings with at least two QI team members present	5.7(4.5)	0-12
- Time spent per meeting per attending team member (hours)	1.4(1.0)	0-3.3
Feedback reports		
• Monthly reports		
- Number of reports reviewed [a]	8.3(3.7)	3-12
- Time spent on reviewing per report per reviewing team member (if reviewed)	1.0(0.6)	0.4-2.5
• Quarterly reports		
- Number of reports reviewed [a]	2.6(1.4)	0-4
- Time spent on reviewing per report per reviewing team member (if reviewed)	1.1(0.7)	0-1.9
Educational outreach visits		
• Number of visits with all QI members attending	26 [b]	n.a.
• Duration		
- First educational visit (hours)	3 (1.5- 4)	1.5- 4
- Second educational visit (hours)	2 (1.5- 3)	1.5- 3

Abbreviations used: QI, quality improvement; n.a., not applicable; SD, standard deviation

[a] *reports were marked as 'reviewed' if at least one QI team member reported time invested*

[b] *reported for all intervention ICUs together; the total number of visits organized was 30 (i.e., two per ICUs)*

Experience with the InFoQI program

Of the 56 questionnaires, 43 (77%) were completed. Minimal one QI team member of each ICU responded. Most of the respondents were intensivists (33%) and ICU nurses (33%), followed by other healthcare professionals, e.g. quality managers (9%). The majority of the 43 respondents were between 46 and 55 years of age (56%), and affiliated to teaching hospitals (56%).

Below we describe for each of the four categories the most important barriers identified, the barriers that were solved by the InFoQI program, and a summary of the responses regarding satisfaction with the different components of the intervention. All results from the questionnaire discussed below were confirmed in the focus group, unless indicated otherwise.

Barriers

Twenty-two of the 47 statements (47%) were considered to be barriers. Top 10 of most important barriers to using the InFoQI program for local, systematic QI is presented in Table 3. Table 4 presents the Top 10 of barriers that were targeted by the InFoQI program. The lower the percentage, the more a statement reflected a perceived barrier.

1. Characteristics of the quality indicators

Of the four categories, most perceived barriers were related to characteristics of the quality indicators. The most reported barrier was ´lack of normative standards´ to determine whether improvements were needed (21%). In the focus group, participants stated that indicators that incorporate a normative standard are more often subject to discussion and to changes over time. For example, for the indicator 'proportion out-of-range glucose measurements' the upper threshold of 8.0 mmol/l was much disputed during our study. At first, ICUs considered this too high based on the study of Van den Berghe et al., [25] while after the publication of the NICE-SUGAR study in 2009 [26] many Dutch ICUs increased their local glucose target to exceed our threshold of 8.0 mmol/l. Other important barriers in this category were: indicators not being up-to-date (26%); the lack of useful benchmark data (30%); and the positive impact of the indicators not outweighing the required effort (31%). Also, 32% of the respondents stated that there was insufficient case-mix adjustment to facilitate determining the need for QI actions. Focus group participants mentioned the example of the benchmark for the indicator 'duration of mechanical ventilation' being difficult to interpret without adequate adjustment for case-mix.

Regarding the indicator 'nurse-to-patient-ratio', 74% of the respondents (strongly) agreed with the national guideline that one qualified ICU nurse should care for a maximum of two patients simultaneously. [27] Prior to the development of the InFoQI program, one perceived barrier was the lack of reliable indicator data. [16] At the end of the study, almost all respondents (91%) agreed that their confidence in the submitted data had improved, and that using structure and process indicators has resulted in improved quality of care (63%) (Table 4). It was also stated in the focus group that participating in the study had improved data quality and increased awareness of data management processes. The participants emphasized that professionals will only act on data if they feel the data are reliable.

2. Characteristics of the professionals

In general, only few barriers concerned the characteristics of professionals. Respondents reported to be familiar with the indicators and their definitions (75%), although some lacked knowledge and skills on how to use the InFoQI intervention for quality improvement at their ICU (22%). Some commented in the focus group that a list of potentially successful actions to improve their practice would have been useful. Most healthcare professionals were motivated to apply the InFoQI intervention to improve the quality of care at their ICU (83%), which was prospectively identified as a barrier. Focus group participants confirmed that that their QI team was very motivated to use quality indicators for performance improvement efforts. The respondents of the questionnaire further stated that they were well informed regarding the definitions of the indicators (70%), and that they considered the definitions of the indicators to be clear (79%).

3. Characteristics of the environment

The most prominent environmental barrier was related to insufficient allocated time to implement the InFoQI program in daily practice (25%). Other barriers were related to insufficient staff for implementing the InFoQI program in daily practice (30%), and probability of interference of third parties outside the ICU (28%). Focus group participants mentioned that it was difficult to allocate time to review the reports since delivery of routine patient care always had the highest priority. Implementation of the InFoQI intervention was further hampered by the presence of temporary healthcare workers not being familiar with ongoing QI activities.

Furthermore, 50% of the respondents reported that there was good communication and cooperation within the ICU, and 62% felt that other staff members were willing to participate in the program. Most of the respondents reported that the responsibility to collect and submit indicator data was appointed to a specific person at their ICU (79%), and that incorporating the implementation in daily routines was no longer perceived a barrier (66%).

4. Characteristics of the InFoQI intervention

Overall, the statement with the lowest percentage respondents agreeing was 'access to the feedback reports by other staff members' (7%), despite of encouragement during the outreach visits to share findings with the rest of the staff. In the focus group, participants stated that the reports were available, e.g., put- online, but not actively discussed with other staff members.

Most of the potential barriers identified in the prospective barrier analysis concerned aspects of the standard NICE feedback reports, e.g. insufficient timeliness, the high level of data aggregation, and a lack of intensity (i.e., how much and how often information is sent).[16] At the end of the study, results from the questionnaire showed that lack of intensity was no longer a barrier (77%), and respondents reported that the InFoQI program led to improved quality of care (63%). Also, the insufficient level of aggregation (51%) and applicability (58%) were no longer prominent barriers. In the focus group, some participants even stated that the intensity was too high, as they did not have enough time to discuss each monthly feedback report. Also, the improved applicability of the indicators was mentioned in the focus group. For example, one ICU had adjusted their protocols at the operating room based on analyzing unexpected ICU deaths. Some participants mentioned that they would like to receive feedback about the relationships between indicators instead of looking at indicators separately because one can draw better conclusions when taking into account the interaction between structure, process and outcome indicator data. For example, the association between a high nurse-to-patient ratio and a lower mortality rate.

Another barrier reported in the focus group was that participating in the InFoQI program was very time-consuming, especially the collection of valid and reliable indicator data. The QI team meetings were difficult to organize, and often only part of the QI team attended.

Table 3 *-Top 10 of most important barriers to using the InFoQI program for local, systematic QI*

Statements	**Category**	**(strongly) agreed** [a]
Other staff members have access to and know where to find the InFoQI feedback reports [b]	intervention	7%
A normative standard for 'ICU Length of Stay' and 'duration of mechanical ventilation' is not required for deciding if improvement is needed [b]	indicators	21%
I know how to use the InFoQI program to improve the quality of care	intervention	22%
Implementation of the InFoQI program in daily practice was feasible due to sufficient allocated time [b]	environment	25%
The indicators are up-to-date and do not need revision	indicators	26%
The collection of indicator data does not increase the probability of interference of third parties outside the ICU	environment	28%
Implementation of the InFoQI program in daily practice was feasible due to sufficient staff	environment	30%
The definition of the indicators contributes to useful benchmark data	indicators	30%
The positive impact of using indicators outweighs the required efforts	indicators	31%
Data are sufficiently adjusted for case-mix to facilitate determining the need for QI actions [b]	indicators	32%

Abbreviations: ICU, intensive care unit; QI, quality improvement

[a] *the lower the percentage, the more important the barrier*

[b] *barriers were also identified in the barrier analysis prior to the implementation of the program*

Table 4 - Top 10 of barriers that were targeted by the InFoQI program

Statements	Category	(strongly) agreed [a]
I trust the quality of our own indicator data [b]	indicators	91%
I am motivated to use indicator data for quality improvement [b]	professional	83%
The definitions of the indicators are clear	professional	80%
At our ICU, someone is responsible for collecting and submitting the indicator data	environment	79%
The frequency of the InFoQI feedback reports was sufficiently high [b]	intervention	77%
I agree with the NVIC guideline that one qualified ICU nurse should care for a maximum of two patients simultaneously	indicator	74%
I am well informed with regard to the definitions of the indicators	professional	70%
I find it easy to adapt my existing routines to implement indicators [b]	environment	66%
The use of the InFoQI program leads to improved quality of patient care	intervention	63%
Using structure- and process indicators has resulted in better quality at my ICU	indicators	63%

Abbreviations: NVIC, Netherlands Society of Intensive Care; ICU, intensive care unit; QI, quality improvement
[a] *the higher the percentage, the less important the barrier*
[b] *barriers were also identified in the barrier analysis prior to the implementation of the program*

Satisfaction

All statements regarding satisfaction with the different components of the InFoQI program were indicated as positive by more than 50% of the respondents. The monthly feedback reports were rated least positive (58%). This was consistent with the abovementioned finding regarding the time investment to discuss each monthly feedback report. Respondents were most satisfied with the educational outreach visits (78%), and the local QI team meetings (71%) because it supported and stimulated them to use indicators for QI.

During the focus group, participants stated that the educational outreach visits helped them to look at their data and processes differently, and encouraged them to critically assess their practice. In addition, some participants mentioned that the establishment of a QI team was a good organizational structure to discuss the feedback reports and data within the team.

DISCUSSION

Our study results showed considerable variation among ICUs regarding the exposure to the InFoQI program. Most perceived barriers to using quality indicators for QI activities regarded characteristics of the indicators themselves. Clinicians' trust in indicator data quality and their motivation to use indicators for quality improvement were no longer perceived as problems. Respondents reported to be satisfied with all components of the InFoQI program.

We found that the InFoQI program effectively targeted part of the prospectively identified barriers.[16] After implementation of InFoQI, 'lack of trust in data' and 'lack of motivation' were no longer perceived a problem. This implies that a tailored multifaceted feedback intervention potentially removes concerns regarding data accuracy, and positively affects clinicians' attitudes towards using performance indicator data to improve their practice. In addition, participants reported to be very satisfied with the InFoQI program, especially with the outreach visits. This is consistent with findings in other studies showing that healthcare professionals prefer educational interventions that are practice-based.[28,29] However, social desirability bias might have resulted in an overestimation of the satisfaction with the visits since the researchers that facilitated the visits were also involved in the process evaluation.

This study also reveals persisting barriers, which might explain why the InFoQI program was not effective. Firstly, many unsolved barriers were related to the characteristics of the indicators, e.g. 'lack of normative standards for deciding if improvement is needed', 'lack of case-mix adjustment', and 'lack of useful benchmark data'. These barriers potentially decreased the interpretability and actionability of the performance feedback.[30-32] Our results warrant ongoing focus by organizations involved in the development of quality indicators on adequate case-mix adjustment of outcome measures, and providing benchmarks against a meaningful standard or comparison group.

Secondly, only very few participants reported that other staff members had access to the feedback reports. On one hand, sharing the feedback more actively may have increased the involvement of the rest of the staff,[33] which is pivotal to expedite actual changes in daily care. On the other hand, participants reported other staff members to be cooperative and positive with regard to the InFoQI program. This suggests that access to the feedback reports was not crucial in convincing colleagues to contribute. Unfortunately, we did not have data available on the exposure and experiences of other staff, impeding investigating this in more detail. In order to ensure broad participation within an organization, however, we suggest that those involved in the development of feedback programs include explicit strategies to support QI teams in involving their organization in the quality improvement endeavour.

Thirdly, characteristics of the environment were the second most reported category of barriers; they mainly referred to time and resource constraints to apply the InFoQI program in practice. This provides a plausible explanation for the fact that none of the participating ICUs implemented the intervention entirely as planned, hampering the impact of the program. [34] On one hand, our study confirms that targeting the lack of allocated time and resources for activities other than direct patient care is complicated. On the other hand, the InFoQI program was perceived to facilitate the use of quality indicators as part of daily routines. This suggests that a multifaceted feedback intervention may partly –but not entirely– solve this problem.

Lastly, although most participants felt that the InFoQI program resulted in improved patient care at their ICU, our trial showed no significant impact of the intervention on the quality of care. This discrepancy between the perceived and the actual impact of their QI activities might partly be explained by the 'lack of information to initiate QI actions', which was reported as a barrier. In addition, Davies and colleagues suggested that clinicians might have a limited understanding of the concepts and methods underlying QI. [35] Based on our study, we suggest providing QI teams with additional tools to translate performance feedback into effective actions. For example, cause-and-effect diagrams for systematic problem analysis, [36] or evidence-based strategies to change daily practice. [37] The effectiveness of such tools should be investigated in future research.

The main strength of our study is that we used a combination of qualitative and quantitative data collection methods, which is increasingly used in health services research and evaluation. [38] This enabled the triangulation of results, and assisted the process of exploring apparent discrepancies between findings. [22]

A limitation of our study is that one quarter of the participants did not complete the questionnaire. Because non-responders might have perceived more or different barriers than responders, some factors that hampered the implementation of the InFoQI program might have been missed. However, since all participating ICUs were represented by at least one QI team member, we believe that we identified the most salient barriers. Furthermore, the ICUs in our study volunteered to participate in the InFoQI program. This implies that they were motivated to change their practice based on performance feedback, and felt their organizational structure would facilitate this. Therefore, extrapolation of our results to settings with less motivated participants should be done with caution. Lastly, our study results do not allow the drawing of conclusions with regard to the causal relationship between identified barriers and the lack of impact of our intervention; this is a limitation inherent to process evaluations.

CONCLUSIONS

In conclusion, our study suggests that a tailored multifaceted feedback intervention potentially stimulates healthcare providers to use quality indicators as input for QI activities, and is a potential first step to integrating systematic QI in daily care delivery. However, time and resource constraints hampered the implementation of the intervention. Additionally, to further facilitate the translation of the feedback into effective actions, adequate case-mix adjustment, meaningful benchmarks, and additional QI tools are required to successfully change healthcare practice. Also, promoting the active involvement of all staff members' merits attention. We believe that our results contribute to a better understanding of how the use of quality indicators result in quality improvement in ICU care, as well as in other clinical domains.

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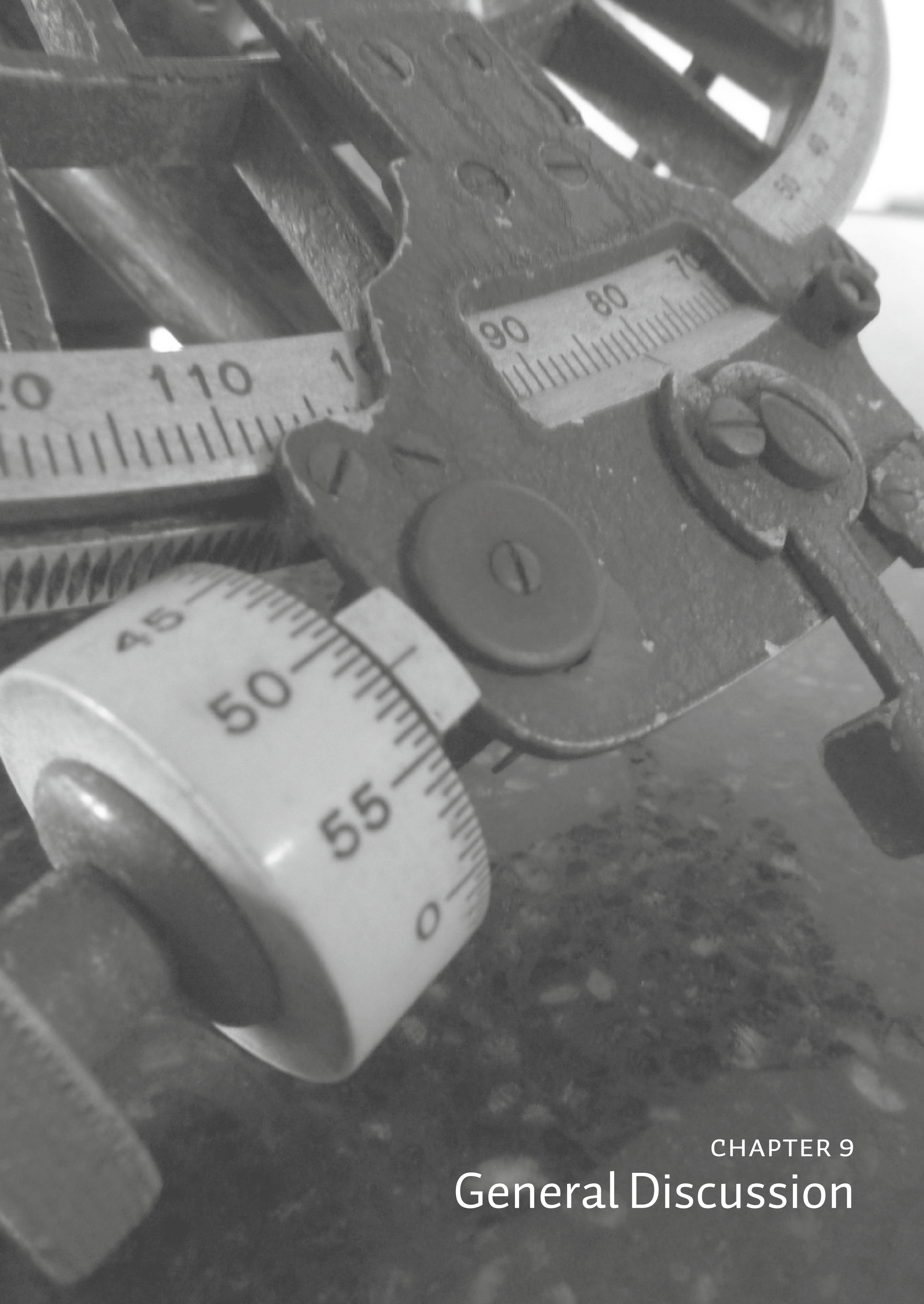

CHAPTER 9

General Discussion

INTRODUCTION

The main objective of this thesis was to generate knowledge about the development and implementation of quality indicators as a tool for quality improvement (QI) at intensive care units (ICUs). In order to reach this aim, the first part of this thesis focused on several activities which enabled us to do an empirical study such as the development of a set of indicators for the intensive care and the development of QI feedback intervention based on indicator data. The second part of this thesis focused on the implementation and evaluation of this QI intervention on the quality of ICU care. We addressed the following main research objectives:

1. To identify a set of quality indicators that measure the quality of ICU care, combining structure, process and outcome indicators.
2. To adopt and develop tailored interventions for the effective use of quality indicators by healthcare professionals with special focus on information feedback in the intensive care setting.
3. To evaluate the effectiveness of the developed feedback intervention (as mentioned above, objective 2) on the quality of ICU care.
4. To gain insight into the barriers and success factors that affected the intervention's impact.

In this final chapter, we summarize and discuss the main findings of our study. In addition, we describe the methodological issues as well as the implications of our findings for practice and future research.

SUMMARY AND DISCUSSION OF MAIN FINDINGS

Part 1: Indicator and program development

A set of quality indicators for intensive care was defined based on literature research and expert opinion combining structure, process and outcome indicators (Chapter 2). In this chapter, we also evaluated the feasibility of the registration of these indicators. This set of indicators is supposed to give a quick scan of the overall quality of ICU care. The availability of a computerized data collection system was reported as important for an acceptable workload and reliable registration.

Prior to the development of a feedback intervention using indicator data, we reviewed the literature concerning implementation strategies for quality indicators and examined their effectiveness in improving the quality of care (Chapter 3). The majority of the included studies used audit and feedback as QI strategy and focused on care processes rather than patient outcomes. We conclude that effective strategies to implement quality indicators do exist, but there is considerable variation in the methods used and the level of change achieved. Feedback reports combined with another implementation strategy seemed to be most effective. In this review, identified barriers to implementation were lack of resources; no support from management; and lack of detailed and reliable data feedback.

In addition, we explored potential barriers to and facilitators of behaviour change that may affect the implementation of quality indicators in Dutch ICUs. In chapter 4, the results of a validated questionnaire completed by 142 healthcare professionals working at 54 Dutch ICUs showed that healthcare professionals and managers are familiar with using quality indicators to improve care and that they have positive attitudes towards the implementation of quality indicators. Although there is a positive attitude, the study also confirmed that barriers exist and differ among type of profession, age group and setting. This is in line with previous results outside the ICU setting. [1, 2] The most prominent barriers were lack of time and resources for the implementation of quality indicators. We conclude that the prospectively identified barriers have to be addressed before healthcare professionals and managers are willing to implement and use quality indicators in daily practice. Administrative support for intensivist, additional education for nurses, and effective feedback of indicator scores for managers may be effective strategies to reduce the identified barriers.

Chapter 3 and 4 provided detailed information for the development of an implementation strategy. Following previous research, [3,4] we translated the prospectively identified barriers into a multifaceted QI feedback intervention using input from evidence and target users. In chapter 5 this multifaceted feedback intervention, called InFoQI (Information Feedback on Quality Indicators), was described in detail and the study was outlined. The InFoQI program included (1) monthly and quarterly feedback reports, (2) establishment of a multidisciplinary QI team and (3) two educational outreach visits. The program aimed to promote the use of quality indicators as input for local systematic QI.

Part 2: Empirical study

The chapters 6, 7 and 8 focused on the actual implementation and evaluation of the InFoQI program on the quality of ICU care. To evaluate the impact of this multifaceted feedback program we conducted a randomized controlled trail (RCT) among Dutch ICUs. Our results showed that the InFoQI program did not improve ICU patient outcomes (chapter 6) and organizational process indicators (chapter 7) compared to sending standard feedback reports only. The patient outcomes we evaluated were ICU length of stay (ICU LOS), duration of mechanical ventilation, mortality, and glucose regulation. Organizational process indicators that we studies were optimal bed occupancy rate and nurse-to-patient ratio.

The InFoQI program increased trust among healthcare professionals in data and improved the data collection process. Prior to the development of the InFoQI program, one perceived barriers was lack of reliable indicator data which implies that a tailored multifaceted feedback intervention potentially removed barriers regarding data accuracy. Another positive effect of the InFoQI program was that it stimulated participants to use quality indicators as input for systematic QI. In addition, participants were satisfied with all elements of the InFoQI program, especially with the outreach visits which is consistent with other studies. [5,6]

Possible reasons why we did not observe any effects on the quality indicators may be related to the limitations of the InFoQI program. Firstly, healthcare professionals had difficulties to translate feedback into effective actions and there may be an underestimation of the required time investments for team members resulting in an unanticipated lack of local resources to perform study activities and execute the QI action plan. The InFoQI program also aimed to intervene at the organizational level, where it might take longer to effectuate change at the individual or patient level.[7] Therefore, a follow-up period of 14 months may be too short to achieve meaningful improvements at the organizational level. Secondly, other reasons for not finding effect may be related to the indicators themselves. Some patient outcome indicators are strongly affected by case-mix which resulted that healthcare professionals indicated that their inconsistent ICU performance was due to their patient population. In addition, conflicting interests regarding the organizational process indicators may also have influenced the interpretation of the data and initiate QI activities. For example, economic beneficial targets such as a bed occupancy rate above 80%, can have negative effects on the quality of care. Finally, the intervention group in chapter 6 and 7 showed better results at baseline compared to the control group resulting in limited room for improvement in the follow-up period.

To better understand the implementation process of the multifaceted feedback intervention and its impact on the quality of ICU care we conducted a process evaluation. Based on this process evaluation (chapter 8) we conclude that the extent to which the InFoQI program was implemented in daily practice varied substantially between ICUs in the intervention arm. We used a questionnaire and focus group to collect data on perceived barriers and satisfaction. Most prominent barriers identified were not sharing feedback with other staff; lack of normative standards and benchmarks, inadequate case-mix adjustment; lack of knowledge on how to apply the intervention for QI; and insufficient allocated time and staff. Some of these barriers were also identified before implementation of the InFoQI program and not target by the intervention. We conclude that it is difficult to systematically develop an intervention and tailoring its content and format to potential identified barriers. Finally, the barriers identified in chapter 8 were in line with the potential reasons reported in chapters 6 and 7 for not finding effect.

METHODOLOGICAL ISSUES

We used a variety of research methods to examine the research objectives of this thesis. These included a systematic literature review, quantitative survey studies, conducting a RCT and a qualitative focus group study. In this section, the most important methodological limitations of this thesis are discussed.

First, several methodological limitations should be mentioned regarding the first part of this thesis. In chapter 4, we explored barriers to and facilitators for the implementation of indicators by using a questionnaire. Respondents of this questionnaire attended a training session aiming to implement indicators at their ICU. Therefore, the results might give a somewhat more positive picture than is the case in ICUs not planning to use quality indicators. More objective methods can be seen as indication for reliable results with a minimal risk of bias. In addition, there is a limited number of ICUs (57%) included in our sample and therefore extrapolation of these results to all ICUs should be done with caution. Nevertheless, it serves as a valuable first attempt to evaluate attitude of healthcare professionals and managers towards implementation of quality indicators in daily practice.

Secondly, we discuss the limitations regarding the second part of this thesis concerning the study design, as well as the participation and measurements of the InFoQI program. To evaluate the effect of the InFoQI program, we applied a clustered RCT. This design is considered to be the best method to evaluate an intervention. [8,9] Other RCTs within the ICU domain showed that a multifaceted QI intervention including performance feedback positively affected ICU practice. [10-12] However, the fact that the control group in our study received standard feedback reports may have disturbed the attribution of the effect. Furthermore, the design of the study did not allow us to quantitatively evaluate the relative effectiveness of the individual components of the InFoQI program. The program was tailored to prospectively identified barriers and therefore a combination of strategies was required. Nevertheless, we conducted a process evaluation to strengthen the study design that provided us with some qualitative information on the satisfaction and feasibility of the implementation of the several components of the program.

As for the participants in the InFoQI program, only ICUs that participate in the NICE registry were capable for submitting indicator data and were eligible for inclusion. Moreover, ICUs that volunteered to allocate resources to establish a local QI team were included. These criteria may have led to a non-representative sample of ICUs, because eligible ICUs are less likely to be understaffed and more likely to have information technology support to facilitate routine collection of indicator data. However this has not affected the internal validity of our results because both study arms consisted of these early adopters and motivated ICUs. Although the generalizability of our findings is limited to ICUs that are motivated and equipped to systematically monitor and improve the quality of care.

Among the participating ICUs in our study a large group of ICUs was excluded from the analyses for the organizational process indicators because of absent or incomplete data. The registration of these indicators was apparently too time-consuming for these ICUs, three times daily, as most of these ICUs had to do this manually.

Another limitation was related to the outcome measurements of our study. To evaluate the impact of the InFoQI program we used patient outcomes and organizational process indicators of ICU care. The selected indicators are influenced by several patient characteristics, providers and practices. In all our analyses we included important confounders for which data were available based on expert opinion or literature. Although adjustments were made for potential covariates, there is the possibility of residual confounding by unmeasured factors. These can include factors that did increase the likelihood of intervention success (e.g. high degree of support from top management) and factors that decrease the likelihood (e.g. lack of resources, high sickness absence) in both arms of the RCT.

We conducted a qualitative study to obtain a more comprehensive understanding of the perception of quality indicators in the ICUs in order to support the design of the InFoQI program. Our results showed a considerable variation among ICUs regarding the exposure to the InFoQI program. Therefore we conducted in both trial papers (chapter 6 and 7) subgroup analyses in which we took into account the reported time investment per QI team member. Finally, in our study we did not analyze the relationship between ICU related barriers and the effect of the intervention. Therefore, the results do not allow us to draw conclusions with regard to the causal relationship between identified barriers and the lack of impact of our intervention.

The main strength of our study is considered to be the use of mixed methods which is increasingly used in health services research and evaluation. This enabled the triangulation of results, and assisted the process of exploring apparent discrepancies between findings. [13,14]

IMPLICATIONS

Based on findings and discussion in this thesis, several recommendations can be made for future research and practice.

Implications for future research

In our study 'lack of information to initiate QI actions' was reported as barrier. Davies et al. [15] suggested that clinicians might have a limited understanding of the concepts and methods underlying QI. Moreover, nurses reported that they would like to receive education and training about the planned change in their practice. Based on these results, we suggest enriching knowledge in healthcare professionals concerning techniques and strategies for systematic QI. More knowledge is needed on effective and useful tools to facilitate ICU clinicians to translate performance feedback into effective QI actions. For example, the use of cause-and-effect diagrams for systematic problem analysis [16] or evidence-based strategies to change daily practice. [17] The effectiveness of such QI tools should be investigated in future research.

Secondly, better understanding of what tools work the best, either alone or in combination with others is needed. We recommend developing methods or designs to evaluate the effectiveness of the individual components of a multifaceted strategy. What strategies or combinations work for whom and in what context other than intensive care? Our study focused primarily on intensive care and therefore it is suggested to consider the potential of replicating the strategy in other setting outside the ICU or comparison studies are suggested between countries.

In addition, risk-adjustment is essential before comparing patient outcomes across hospitals or providers. [18] Risk adjustment may be most important for outcome indicators. [19] From the start of the NICE registry, risk-adjusted mortality rates were already reported to the participants after benchmarking. In addition, case-mix adjustments should be considered for the outcome indicators 'LOS' and 'duration of mechanical ventilation'. It is recommended that future research should investigate models for case-mix adjustments for these indicators.

The InFoQI program aimed to intervene at the organizational level, where it might take longer to effectuate change at the individual or patient level.[7] During the study period the participants needed to gain insight in the data followed by understanding the reasons for aberrant data. They needed to define improvement actions, discuss them with their co-workers, implement these changes and measure the effect. Therefore, it would be interesting to investigate the effects of our intervention on the quality of care after a longer period of follow-up. Moreover, future implementation research should take into account a longer follow-up period to evaluate the effect of an intervention that intervenes at the organizational level.

Because a RCT is considered to be the best method to evaluate an intervention, [8,9] we suggest that future research could evaluate the impact of a multifaceted feedback intervention compared to ICUs receiving no feedback report. Unfortunately, a pure control group was lacking in our study because ICUs expected feedback from their data submitted to the NICE registry. However, this is recommended for studies that are willing to evaluate a QI strategy.

The heightened awareness of rising expenditure in healthcare would seem to create the perfect climate for cost-effectiveness analysis. Cost-effectiveness analysis is a method for evaluating the health outcomes and resource costs of health interventions. [20] Moreover, the cost of a QI intervention was viewed as an important factor in the potential for improvements. [20] Therefore, to gain insight in the costs and effects of the InFoQI program a follow-up study is suggested to address the cost-effectiveness of the program. In this way, the cost and benefits on the quality of care become clear, which enhance the scientific underpinning and argumentation for the use of QI interventions in healthcare.

Finally, our study focused on the effectiveness of a multifaceted feedback intervention on organizational process indicators and patient outcomes. However to quantify the benefits of the implementation strategy used, patient related outcomes measures are increasingly adopted. Currently, more and more attention is paid on the development of Patient Reported Outcome Measures (PROMs) that measure quality from the patient perspective. [21, 22] Therefore, future research could focus on measuring quality of life among survivors after intensive care. [23-25] This health-related quality of life (HRQL) is one of the most relevant outcome measure in intensive care for patients, families, physicians and society. [26]

Implications for practice

Several recommendations can be made for future initiatives on the use of quality indicators in order to facilitate systematic QI:

1. Prior to the implementation of indicators in daily practice, an important step is to create a sense of urgency. Identification and awareness of potential QI needs to be established. In order to bring about a change in medical practices, the QI should be the answer to an acknowledged problem to be solved at the ward or hospital. Next to this, managers and healthcare professionals need to be aware of the fact that the use of indicators is indispensable for QI. [27] At the time that the sense of urgency is apparent, an actionable set of valid indicators must be present. Implementation of this indicator set should be tailored to prospectively identified barriers. [4]
2. In our study, lack of time and resources were identified as one of the most important barriers. These barriers were also reported in other implementation studies. [28-31] Therefore it is crucial to facilitate and enable participants to have the needed time to be actively involved in the change processes. [32-34] Moreover, assure that the time required for the QI teams to implement changes based on indicator data is not underestimated. In addition, teams need a dedicated person who would have a significant amount of time and is responsible for coordination. For example, consider to provide administrative support for implementing changes. [35]
3. To implement and use more 'actionable' indicators. The indicators used in our study were not the best basis for actionable performance feedback. An indicator can be considered 'actionable' if it clearly refers to the desired QI. This requires that the desired goals for QI are clear and that the indicator gives clear instructions for improvement activities. Our process evaluation showed that there was a lack of normative standards and therefore it was difficult to determine whether QI actions were needed. For example, for the indicators 'LOS' and 'duration of mechanical ventilations' no *golden standards* were available and therefore these indicators were much disputed during our study. We therefore recommend developing indicators based on evidence to achieve a high degree of construct validity and included normative standards if possible.

4. To facilitate routine collection of indicator data. Moreover, it is suggested that there needs to be a local registration plan in order to organize the data collection in daily workflow; to divide registration between several persons; to connect the data collection to functions instead of individual persons; and to have someone responsible for the completeness and quality of data collection.
5. To provide feedback about meaningful benchmark data. Therefore to facilitate better comparisons of ICUs, benchmark ICUs of similar volume or similar organizational structure as these items have a relation with processes or outcomes that are measured by process and outcome indicators.[27] In addition, give feedback about the relationship between indicators instead of looking at indicators separately because one can draw better conclusions when taking into account the interaction between structure, process and outcome indicator data. For example, provide feedback about the relationship between a low bed occupancy rate and a lower mortality rate.
6. Communicate and share information with staff for successful implementation. [36] Our process evaluation showed that the feedback of the indicator data was, in general, not shared with the rest of the staff. Sharing the feedback more actively may have increased the involvement of the rest of the staff which is pivotal to expedite actual changes in daily care. [37] Therefore, it is recommended to communicate results on critical indicators across the organization and to keep everyone informed of the process and data behind decisions. [34]

GENERAL CONCLUSION

Closing the quality gap relies on implementation research to create effective QI interventions. [38] In this thesis, we generated knowledge about indicator development and implementation as a tool for QI. Our study showed that using indicators as a tool for systematic QI is important but much more complex than assumed at first glance. Even though a multifaceted intervention is tailored to potential barriers, persistent problems do exist. Especially, organizational constraints hampered the implementation process as well as the way feedback of indicators is provided. To successfully implement indicators it is crucial to have time, staff and a registration available as well as sharing findings with staff. Additionally, to further facilitate translation of the feedback of indicators into effective actions, adequate case-mix adjustments, meaningful benchmarks and additional tools are required to successfully change healthcare practice. Future research aimed at implementing indicators in daily practice should focus on how to address the identified barriers in this study. In addition, a subsequent QI strategy should be designed and its effectiveness on the quality of healthcare should be tested.

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Summary

Quality and safety issues have become increasingly important in healthcare. In order to measure the quality of care, often quality indicators are used, ideally combining measures of structure, process and outcome of care. Currently, many indicators have been developed worldwide to assess the quality of hospital care. However, it remains unclear if the quality of care can be supported effectively by the use of quality indicators. Only few randomized controlled trials showed that the use of indicators significantly improved the quality of hospital care, and some studies failed to demonstrate an effect. This may be related to challenges around the implementation of quality indicators, e.g. the creation of a sense of urgency to use indicators for systematic quality improvement (QI), to set up a reliable and valid registration, and how to provide feedback and make use of the analyzed data. At present, there is no clear evidence on how indicators should be implemented to optimize their use for QI.

Often feedback reports are part of an implementation strategy provided by medical quality registries. The Dutch National Intensive Care Evaluation (NICE) systematically and continuously collects and reports data on the quality of care delivered at Dutch intensive care units (ICUs). However, the impact of feedback of these data is not further explored. The studies in this thesis deal with the different aspects of the use of quality indicators in the ICU.

The main objective of this thesis was to study the use of quality indicators in intensive care medicine. The thesis includes the development of indicators, implementation and the use of indicators in continuous QI programs. The first part of this thesis focuses on the development of a set of indicators for the intensive care and the development of a QI feedback strategy based on indicator data. The second part of this thesis focuses on the implementation and the effect of this QI intervention on the quality of ICU care.

We addressed the following main research objectives:

1. To identify a set of quality indicators that measure the quality of ICU care, combining structure, process and outcome indicators.
2. To adopt and develop tailored interventions for the effective use of quality indicators by healthcare professionals with special focus on information feedback in the intensive care setting.
3. To evaluate the effectiveness of the developed feedback intervention (as mentioned above, objective 2) on the quality of ICU care.
4. To gain insight into the barriers and success factors that affected the intervention's impact.

In **chapter 2** a set of quality indicators for intensive care was defined based on literature research and expert opinion. A balanced set with structure, process and outcome indicators was developed. The following structure indicators were selected: availability of intensivist (hours per day), patient-to-nurse ratio, strategy to prevent medication errors, measurement of patient/family satisfaction. Four process indicators were selected: length of ICU stay, duration of mechanical ventilation, proportion of days with all ICU beds occupied, and proportion of glucose measurement exceeding 8.0 mmol/L or lower than 2.2 mmol/L. The selected outcome indicators were as follows: standardized mortality (compared to the original APACHE II and IV reference population), incidence of pressure ulcers, and number of unplanned extubations. In this chapter, we also evaluated the feasibility of the registration of these indicators. This set of indicators is supposed to give a quick scan of the overall quality of ICU care. The availability of a computerized data collection system was reported as important for an acceptable workload and reliable registration.

In **chapter 3** we systematically reviewed the literature concerning implementation strategies for quality indicators and examined their effectiveness in improving the quality of care. We included a total of 21 studies. The majority of the included studies used audit and feedback as QI strategy and focused on care processes rather than patient outcomes. We conclude that effective strategies to implement quality indicators do exist, but there is considerable variation in the methods used and the level of change achieved. Feedback reports combined with another implementation strategy seemed to be most effective. In this review, identified barriers to implementation were lack of resources; no support from management; and lack of detailed and reliable data feedback.

In **chapter 4** we explored potential barriers to and facilitators of behaviour change that may affect the implementation of quality indicators in Dutch ICUs. The results of a validated questionnaire completed by 142 healthcare professionals working at 54 Dutch ICUs showed that healthcare professionals and managers are familiar with using quality indicators to improve care and that they have positive attitudes towards the implementation of quality indicators. Although there is a positive attitude, the study also confirmed that barriers exist and differ among type of profession, age group and setting. This is in line with previous results outside the ICU setting.

The most prominent barriers were lack of time and resources for the implementation of quality indicators. We conclude that the prospectively identified barriers have to be addressed before healthcare professionals and managers are willing to implement and use quality indicators in daily practice. Administrative support for intensivist, additional education for nurses, and effective feedback of indicator scores for managers may be effective strategies to reduce the identified barriers.

Chapter 5 describes in detail the development of multifaceted feedback intervention based on evidence from literature, input from future users, and expert knowledge, called InFoQI (Information Feedback on Quality Indicators). The InFoQI program included (1) monthly and quarterly feedback reports, (2) establishment of a local multidisciplinary QI team and (3) providing two educational outreach visits. The program aimed to promote the use of quality indicators as input for local systematic QI. This chapter also contains the study protocol for assessing the impact of the InFoQI program on patient outcome and organizational process measures of care, and to gain insight into barriers and success factors that affected the program's impact. The results are presented in chapter 6 and 7.

Chapter 6 and 7 present the findings of a randomized controlled trial in which 30 Dutch ICUs participated. ICUs were randomly assigned to receiving either the InFoQI program or standard feedback reports. In chapter 6 the endpoints were related to patient outcomes such as ICU length of stay, duration of mechanical ventilation, out-of-range glucose measurements, and all-cause hospital mortality. In chapter 7 the endpoints were related to organizational processes such as bed occupancy rate and nurse-to-patient-ratio. Our results showed that the InFoQI program did not improve ICU patient outcomes and organizational process indicators compared to sending standard feedback reports only. The intensity of the InFoQI activities differed markedly between the ICUs. However subgroup analyses, taking into account the different levels of activities in the ICUs, also showed no significant improvements in the indicators. Though we did not found any improvements in the indicators, the InFoQI program increased trust among healthcare professionals in data and improved the data collection process.

Chapter 8 explores the actual exposure to and experience with the InFoQI program aiming to contribute to a better understanding of the implementation process of a multifaceted indicator feedback intervention, and its impact on the quality of ICU care. Based on this process evaluation we conclude that the extent to which the InFoQI program was implemented in daily practice varied substantially between ICUs in the intervention arm. We used a questionnaire and focus group to collect data on perceived barriers and satisfaction. Most prominent barriers identified were not sharing feedback with other staff; lack of normative standards and benchmarks; inadequate case-mix adjustment; lack of knowledge on how to apply the intervention for QI; and insufficient allocated time and staff. We conclude that it is difficult to systematically develop an intervention and tailoring its content and format to potential identified barriers in the complex intensive care setting. Finally, the barriers identified in chapter 8 hampered the implementation of the intervention and this might explain why we did not observe any effect on the outcome measurements.

Finally, in **Chapter 9**, the main findings of this thesis were summarized and discussed. In addition, we described study limitations as well as the implications of our findings for daily practice and future research. The overall conclusion of the studies is that the use of quality indicators to improve the quality of care in intensive care medicine is much more complex than assumed at first glance. Even though a multifaceted intervention is tailored to potential barriers, improvement is not self evident. Especially, organizational constraints hampered the implementation process as well as the way feedback of indicators is provided. To successfully implement indicators, it is crucial to have time, staff and a registration available as well as sharing findings with staff. Additionally, to further facilitate translation of the feedback of indicators into effective actions, adequate case-mix adjustments, meaningful benchmarks and additional tools are required to successfully change healthcare practice. Future research aimed at implementing indicators in daily practice should focus on how to address the identified barriers in this study. In addition, a subsequent QI strategy should be designed and its effectiveness on the quality of healthcare should be tested.

Samenvatting (Summary in Dutch)

Kwaliteit en veiligheid worden steeds belangrijker in de gezondheidszorg. Om de kwaliteit van de gezondheidszorg te meten worden bij voorkeur structuur-, proces- en uitkomstindicatoren van zorg gebruikt. Op dit moment zijn er wereldwijd veel indicatoren ontwikkeld om de kwaliteit van de ziekenhuiszorg te meten. Het blijft echter onduidelijk of de kwaliteit van zorg effectief verbeterd kan worden door het gebruik van kwaliteitsindicatoren. Slechts enkele gerandomiseerde, gecontroleerde studies hebben laten zien dat het gebruik van indicatoren de kwaliteit van de ziekenhuiszorg aanzienlijk verbetert. Andere studies zijn er niet in geslaagd om een effect aan te tonen. Dit kan gerelateerd worden aan de problemen rondom de implementatie ervan, zoals het creëren van een gevoel van urgentie om de indicatoren te gebruiken voor systematische kwaliteitsverbetering, het ontbreken van een betrouwbare en valide registratie, de wijze van feedback geven en het gebruik maken van de geanalyseerde data. Op dit moment is er geen duidelijk bewijs hoe indicatoren het best geïmplementeerd kunnen worden om daarmee kwaliteitsverbetering te optimaliseren. Vaak is het aanbieden van data feedback een onderdeel van een implementatiestrategie die geleverd wordt door medische kwaliteitsregistraties. De Nederlandse Intensive Care Evaluatie (NICE) verzamelt en rapporteert systematisch en continue gegevens over de kwaliteit van zorg, geleverd door Nederlandse intensive cares (IC's). Echter, de impact van deze feedback is nog niet onderzocht. De studies in dit proefschrift hebben betrekking op verschillende aspecten van het gebruik van kwaliteitsindicatoren in de IC.

Het voornaamste doel van dit proefschrift is om het gebruik van indicatoren in de intensive care te onderzoeken. Het proefschrift richt zich op de ontwikkeling van indicatoren en de implementatie en het gebruik ervan in continue kwaliteitsverbeteringsprogramma's. Het eerste deel van dit proefschrift bestaat uit de ontwikkeling van een set indicatoren voor de IC en de ontwikkeling van een nieuwe, multicomponenten feedbackstrategie, gebaseerd op indicatoren. Het tweede deel van dit proefschrift richt zich op de implementatie van de feedbackstrategie en het effect ervan op de kwaliteit van IC zorg.

De volgende specifieke onderzoeksdoelen werden geformuleerd:

1. Het identificeren van een set kwaliteitsindicatoren die de kwaliteit van de IC zorg meet en die bestaat uit structuur-, proces- en uitkomstindicatoren.
2. Het vaststellen en ontwikkelen van een interventie die zorgprofessionals ondersteunt bij het effectief gebruiken van kwaliteitsindicatoren met een speciale focus op feedback in de intensive care.
3. Het evalueren van de effectiviteit van de ontwikkelde feedbackinterventie (zoals boven beschreven, doel 2) op de kwaliteit van IC zorg.

4. Inzicht verkrijgen in de barrières and succesfactoren die het effect van de interventie hebben beïnvloed.

In **hoofdstuk 2** werd een set kwaliteitsindicatoren, bestaande uit structuur, proces- en uitkomstindicatoren voor de intensive care gedefinieerd op basis van literatuuronderzoek en kennis van experts. De volgende structuurindicatoren zijn geselecteerd: beschikbaarheid intensivist, verpleegkundige- patiëntratio, beleid om medicatiefouten te voorkomen en het registreren van patiënt-/familietevredenheid. Vier procesindicatoren zijn geselecteerd: verblijfsduur op IC, beademingsduur, aantal kalenderdagen dat op enig moment alle IC bedden bezet waren en glucoseregulatie met metingen groter dan 8,0 mmol/L of lager dan 2,2 mmol/L. De geselecteerde uitkomstindicatoren waren: gestandaardiseerde sterfte (ten opzichte van de oorspronkelijke APACHE II en IV referentiepopulatie), decubitusincidentie en het aantal ongeplande extubaties. In dit hoofdstuk hebben we tevens de haalbaarheid van de registratie van deze indicatoren geëvalueerd. Deze set indicatoren dient een globaal beeld te geven van de algehele kwaliteit van IC zorg. De beschikbaarheid van een geautomatiseerd registratiesysteem bleek belangrijk voor een aanvaardbare werkdruk en betrouwbare registratie.

In **hoofdstuk 3** hebben we een systematische literatuurstudie uitgevoerd naar mogelijke strategieën om kwaliteitsindicatoren te implementeren en de effecten ervan op de kwaliteit van zorg. Uiteindelijk zijn 20 studies geïncludeerd. Een meerderheid van deze studies gebruikte audits en feedback als implementatiestrategie en richtte zich op zorgprocessen in plaats van patiëntuitkomsten. We concludeerden dat effectieve strategieën om kwaliteitsindicatoren te implementeren bestaan, maar dat er een aanzienlijke variatie zit in de methoden die gebruikt worden en de kwaliteitsverbetering die bereikt wordt. Het meest effectief bleken feedbackrapporten gecombineerd met een andere implementatiestrategie. De belangrijkste barrières voor de implementatie van indicatoren in deze literatuurstudie waren een gebrek aan middelen, het ontbreken van steun vanuit het management en een gebrek aan gedetailleerde en betrouwbare data feedback.

In **hoofdstuk 4** onderzochten we mogelijke barrières en succesfactoren voor gedragsverandering die de implementatie van kwaliteitsindicatoren in Nederlandse IC's kunnen beïnvloeden. De resultaten van een gevalideerde vragenlijst, ingevuld door 142 zorgprofessionals werkzaam in 54 Nederlandse IC's, toonden aan dat zorgprofessionals en managers vertrouwd zijn met het gebruik van kwaliteitsindicatoren om de zorg te verbeteren en dat ze een positieve houding hebben ten opzichte van de implementatie ervan. Hoewel er een positieve houding was, bevestigde deze studie dat er barrières zijn. Deze barrières verschillen tussen beroepsgroepen, leeftijd en setting. De bevindingen zijn in overeenstemming met eerdere resultaten buiten de IC setting. De meest prominente barrières waren een gebrek aan tijd en middelen voor de implementatie van kwaliteitsindicatoren. We concludeerden dat de prospectief waargenomen barrières moeten worden weggenomen voordat zorgprofessionals en managers bereid zijn om indicatoren te implementeren en te gebruiken in de dagelijkse praktijk. Effectieve strategieën om de waargenomen barrières te verminderen, waren administratieve ondersteuning voor intensivisten, extra onderwijs voor verpleegkundigen en effectieve feedback voor managers.

Hoofdstuk 5 beschrijft in detail de ontwikkeling van een multicompenenten feedbackstrategie op basis van informatie uit wetenschappelijke publicaties, de input van toekomstige gebruikers, en kennis van experts, genaamd InFoQI (Informatie Feedback op Quality Indicators). Het InFoQI programma bestond uit (1) maand-en kwartaalrapportages, (2) het opzetten van een lokaal multidisciplinair kwaliteitsverbeterteam en (3) het instrueren en begeleiden van ICs door middel van bezoeken aan de IC's. Het doel van het programma was om het gebruik van kwaliteitsindicatoren als input voor lokale systematische kwaliteitsverbetering te bevorderen. Dit hoofdstuk bevat ook een studieprotocol voor de evaluatie van de effectiviteit van het InFoQI programma op patiëntuitkomsten en organisatorische zorgprocessen en het verkrijgen van inzicht in de barrières en succesfactoren die de impact van het programma hebben beïnvloed. De resultaten hiervan zijn uiteengezet in hoofdstuk 6 en 7.

Hoofdstuk 6 en 7 presenteren de resultaten van een gerandomiseerde gecontroleerde trial waarin 30 Nederlandse IC's hebben deelgenomen. Het InFoQI programma of de standaard feedbackrapporten werden willekeurig aan de IC's toegewezen. In hoofdstuk 6 zijn de primaire indicatoren gerelateerd aan patiëntuitkomsten zoals verblijfsduur, beademingsduur, glucoseregulatie, en ziekenhuissterfte. In hoofdstuk 7 zijn de indicatoren gerelateerd aan organisatorische zorgprocessen zoals de bezettingsgraad en het verpleegkundige-patiënt ratio. Onze resultaten toonden aan dat het InFoQI programma geen verbeteringen liet zien in de patiëntuitkomsten en organisatorisch zorgprocessen in vergelijking met het verzenden van standaard feedbackrapporten alleen. De mate waarin de InFoQI activiteiten waren geïmplementeerd, varieerde sterk tussen de IC's. Echter subgroepanalyses, die rekening hielden met deze variatie in de IC's, toonden geen significante verbeteringen in de indicatoren. Desondanks heeft het InFoQI programma ervoor gezorgd dat zorgprofessionals meer vertrouwen hebben gekregen in de data(verzameling).

Om een beter beeld te krijgen van het implementatieproces van een multicomponenten feedbackstrategie en de impact ervan op de kwaliteit van de IC zorg, onderzochten we in **hoofdstuk 8** de mate van implementatie en ervaring met het InFoQI programma. Op basis van deze procesevaluatie concludeerden we dat de mate waarin de InFoQI programma is geïmplementeerd aanzienlijk varieerde tussen de IC's in de interventiegroep. Data met betrekking tot de barrières en de tevredenheid werden verzameld door middel van een vragenlijst en een focusgroepstudie. De meest prominente barrières waren: het niet delen van de feedback met andere stafleden; gebrek aan normen en benchmarks; ontoereikende casemix correctie; gebrek aan kennis over hoe kwaliteitsverbetering te bewerkstelligen; en onvoldoende gereserveerde tijd en mankracht. We concludeerden dat het ontwikkelen van een op maat gemaakte, barrièregestuurde interventie in de complexe intensive care setting lastig is. Tot slot, de beschreven barrières in hoofdstuk 8 lijken de implementatie van de interventie belemmerd te hebben en dat zou kunnen verklaren waarom we geen effect hebben gevonden op de gekozen indicatoren.

Tenslotte worden in **hoofdstuk 9** de belangrijkste bevindingen van dit proefschrift samengevat en bediscussieerd. Daarnaast hebben we de beperkingen van het onderzoek beschreven, gevolgd door gevolgen van onze bevindingen voor de praktijk en toekomstig onderzoek. De algemene conclusie van het proefschrift is dat het gebruik van kwaliteitsindicatoren om de kwaliteit van IC zorg te verbeteren, veel complexer is dan op het eerste gezicht werd verondersteld. Ook als een multicomponenten interventie afgestemd is op potentiële barrières, is kwaliteitsverbetering niet vanzelfsprekend. Vooral organisatorische barrières en de wijze waarop feedback van indicatoren werd verstrekt, belemmerden het implementatieproces. Om indicatoren succesvol te implementeren, is het belangrijk om tijd, mankracht en een registratie ter beschikking te hebben en om feedback met stafleden te delen. Om veranderingen in de praktijk te bewerkstelligen zijn toereikende casemix correcties, zinvolle benchmarks en extra tools nodig zodat feedback van de indicatoren in effectieve acties vertaald kan worden.

Toekomstig onderzoek dat indicatoren wil implementeren in de dagelijkse praktijk moet zich richten op de vraag hoe de waargenomen barrières uit deze studie kunnen worden weggenomen. Vervolgens zal er nieuwe implementatiestrategie ontwikkeld moeten worden en de effectiviteit ervan op de kwaliteit van zorg moet geëvalueerd worden.

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Curriculum Vitae

Maartje de Vos graduated from secondary school at the Van Maerlantlyceum in Eindhoven in 1997. She studied Tourism and Leisure at Breda University of Applied Science from 1997 until 2001. After her graduation, she studied Organization Studies at Tilburg University.

After obtaining her master degree, she began working in 2004 at the National Institute for Public Health and the Environment (RIVM) in Bilthoven. Here, she participated in several projects from the Dutch Inspectorate (IGZ) related to the development and implementation of quality indicators in healthcare.

In March 2007, Maartje started her PhD trajectory at the department of Tranzo at Tilburg University. The project was financially supported by Strategic Research RIVM. The project focused on the development and implementation of indicators as a tool for quality improvement. The results are presented in this thesis.

From august 2010 onwards, Maartje has been working as a project officer at the department of Quality and Safety at the Amphia hospital in Breda. Here, she works on various projects related to patient safety such as culture measurements, incident reporting and the use of performance indicators.

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