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Complete List of Authors:	strauch, ulrich; Maastricht University Medical Centre, Intensive Care Medicine Bergmans, Dennis; Masstricht University Medical Centre, Intensive Care Medicine Habers, Joachim; Emergency Medical Service district of Aachen jansen, Jochen; Emergency Medical Service South Limburg Winkens, Bjorn; Maastricht University, Veldman, Dirk; Maastricht University, MEMIC Center for data and information management Roekaerts, Paul; Masstricht University Medical Centre, Intensive Care Medicine Beckers, Stefan; Emergency Medical Service, Fire Department, City of Aachen
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QUIT EMR trial:

a protocol for a prospective, observational, multicentre study to evaluate quality and 24 hours post transport morbidity of interhospital critical care transportation

Ulrich Strauch*, Dennis CJJ Bergmans*, Joachim Habers, Jochen Jansen***, Bjorn Winkens ****, Dirk J Veldman #, Paul MHJ Roekaerts*, Stefan K Beckers##**

Ulrich Strauch *Corresponding author*
Maastricht University Medical Centre+, Department of Intensive Care *
P. Debyelaan 25 PO Box 5800, 6202 AZ Maastricht (The Netherlands)
Fone: 0031433876385 E mail: u.strauch@mumc.nl

Dennis CJJ Bergmans Maastricht University Medical Centre+, Department of Intensive Care *
P. Debyelaan 25 PO Box 5800,6202 AZ Maastricht (The Netherlands)
E mail: d.bergmans@mumc.nl

Joachim Habers Emergency Medical Service district of Aachen**
Zollernstrasse 20, 52070 Aachen (Germany)
E mail : aelrd_staedteregion-aachen@web.de

Jochen Jansen Emergency Medical Service South Limburg***
Geleenbeeklaan 2, 6166 GR Geleen (The Netherlands)
E Mail: j.jansen@ggdzl.nl

Bjorn Winkens Maastricht University, Department of Methodology and Statistics****
CAPHRI School for Public Health and Primary Care
PO Box 616, 6200 Maastricht, The Netherlands
E Mail: bjorn.winkens@maastrichtuniversity.nl

Dirk JVeldman Maastricht University, MEMIC Center for data and information management #
P. Debyeplein 1, Postbus 616, 6200 MD Maastricht, The Netherlands
E Mail: d.veldman@maastrichtuniversity.nl

Paul MHJ Roekaerts Maastricht University Medical Centre+, Department of Intensive Care *
P. Debyelaan 25 PO Box 5800,6202 AZ Maastricht (The Netherlands)
E mail: p.roekaerts@mumc.nl

Stefan Beckers Emergency Medical Service, Fire Department, City of Aachen##
Stolberger Str. 155, 52068 Aachen (Germany)
and Department of Anaesthesiology, University Hospital RWTH Aachen,
Pauwelsst. 30, 52074 Aachen (Germany) ##
E Mail: aelr@mail.aachen.de

Abstract

Introduction

Transport (intra- and interhospital) of critically ill patients is known to be a high risk procedure. Evidence based criteria to determine the quality of a transport system and the impact of transport on the patient's outcome are missing, instead proxy parameters as adverse event rate or short term mortality are used. Therefore two scoring systems, one to monitor quality of a transport system (Quality of interhospital critical care transportation in the Euregion Meuse-Rhine: QUIT EMR Score) and the other to detect changes in patient's clinical condition 24 hours after transport (Simplified EMR outcome score: SEMROS) have been developed by the group of investigators. Both scores have been validated retrospectively, the EMR score by comparing experts' opinion with the results of the score and SEMROS by comparing the results of the score with changes in the Sequential Organ Failure Score (SOFA score) from the day of transport and 24 hours after transport. The primary objective of this study is to validate the QUIT EMR Score in a prospective, observational study. Whereas secondary objectives are to analyse if negative transport outcome influences 24 hour post transport morbidity/mortality by using SEMROS and to detect predictive outcome parameters for 24 hours post transport mortality.

Methods and Analysis

About 150 pre, intra and post transport items of adult patients (age>18), undergoing an interhospital transport with indication for direct supervision of a physician with the departing hospital being located within the study region will be documented in a web based application.

To validate the EMR score 3 pre-defined levels of transport facilities (high/medium/low standard) will be compared using the QUIT EMR score, with the high standard system being defined as the golden standard. Subsequently the effect of transport quality on 24 hours post transport morbidity will be measured by using SEMROS:

The expected number of transports in the study region is about 3000/ year, with an expected registration rate of 50% and the inclusion takes place from April 1st 2015 until December 31st 2017.

Ethics and Dissemination

The Trial was approved by the Ethics committees of the university hospitals Maastricht (NL) and Aachen (Germany) and results of the study will be published. Depending on the results a prospective randomised trial will be conducted with defined patient categories being randomised to different levels of transport systems.

Trial Registration: NTR4937

Keywords

Interhospital Transport, Mobile Intensive Care, Critical Care Transportation, Quality of critical care transportation

Strengths and limitations of the study

- Using a web based, uniform way of registration of interhospital transports of critically ill patients with a substantial variety in terms of transport systems, severity of illness and urgency we will create an unique database with at least the opportunity to introduce two new developed scoring systems into research and clinical practice
- A clinically relevant quality monitoring score will be validated in a prospective, international multicentre trial setting
- The effect of transport quality on 24 hours post transport morbidity will be measured using a new developed and validated score
- Registrations of transport data is voluntary and will be performed by transport teams, therefore bias in the registration of transports cannot be ruled out

Introduction

Transport of critically ill patients is known to be a high-risk procedure with a significant rate of adverse events [1]. Especially during interhospital transportation, the patient's safety is often compromised due to the absence of highly qualified staff and the lack of sophisticated resuscitation equipment [2-10]. Regarding important changes in ageing of the European population, the rising number of highly complex treatment strategies and a clear trend towards centralization of health care providers, there will be a growing need for well structured, high quality interhospital transport facilities [11-14].

This is true for both principal categories of interhospital critical care transportation, known as

1) Urgent transport with need for immediate transfer of the patient towards an expertise center for a potentially lifesaving intervention
2) Scheduled transports with the opportunity to transport all kinds of ICU patients including those with additional medical devices as Extra Corporeal Membrane Oxygenation (ECMO), Intraaortic balloon counter pulsation (IABP) or Nitric Oxide (NO) ventilation.

Both categories are resource intense and therefore interhospital critical care transport is an important financial burden within public health and it is difficult for a single organization to provide a sufficient 24/7 coverage of both transport functions. Regarding this and based on a grown successful history of cross border support in emergency and disaster management in the Euregion Meuse Rhine (EMR) a dutch/german project group investigated the opportunities for cross border collaboration in interhospital transport of critically ill patients. Despite relevant differences [15-17] in the organizational structure of interhospital transport within the two countries the project group realized at an early stage that there is a lack of established parameters to monitor quality [18-27] of the different transport facilities. Since valid data are fundamental to design an effective, safe and reliable cross border collaboration, the project group designed this study. Considering that the transport of a critically ill patient is not a medical intervention with the intention to improve the patient's situation, the investigators are interested in detecting patients where transport leads to deterioration of the health status and furthermore aim to detect transports with inadequate management of the transport team. Well established Intensive Care scores, as the SOFA score, to monitor changes in the patient´s condition usually need laboratory values which will not be available in the context of an urgent interhospital transport.

The group of investigators worked out a monitoring tool which consists of:

- Number and severity of adverse events (AE)
- Quality of interhospital critical care transportation in the Euregion Meuse-Rhine (QUIT EMR Score) which is a dichotomized score with 1 indicating that there was no necessity for a transport team intervention or that there have been adequate interventions being performed and 0 indicating that there were inadequate interventions or no interventions despite physiologic parameter being beyond predefined thresholds
- Short term mortality and morbidity measured by the Simplified EMR Outcome Score (SEMROS) which is a dichotomized score with 1 indicating that the patient's status remained unchanged or improved within 24 hours after transport and 0 indicating that the patient's condition deteriorated within 24 hours after transport

The acceptable AE rate is based on literature defined as 5-10%.

Both scores have been validated retrospectively in a small number of cases.

Concerning the QUIT EMR score, 100 transport charts of the Mobile Intensive Care Unit (MICU) from Maastricht University Medical Center+ (MUMC+) have been used to calculate the QUIT EMR score .All calculation have been done by the coordinating investigator. Then four experts (all anaesthesiologists experienced in interhospital transport from Maastricht University Medical Center+ revised the transport charts, with none of them being informed about the QUIT EMR score in detail.

The following criteria were used by the experts to score a transport with 1 (positive judgement) or 0 (negative judgement):

- Stable situation during transport without intervention 1
- Stable situation with adequate intervention 1
- Unstable situation with adequate intervention 1
- Unstable situation or important physiologic parameters beyond threshold without adequate intervention or with inadequate intervention 0

Experts were free to define stable versus unstable situation, adequate versus inadequate intervention and to define thresholds for physiologic parameters.
Finally, the results of the QUIT EMR score and those of the 4 experts have been compared, with a level of agreement of 84%-92% (Table 1). The inter-observer level of agreement reached85.0% to 92.9% (Table 2).

Level of agreement Experts/QUIT EMR score	**%**
Expert 2	84.0
Expert 3	88.0
Expert 4	92.0
Expert 5	86.7
Range	**84-92%**

Table 1: Level of agreement expert opinion and QUIT EMR score

Expert versus expert	**Expert A**	**Expert B**	**Expert C**	**Expert D**	**range**
Expert A		86.0	85.0	85.7	**85%-86%**
Expert B	86.0		91.0	92.9	**86%-92.9**
Expert C	85.0	91.0		92.9	**85%-92.9%**
Expert D	85.7	92.9	92.9		**85.7-92.9%**
all					**85%-92.9%**

Table 2: Interobserver Level of agreement

Regarding the SEMROS, a total of 110 transports (from the MICU Maastricht) have been revised by the coordinating investigator. Here 90 complete datasets were available to calculate pre- and post-transport Sequential Organ failure score (SOFA score) [28] and the SEMROS

In these 90 cases, the observed level of agreement of score and SEMROS was 88,9% with the following definitions being used with regards to changes in the SOFA score:

1 (positive outcome) or 0 (negative outcome)

- SOFA score pre transport < SOFA score post transport 0
- SOFA score pre transport = SOFA score post transport 1
- SOFA score pre transport > SOFA score post transport 1

Specially designed algorithms for an automatic calculation of these two scores will be implemented in the study web application.

Objectives

Primary Objective:

To validate the QUIT EMR score in a prospective multicentre study by comparing three defined levels of transport systems.

Hypothesis:

Transports with high standard ground transport systems compared with medium and/or low standard ground transport systems (Table 3) will show for specific subgroups significant differences and for the whole population at least trends in

- *The developed QUIT EMR score and/or*
- *Number and severity of adverse events*

	Minimum requirements ambulance/equipment	***Minimum requirements teammember 1***	***Minimum requirements teammember 2***
System A (high)	*MICU/ITW*[1]	*Intensivist*[2]	*ICU nurse* *IC Paramedic*[3]
System B (medium)	*IC ambulance*[4]	*ICU Physician*[5]	*Paramedic*
System C (low)	*Standard Ambulance*	*Physician*	*Paramedic*

Table 3: Definitions of different levels of ground transport systems

1) *High volume ambulance with boarding ramp, standard ambulance equipment and ICU equipment including ICU ventilator, minimum of 6 infusion pumps, invasive monitoring, ability to reach the patient from all sides, ability to transport patients with additional medical devices as ECMO, NO, IABP, back-up systems for ventilator/monitoring/defibrillation unit/ suction unit, minimum of 6,000 l Oxygen, if the ventilator is dependent on pressured air also 6,000 l of pressured air in the ambulance, stand-alone capacity 120 min,*
2) *Board certified Intensivist*
3) *Paramedic with Intensive Care qualification in addition*
4) *Standard ambulance with standard ambulance equipment and IC transport ventilator, minimum of 4 infusion pumps, invasive monitoring, 2,000 l of oxygen in the ambulance, stand-alone capacity of 60 min*
5) *FCCS or FCCS like trained physician with at least 6 months Intensive Care experience*

Secondary Objectives:

a) To analyse if transport outcome (measured by QUIT EMR score) influences 24-hour post transport morbidity (measured by SEMROS).

Hypothesis:

Negative transport outcome leads to a higher 24-hour post transport morbidity.

b) To detect characteristics that define the patient's needs in terms of level of transportation facility.

Hypothesis:

Pre transport data that indicate a benefit of using a high standard transport system can be detected and defined.

c) To detect predictive outcome parameters concerning 24-hour post transport mortality

Hypothesis:

Pre transport data that indicate 24-hour post transport mortality will be detected and defined.

Methods/Design

Design

"Quality and efficacy of interhospital critical care transportation in the Euregion Meuse-Rhine" is an international, prospective, observational, multicentre cohort study. No intervention will be performed, only completely anonymised data will be analysed. The study will be open for inclusion from April 1st 2015 until December 31st 2017.

Population/ inclusion criteria

Adult patients (18 years or older) undergoing an interhospital transport with indication for a physician supervised transport within the study region (MICU region Maastricht (NL), district of Aachen (D), City of Aachen (D), district of Heinsberg (D)).

The actual registration of these transports suggest up to 3000 interhospital transports per year under direct supervision of a physician within the study region.

Study parameters

About 150 pre, intra and post transport items will be scored. The main sections of registration are divided into

a) Demographics (patient related, equipment/ambulance/team related)

b) Patient status obtained during the intake call

c) Patient status at arrival of transport team

d) Patient status at the end of the transport

e) Interventions performed by the transport team

f) Adverse events

g) 24-hours follow up

Data Registration

Web application

A web application has been developed to facilitate data registration. The initial registration will be performed by level 1 users (medical staff present during transport), whereas follow-up data will be obtained by level 2 users. All changes applied to case data will be registered in an audit layer in the database together with details of the user who made the alterations.

Level 1 users

A standardized dataset of patients demographics, aspects of the transport system (vehicle, equipment, team qualification), the status of the patients at the moment of the intake call, at the moment of arrival of the transport team at the patient and at the end of transport, interventions performed by the transport team, and adverse events will be documented in a web based database (part 1-4) by the transport team (responsible physician, level 1 user"). The database (URL: www.eumic.eu) will be accessible through general username/password combinations. Each participating hospital will receive one unique username/password combination. Alternatively, access will be possible using a global username/password combination for each ambulance, based on the cap codes of the vehicles.
After having finalized the case, the level 1 user gets the opportunity to receive a PDF file of the documented items. Furthermore, there will be a feedback link to send an e-mail comment directly to the coordinating investigator or to the technical support staff of Maastricht University.
There will be no registration of personal data such as name or date of birth to ensure patient privacy. The unique transport code given by the responsible dispatch centre will be noted.
Level 1 users will only be able to fill in a transport sheet, there will be no further grants given to level 1 users to look at or change other patient charts.

Level 2 users

Twenty-four hours after transport status information of the patient will be obtained by contacting the ICU in the accepting hospital.
To this end, a group of level 2 users will get access to the database via a personalised username/password combination. This group will be authorised to complete data sets and to visually inspect not yet finalized transportations in the region the level 2 user is authorised for. Level 2 users are not authorised to change items scored by level 1 users.
The workflow for level 2 users will be as follows:

a) Daily log-in to the database
b) Level 2 users will get an overview of transports being finalized by level 1 users in the region the level 2 user is authorised for
c) The Level 2 user will obtain the transport code and alarm time from the patient chart
d) Consequently, the responsible dispatch centre will be contacted to get patients identification (name, date of birth).
e) The Level 2 user will contact the ICU of the accepting hospital to get the standardised information about patient's status 24 hours after transport, this data will be documented in part 6 of the database

f) After finishing the registration, the level 2 user will finalize the case, after which the level 2 user will no longer be able to view the case.

Level 3 users

There will be at least weekly check-ups of data reliability by level 3 users . These are the regional study coordinators, who are granted access to the application given a personalised username/password combination. All log in events will be documented and stored.
All data sheets must be authorised by a level 3 user before entering the final database.
If a case will not be authorised for entering the database, it will be stored in a separate database for unauthorized cases.
The level 3 users will get an overview of new cases divided in complete and incomplete cases. All incomplete cases will be opened and revised by the level 3 user who is authorised to add missing information or to overwrite incorrect data. If the registered data have missing values which do not allow calculation of at least the QUIT EMR score, the dataset will not be admitted to the final database.
Furthermore, this small group of users will be authorised to view all open cases, and those that are stored in the databases.
After approving a case for the final database, case identification data will be deleted to ensure that the data in the central database are completely anonymous.

Technical controlling

Next to the medical administrator group there will be continuous technical controlling and data safety monitoring done by a technical administrator group from Maastricht University. This group will work independently from the medical coordinators.
Access to the database will only be possible after authorization by the coordinating investigator and the technical control staff.

Statistical Analysis

Baseline characteristics will be presented by mean (SD), or median (interquartile range, IQR) where appropriate, for numerical variables, and by number (%) for categorical variables. All analyses will be performed using IBM SPSS Statistics for Windows. A p-value ≤ 0.05 will be considered statistically significant.
The difference in changes in QUIT EMR score and SEMROS, and the number of interventions between high and medium/low standard ground transport systems will be assessed using independent samples t-test or Mann-Whitney U-test where appropriate. The difference in proportion of adverse events between the two transport systems will be tested using Chi-square or Fisher's exact test. To account for potential confounders, linear and logistic regression analysis will be performed for numerical and binary outcomes, respectively, where group (high versus medium/low standard ground transport system) and all baseline variables known to be related to the outcome are included in the model.
Logistic regression analysis will be performed to determine which pre transport variable is an independent risk factor for 24 hours post transport mortality.
In case the data set suits data mining to identify important variables, this will also be performed.

Ethical considerations

The study will be conducted according to the principles of the Declaration of Helsinki amended by the WMA General Assembly in October 2013.

Only anonymous data of adult patients undergoing interhospital transport with indication for supervision of a physician will be used for analysis. No interventions will be performed.

Therefore, the MREC's of the university hospitals Maastricht (NL) and Aachen (Germany) indicated that there is no need for obtaining patient's informed consent.

The study is registered in the Netherlands National Trial Registration: NTR4937

Discussion

The interhospital transport of critically ill patients is a medical intervention with well described risks for this special group of patients, highly dependent on ventilatory and or hemodynamic support. In the ongoing discussion of centralization of health care facilities, a reliable, efficient and proven safe transport modality which meets the individual patient needs is in the author's opinion a key factor for success in all future developments in this direction.

Actually the logistic and financial burden of 24/7 coverage on transportation facilities remains high. Therefore close cooperation within a regional network is necessary. Such a network might include, as in the Euregion Meuse Rhine, a cross border collaboration where a standardized quality monitoring is from utmost importance.

With this study a quality monitoring score will be validated and might then be used for further research or might be applied into clinical practice. Beside the quality monitoring, the group of investigators is interested in clinical relevant effects of interhospital transportation on patients' morbidity 24 hours after transport. Therefore we introduce a clinical, laboratory value independent score.

Finally, there is a need for efficient resource utilisation, therefore a reliable pre-transport analysis of the needs of the individual patient in terms of transport facility is warranted

Having a validated quality monitoring, linked to 24 hours post transport outcome, a prospective trial randomising predefined patient categories to different transport facilities to proof safety of the different transport systems can be conducted.

So, the authors believe that the current study is a first important step towards an evidence based organisation of interhospital transport of the critically ill patients

List of abbreviations

AE	Adverse event
ECMO	Extracorporeal membrane oxygenation
EMS	Emergency Medical Service
EUMIC	Euregional Mobile Intensive Care
FCCS	Fundamental Critical Care Support
IABP	Intra aortic ballon pump
ICU	Intensive Care Unit
MREC	Medical research ethics committee
MICU	Mobile Intensive Care Unit
MUMC+	Maastricht University Medical Centre +
NO	Nitric Oxide
SEMROS	Simplified Euregion Meuse Rhine Outcome Score
SD	Standard deviation
SOFA	Sequential Organ Failure Assessment
QUIT EMR	Quality and efficacy of interhospitall critical care transport in the Euregion Meuse-Rhine

Competing interests

The authors declare that they have no competing interests.

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Authors' contribution

US	is coordinating investigator, has been involved in the planning and drafted the manuscript
DB	has been involved in planning the study design and revised the manuscript
JH	has been involved in planning the study design and revised the manuscript
JJ	has been involved in planning the study design and revised the manuscript
BW	has been involved in planning the study design and revised the manuscript
DV	has been involved in planning the study design, is responsible for the web application and revised the manuscript
PR	has been involved in planning the study design and revised the manuscript
SB	has been involved in planning the study design, revised the manuscript and has given final approval

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Ulrich Strauch *Corresponding author*
Maastricht University Medical Centre+, Department of Intensive Care *
P. Debyelaan 25 PO Box 5800, 6202 AZ Maastricht (The Netherlands)
Fone: 0031433876385 E mail: u.strauch@mumc.nl

Dennis CJJ Bergmans Maastricht University Medical Centre+, Department of Intensive Care *
P. Debyelaan 25 PO Box 5800,6202 AZ Maastricht (The Netherlands)
E mail: d.bergmans@mumc.nl

Joachim Habers Emergency Medical Service district of Aachen**
Zollernstrasse 20, 52070 Aachen (Germany)
E mail : aelrd_staedteregion-aachen@web.de

Jochen Jansen Emergency Medical Service South Limburg***
Geleenbeeklaan 2, 6166 GR Geleen (The Netherlands)
E Mail: j.jansen@ggdzl.nl

Bjorn Winkens Maastricht University, Department of Methodology and Statistics****
CAPHRI School for Public Health and Primary Care
PO Box 616, 6200 Maastricht, The Netherlands
E Mail: bjorn.winkens@maastrichtuniversity.nl

Dirk JVeldman Maastricht University, MEMIC Center for data and information management #
P. Debyeplein 1, Postbus 616, 6200 MD Maastricht, The Netherlands
E Mail: d.veldman@maastrichtuniversity.nl

Paul MHJ Roekaerts Maastricht University Medical Centre+, Department of Intensive Care *
P. Debyelaan 25 PO Box 5800,6202 AZ Maastricht (The Netherlands)
E mail: p.roekaerts@mumc.nl

Stefan Beckers Emergency Medical Service, Fire Department, City of Aachen##
Stolberger Str. 155, 52068 Aachen (Germany)
and Department of Anaesthesiology, University Hospital RWTH Aachen,
Pauwelsst. 30, 52074 Aachen (Germany) ##
E Mail: aelr@mail.aachen.de

Abstract

Introduction

Transportation (intra- and interhospital) of critically ill patients is known to be a high risk procedure. Evidence based criteria to determine the quality of a transport system and the impact of transport on the patient's outcome are missing. Two scoring systems, one to monitor quality of a transport system (Quality of interhospital critical care transportation in the Euregion Meuse-Rhine: QUIT EMR Score) and the other to detect changes in patient's clinical condition 24 hours after transport (Simplified EMR outcome score: SEMROS) have been developed and validated retrospectively. The primary objective of this study is to validate the QUIT EMR Score in a prospective, observational study. Whereas secondary objectives are to analyse if negative transport outcome influences 24 hour post transport morbidity/mortality by using SEMROS and to detect predictive outcome parameters for 24 hours post transport mortality.

Methods and Analysis

About 150 pre, intra and post transport items of adult patients (age>18), undergoing an interhospital transport indicated to be supervised by a physician, with the departing hospital being located within the study region will be documented in a web based application.

To validate the QUIT EMR score 3 pre-defined levels of transport facilities (high/medium/low standard) will be compared using the QUIT EMR score.. Subsequently the effect of transport quality on 24 hours post transport morbidity will be measured using SEMROS.

The expected number of transports in the study region is about 3000/year. The study is open for inclusion from April 1st 2015 until December 31st 2017

Ethics and Dissemination

The trial was approved by the Ethics committees of the university hospitals Maastricht (NL) and Aachen (Germany) and results of the study will be published. Depending on the results a prospective randomised trial will be conducted with defined patient categories being randomised to different levels of transport systems.

Trial Registration: NTR4937

Keywords

Interhospital Transport, Mobile Intensive Care, Critical Care Transportation, Quality of critical care transportation

Strengths and limitations of the study

- Using a web based, uniform way of registration of interhospital transports of critically ill patients we will create an unique database that will enable us to introduce two new developed scoring systems into research and clinical practice
- A clinically relevant quality monitoring score will be validated in a prospective, international, multicentre trial setting
- The effect of transport quality on 24 hours post transport morbidity will be measured using a new developed and validated score
- Registrations of transport data is voluntary and will be performed by transport teams, bias in the registration of transports cannot be ruled out
- Follow up data might not be available for all transports, which can lead to extra registration bias

Introduction

Transportation of critically ill patients is known to be a high-risk procedure with a significant rate of adverse events [1]. Especially during interhospital transportation, the patient's safety can be compromised due to the absence of highly qualified staff and the lack of sophisticated resuscitation equipment [2-10]. Focusing on interhospital transportation there are two categories of patients with different needs in terms of transport facilities. On the one hand there are patients in need or an urgent lifesaving intervention in an expertise center, on the other hand there are patients with the need for continuous Intensive Care Unit (ICU) therapy including possible use of extracorporeal devices during transport. In the daily German and Dutch practice different types of ground ambulances are available for the transport of critically ill patients, known as:
standard ambulance, ICU ambulance, Mobile Intensive Care Unit / Intensivtransportwagen (MICU/ITW).
The transport teams usually consist of a paramedic and a physician, transports with a MICU/ITW are frequently accompanied by a physician and a nurse both trained and experienced in ICU therapy.
In general the responsible dispatch centre coordinates all transports, the decision about the most appropriate available transport system is based on urgency and severity of illness. Providing 24/7 facilities for interhospital transport is resource intense, though, the cooperation of different regions seems useful.
Within in the Euregion Meuse Rhine a cross border (Netherland, Germany) project group worked out a plan for cooperation with regard to emergency and MICU/ITW transportation. Facing substantial differences in organization and legislation of interhospital transport in the two countries the project group stated that there is a need for an uniform manner of measuring quality of transport systems. Currently, parameters as adverse event rate, short term mortality, changes in SOFA scores before and after transport are used to describe the quality of transport systems [11-19].
As it is difficult to determine whether a deterioration of the patient's condition during or immediately after transport is caused by transport related aspects or due to the natural course of the disease[15] the "Quality of interhospital critical care transportation in the Euregion Meuse-Rhine trial (QUIT EMR trial)"was initiated by the project group.
As a first step two scores were developed, one for the measurement of transport system quality and one to detect relevant changes in the patient's clinical condition 24 hours after transport:

- The QUIT EMR Score is a dichotomized score with 1 indicating that there was no necessity for a transport team intervention or that there adequate interventions were performed and 0 indicating that there were inadequate interventions or no interventions despite physiologic parameters beyond predefined thresholds. The score does not solely focus on changes in physiologic parameters, but combines these changes with documented interventions being performed by the transport team. The used data can be found in the additional file "web application" at part 2.2, part 2.3 and part 3.
- The Simplified EMR Outcome Score (SEMROS) is a dichotomized score with 1 indicating that the patient's status remained unchanged or improved within 24 hours after transport and 0

indicating that the patient's condition deteriorated within 24 hours after transport. The used data can be found in the additional file "web application" at part 2.1 and part 6.

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Concerning the QUIT EMR score, 100 transport charts of the Mobile Intensive Care Unit (MICU) from Maastricht University Medical Centre+ (MUMC+) have been used to calculate the QUIT EMR score. All calculations have been done by the coordinating investigator. Then four experts (anaesthesiologists and/or intensivists experienced in interhospital transport from MUMC+ revised the transport charts.

The following criteria were used by the experts to score a transport with 1 (positive judgement) or 0 (negative judgement):

- Stable situation during transport without intervention 1
- Stable situation with adequate intervention 1
- Unstable situation with adequate intervention 1
- Unstable situation or important physiologic parameters beyond threshold without adequate intervention or with inadequate intervention 0

Experts were free to define stable versus unstable situation, adequate versus inadequate intervention and to define thresholds for physiologic parameters.
Finally, the results of the QUIT EMR score and those of the 4 experts have been compared, with a level of agreement of 84%-92% and an inter-observer level of agreement of 85.0% to 92.9%

Regarding SEMROS, a total of 110 MICU transports towards MUMC+ have been revised by the coordinating investigator. Here 90 complete datasets were available to calculate pre- and post-transport Sequential Organ failure score (SOFA score) [20] and the SEMROS .
In these 90 cases, the observed level of agreement of the SOFA score and SEMROS was 88,9%. This was true for 2 different versions of the score, the first one including Bilirubin, lactate and pH and the second one without these laboratory parameters.
The following definitions have been used with regards to changes in the SOFA score:

1 (positive outcome) or 0 (negative outcome)

- SOFA score pre transport < SOFA score post transport 0
- SOFA score pre transport = SOFA score post transport 1
- SOFA score pre transport > SOFA score post transport 1

On this basis a web based application to register all necessary data has been developed by the centre for data and information management of Maastricht University. Specially designed algorithms for automatic calculation of the two scores will be implemented in the study web application.

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Objectives

Primary Objective:

To validate the QUIT EMR score in a prospective multicentre study by comparing three, within the study region commonly used, transport systems.

Hypothesis:

Transports with high standard ground transport systems compared with medium and/or low standard ground transport systems (Table 1) will show significant differences in specific subgroups and trends in the whole population in

- *the recently developed QUIT EMR score and/or*
- *number and severity of adverse events*

	Minimum requirements ambulance/equipment	***Minimum requirements teammember 1***	***Minimum requirements teammember 2***
System A (high)	*MICU/ITW*[1]	*Intensivist*[2]	*ICU nurse* *IC Paramedic*[3]
System B (medium)	*IC ambulance*[4]	*ICU Physician*[5]	*Paramedic*
System C (low)	*Standard Ambulance*	*Physician*	*Paramedic*

Table 1: Definitions of different levels of ground transport systems

1) *High volume ambulance with boarding ramp, standard ambulance equipment and ICU equipment including ICU ventilator, minimum of 6 infusion pumps, invasive monitoring, ability to reach the patient from all sides, ability to transport patients with additional medical devices as ECMO, NO, IABP, back-up systems for ventilator/monitoring/defibrillation unit/ suction unit, minimum of 6,000 l Oxygen, if the ventilator is dependent on pressured air also 6,000 l of pressured air in the ambulance, stand-alone capacity 120 min,*
2) *Board certified Intensivist*
3) *Paramedic with Intensive Care qualification in addition*
4) *Standard ambulance with standard ambulance equipment and ICU transport ventilator, minimum of 4 infusion pumps, invasive monitoring, 2,000 l of oxygen in the ambulance, stand-alone capacity of 60 min*
5) *FCCS or FCCS like trained physician with at least 6 months Intensive Care experience*

Secondary Objectives:

a) To determine whether transportation outcome (measured by QUIT EMR score) influences 24-hour post transport morbidity (measured by SEMROS).

Hypothesis:

Negative transport outcome leads to a higher 24-hour post transport morbidity.

b) To detect characteristics that define the patient's needs in terms of level of transportation facility.

Hypothesis:

Pre transport data that indicate a benefit of using a high standard transport system can be detected and defined.

c) To detect predictive outcome parameters concerning 24-hour post transport mortality

Hypothesis:

Pre transport data that indicate 24-hour post transport mortality will be detected and defined.

Methods/Design

Design

"Quality and efficacy of interhospital critical care transportation in the Euregion Meuse-Rhine" is an international, prospective, observational, multicentre cohort study. No intervention will be performed, only completely anonymised data will be analysed. The study is open for inclusion from April 1st 2015 until December 31st 2017.

Population/ inclusion criteria

Adult patients (18 years or older) undergoing an interhospital transport with an indication for direct supervision of a physician, transported within the study region (MICU region Maastricht (NL), district of Aachen (D), City of Aachen (D), district of Heinsberg (D)).

The actual registration of these transports suggest, that up to 3000 interhospital transports per year take place under direct supervision of a physician within the study region.

Study parameters

About 150 pre, intra and post transport items will be scored, an overview of these data can be found in the extra file "web application". The main sections of registration are divided into

1	Demographics (patient related, equipment/ambulance/team related)
2.1	Patient status obtained during the intake call
2.2	Patient status at arrival of transport team
2.3	Patient status at the end of the transport
3	Interventions performed by the transport team
4	Adverse events
5	Data dispatch center
6	24-hours follow up

Data Registration

Web application

A web application has been developed to facilitate data registration. The initial registration will be performed by level 1 users (medical staff present during transport), whereas follow-up data will be obtained by level 2 users. All changes applied to case data will be registered in an audit layer in the database together with details of the user who made the alterations.

Level 1 users

A standardized dataset of patients demographics, aspects of the transportation system (vehicle, equipment, team qualification), the status of the patients at the moment of the intake call, at the moment of arrival of the transportation team at the patient and at the end of transportation, interventions performed by the transportation team, and adverse events will be documented in a web based database (part 1-4) by the transportation team (responsible physician, level 1 user). The database (URL: www.eumic.eu) will be accessible through general username/password combinations. Each participating hospital will receive one unique username/password combination. Alternatively, access will be possible using a global username/password combination for each ambulance, based on the cap codes of the vehicles.

After having finalized the case, the level 1 user gets the opportunity to receive a PDF file of the documented items. Furthermore, there will be a feedback link to send an e-mail comment directly to the coordinating investigator or to the technical support staff of MUMC+.

There will be no registration of personal data such as name or date of birth to ensure patient privacy. The unique transport code given by the responsible dispatch centre will be noted.

Level 2 users

Twenty-four hours after transportation, status information of the patient will be obtained by contacting the ICU in the accepting hospital.

To this end, a group of level 2 users will get access to the database via a personalised username/password combination. This group will be authorised to complete data sets and to visually inspect not yet finalized transportations in the region the level 2 user is authorised for. Level 2 users are not authorised to change items scored by level 1 users.

The workflow for level 2 users will be as follows:

a) Daily log-in to the database
b) Level 2 users will get an overview of transports being finalized by level 1 users in the region the level 2 user is authorised for
c) The Level 2 user will obtain the transport code and alarm time from the patient chart
d) Consequently, the responsible dispatch centre will be contacted to get patients identification (name, date of birth).
e) The Level 2 user will contact the ICU of the accepting hospital to get the standardised information about patient's status 24 hours after transport, this data will be documented in part 6 of the database
f) After completion of the registration, the level 2 user will finalize the case, after which the level 2 user will no longer be able to view the case.

Level 3 users

There will be at least weekly check-ups of data reliability by level 3 users . These are the regional study coordinators, who are granted access to the application given a personalised username/password combination. All log in events will be documented and stored.

All data sheets must be authorised by a level 3 user before entering the final database.

If a case will not be authorised for entering the database, it will be stored in a separate database for unauthorized cases.

The level 3 users will get an overview of new cases divided in complete and incomplete cases. All incomplete cases will be opened and revised by the level 3 user who is authorised to add missing information or to overwrite incorrect data. If the registered data have missing values which do not allow calculation of at least the QUIT EMR score, the dataset will not be admitted to the final database. Furthermore, this small group of users will be authorised to view all open cases, and those that are stored in the databases.

After approving a case for the final database, case identification data will be deleted to ensure that the data in the central database are completely anonymous.

Technical control

Next to the medical administrator group there will be continuous technical control and data safety monitoring done by a technical administrator group from Maastricht University. This group will work independently from the medical coordinators.

Access to the database will only be possible after authorization by the coordinating investigator and the technical control staff.

Statistical Analysis

Baseline characteristics will be presented by mean (SD), or median (interquartile range, IQR) where appropriate, for numerical variables, and by number (%) for categorical variables. All analyses will be performed using IBM SPSS Statistics for Windows. A p-value ≤ 0.05 will be considered statistically significant.

The difference in changes in QUIT EMR score and SEMROS, and the number of interventions between high and medium/low standard ground transport systems will be assessed using independent samples t-test or Mann-Whitney U-test where appropriate. The difference in proportion of adverse events between the transport systems will be tested using Chi-square or Fisher's exact test. To account for potential confounders, linear and logistic regression analysis will be performed for numerical and binary outcomes, respectively, where group (high versus medium/low standard ground transport system) and all baseline variables known to be related to the outcome are included in the model.

Logistic regression analysis will be performed to determine which pre transport variable is an independent risk factor for 24 hours post transport mortality.

In case the data set suits data mining to identify important variables, this will also be performed.

Ethics and dissemination

The study will be conducted according to the principles of the Declaration of Helsinki amended by the WMA General Assembly in October 2013.

Only anonymous data of adult patients undergoing interhospital transportation indicated to be supervised directly by a physician will be used for analysis. No interventions will be performed. Therefore, the Medical Research Ethics Committees (METC) of the university hospitals Maastricht (The Netherlands) and Aachen (Germany) concluded that there is no need for obtaining patient's informed consent.

The study is registered in the Netherlands National Trial Registration: NTR4937

The available data of the validation process of both scores are in preparation for publication.

Depending on the results of this study, a prospective randomised trial will be conducted with defined patient categories being randomised to different levels of transportation systems.

Discussion

With this study a quality monitoring score is expected to be validated, which then can be used for further research. Beside quality monitoring, the group of investigators is interested in clinical relevant effects of interhospital transportation on patients' morbidity 24 hours after transport. Therefore we introduce a clinical, laboratory value independent score.

In the on-going discussion of centralization of health care facilities, a reliable, efficient and proven safe transport modality which meets the individual patient needs is regarded the key factor for success in all future developments in this field [21-25].

Actually, the logistic and financial burden of 24/7 coverage of transportation facilities remains high. Therefore, close cooperation within a regional network is necessary. Such a network might include, as in the Euregion Meuse Rhine, a cross border collaboration where a standardized quality monitoring is highly important. Using numbers of critical events during transport, or the number of parameters beyond defined thresholds does not necessarily reflect the quality of a transport system.[15] These events can take place due to the natural course of the patient's disease of due to transport related effects.

As an approach to determine whether patient related or transport related factors lead to a deterioration of the patient's condition, the presented QUIT EMR score combines performed interventions of the transport team with changes in the physiologic status of the patient.

Thus, a blood pressure drop beyond the defined threshold despite an increase in dosage of vasoactive medication will not lead to a negative judgement. To the best of our knowledge, no such approach to determine quality of interhospital transportation of critically ill patients has been described.

The second objective of interest of this study is, whether a clinically relevant influence of transport quality on patient's 24 hours post transport morbidity and/or mortality can be detected. Available, validated ICU scores , as the SOFA score use laboratory values as Bilirubin level and Thrombocytes. As these values usually are not available at the day of transport in case of an emergency transport we introduce a new score to determine whether the condition of the patient has been worsened 24 hours after transport or not.

Moreover, we expect to get enough information to create new, concrete hypothesis to conduct a randomised controlled non inferiority trial for transportations of certain patient categories with an ICU ambulance versus a Mobile Intensive Care Unit using the presented quality and outcome monitoring.

If we can detect a link between outcome and quality of transport systems for certain patient categories a more rational use of resource intense systems as a MICU can be postulated.

Certainly, our study has limitations.

First, the transport data registration is voluntary, therefore bias in registration cannot be ruled out.

Second, all transport data are registered by the transportation team, no online data are available.

Third, the design of the web application is the result of a compromise between practical issues (how much time is necessary to complete the registration) and research questions, with the result that some aspects in the registration offer certain space for own interpretation of the transportation team members.

Fourth, the logistic burden to obtain follow up information is high, therefore follow up data might not be available for all transportations.

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In conclusion, there is a need for efficient resource utilisation, therefore a reliable pre-transport analysis of the needs of the individual patient in terms of transportation facility in combination with standardised quality monitoring is warranted. The authors believe that the current study can be an important step towards a more evidence based organisation of interhospital transportation of critically ill patients.

List of abbreviations

AE	Adverse event
ECMO	Extracorporeal membrane oxygenation
EMS	Emergency Medical Service
EUMIC	Euregional Mobile Intensive Care
FCCS	Fundamental Critical Care Support
IABP	Intra aortic ballon pump
ICU	Intensive Care Unit
METC	Medisch-Etische Toetsings Commissie
MICU	Mobile Intensive Care Unit
MUMC+	Maastricht University Medical Centre +
NO	Nitric Oxide
SEMROS	Simplified Euregion Meuse Rhine Outcome Score
SD	Standard deviation
SOFA	Sequential Organ Failure Assessment
QUIT EMR	Quality and efficacy of interhospitall critical care transport in the Euregion Meuse-Rhine

Competing interests

The authors declare that they have no competing interests.

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Authors' contribution

US	is coordinating investigator, has been involved in the planning and drafted the manuscript
DB	has been involved in planning the study design and revised the manuscript
JH	has been involved in planning the study design and revised the manuscript
JJ	has been involved in planning the study design and revised the manuscript
BW	has been involved in planning the study design and revised the manuscript
DV	has been involved in planning the study design, is responsible for the web application and revised the manuscript
PR	has been involved in planning the study design and revised the manuscript
SB	has been involved in planning the study design, revised the manuscript and has given final approval

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Addendum/database Part 1 demographics

Part 1 General demographics

Section finished?	☐
Date	
Time of alarm	○ 08.00-17.00h ○ 17.00-23.00h ○ 23.00-08.00h
Transport unit	○ MICU / ITW ○ IC ambulance ○ Standard ambulance ○ Helicopter
Transport team	
First member	☐ EMT ☐ Intensivist / Anesthesiologist ☐ Internist ☐ Surgeon ☐ First aid specialist (SEH-arts) ☐ Trainee ICU / anesthesia ☐ Trainee internal medicine ☐ Trainee surgery ☐ EMS physician ☐ Others, namely
Second member	○ ICU nurse ○ Paramedic

	○ Others, namely
Third member	○ ICU nurse ○ Paramedic ○ Driver ○ Others, namely
Transport number (code)	
Responsible dispatch center	○ Aachen ○ Noord Limburg ○ Zuid Limburg ○ Zuidoost Brabant
Departing hospital	
Receiving hospital	
Year of birth (yyyy)	
Length (cm)	
Body weight (kg)	
Sex	○ Male ○ Female
Reason of transfer	○ Treatment in expertise centre ○ No ICU / IIMC bed available

- Return to patient's region
- Follow up treatment
- Others

Treatment in expertise centre

- Cardio vascular surgery
- Cardiologie
- General surgery
- ICU
- Neurosurgery
- Others, namely

Requested urgency of transport

- < 30 min
- 30-120 min
- > 120 min

Accomplished within urgency timespan?

- Yes
- No

Major diagnosis
more than one option possible

- Acute kidney injury
- Acute liver failure
- Cardiac diagnosis
- Multitrauma
- Neurological diagnosis (except neurotrauma)
- Neurotrauma
- Pulmonary diagnosis
- Sepsis
- Status after expertise treatment

	☐ Others, namely
	
Additional diagnosis *more than one option possible*	☐ Multitrauma ☐ Neurotrauma ☐ Scepsis ☐ Not applicable/None
Intervention planned within 24 hours *more than one option possible*	☐ Assist device ☐ Operation ☐ PTCA ☐ TIPPS ☐ Others, namely
	

Addendum Database Part 2.1 Patient status intake call

Section finished? ☐

Neurological status

- ○ Altered
- ○ Awake
- ◉ Comateus
- ○ Sedated

Pupil reaction

Left
- ○ Yes
- ○ No

Right
- ○ Yes
- ○ No

Pupil size

Left
- ○ Normal
- ○ Wide

Right
- ○ Normal
- ○ Wide

Cardiac/hemodynamic status

Rhythm
- ○ AF
- ○ Pacemaker
- ○ SR
- ○ Other

Frequency

Vasoactive medication
- ○ No iv vasoactive medication
- ○ 1 iv vasoactive medication
- ○ > 1 iv vasoactive medication

Systolic BP

Diastolic BP

Pulmonary status

SpO2 ☐ Not measurable/unknown

Breathing frequency

Ventilation

- Not ventilated
- Noninvasive ventilation
- Invasive ventilation

Not ventilated

- No oxygen
- Nasal oxygen
- Oxygen mask

Noninvasive ventilation FiO2 (in percent)

Noninvasive ventilation PeeP

Noninvasive ventilation Minute Volume

Invasive ventilation FiO2 (in percent)

Invasive ventilation PeeP

Invasive ventilation Minute Volume

ABG

☐ Data unknown

pH

PaO2 *kPa* *mmHg*

PaCO2 *kPa* *mmHg*

Lactat *mmol/L*

Nefrologic status

Diuresis

- Data unknown
- > 0,5 ml/kg/h
- < 0,5ml/kg/h
- Anurie / CVVH

Chronic RF	☐
Laboratory findings	☐ Data unknown
	Hb ____ *unit 1* ____ *unit 2* Thrombocytes ____ *unit 1* ____ *unit 2* K ____ *unit 1* ____ *unit 2* aptt/INR ____ *unit 1* ____ *unit 2* Bilirubin ____ *unit 1* ____ *unit 2*
Others	
Additional medical devices *more than one option possible*	☐ ECMO V-A ☐ ECMO V-A +IABP ☐ ECMO V-V ☐ IABP ☐ NO ☐ EECC02 ☐ Others, namely
Situation stable within last 2 hours before transport	○ Yes ○ No

Addendum database Part 2.2 Patient status at arrival

Section finished?	☐
Changes in status	◉ Yes ○ No
ABG measured within last 30 minutes	☐
ABG	☐ Data unknown pH ____ PaO2 ____ *kPa* ____ *mmHg* PaCO2 ____ *kPa* ____ *mmHg* Lactat ____ *mmol/L*
Neurological status	◉ Altered ○ Awake ○ Comateus ○ Sedated
Pupil reaction	Left ◉ Yes ○ No Right ◉ Yes ○ No
Pupil size	Left ◉ Normal ○ Wide Right ◉ Normal ○ Wide
Cardiac/hemodynamic status	

Rhythm	○ AF ○ Pacemaker ○ SR ◉ Other Frequency
Vasoactive medication	◉ No iv vasoactive medication ○ 1 iv vasoactive medication ○ > 1 iv vasoactive medication
	Systolic BP Diastolic BP
Pulmonary status	
SpO2	☐ Not measurable/unknown
Breathing frequency	
Ventilation	◉ Not ventilated ○ Noninvasive ventilation ○ Invasive ventilation
Not ventilated	○ No oxygen ○ Nasal oxygen ○ Oxygen mask
Noninvasive ventilation FiO2 (in percent)	
Noninvasive ventilation PeeP	
Noninvasive ventilation Minute Volume	
Invasive ventilation FiO2 (in percent)	
Invasive ventilation PeeP	
Invasive ventilation Minute Volume	

Other changes in status

Addendum database Part 2.3 Patient status end of transport

Section finished?	☐
Changes in status	◉ Yes ○ No
ABG measured within last 30 minutes	☐
ABG	☐ Data unknown pH ____ PaO2 ____ *kPa* ____ *mmHg* PaCO2 ____ *kPa* ____ *mmHg* Lactat ____ *mmol/L*
Neurological status	○ Altered ○ Awake ○ Comateus ◉ Sedated
Pupil reaction	Left ◉ Yes ○ No Right ◉ Yes ○ No
Pupil size	Left ◉ Normal ○ Wide Right ◉ Normal

	○ Wide
Cardiac/hemodynamic status	
Rhythm	○ AF ○ Pacemaker ○ SR ◉ Other Frequency
Vasoactive medication	◉ No iv vasoactive medication ○ 1 iv vasoactive medication ○ > 1 iv vasoactive medication
	Systolic BP Diastolic BP
Pulmonary status	
SpO2	☐ Not measurable/unknown
Breathing frequency	
Ventilation	◉ Not ventilated ○ Noninvasive ventilation ○ Invasive ventilation
	Not ventilated ○ No oxygen ○ Nasal oxygen ○ Oxygen mask *Noninvasive ventilation FiO2 (in percent)* *Noninvasive ventilation PeeP* *Noninvasive ventilation Minute Volume* *Invasive ventilation FiO2 (in percent)*

	Invasive ventilation PeeP	
	Invasive ventilation Minute Volume	
Other changes in status		

Addendum database Part 3 Transport team interventions

Section finished? ☐

Intervention done
- ◉ Yes
- ○ No

Situation stable during transport
- ◉ Yes
- ○ No

A (Airway)

Intubation ☐

Alternative airway ☐

Others

B (Breathing)

Changes in ventilator settings

☐ PeeP
- ○ Increase
- ○ Decrease

☐ Tidal volume/ inspiratory pressure
- ○ Increase
- ○ Decrease

☐ FiO2 (in percent)
- ○ Increase

Decrease

C (Circulation)

CPR

Volume therapy

No additional volume

500 ml extra volume

500-1000 ml extra volume

> 1000 ml extra volume

Bleeding control

Others

D (Disability)

Medication

Changes in vasoactive medication

Increase in dosage

Decrease in dosage

IV Bolus application

more than one option possible

Adrenaline

Analgetics

Atropine

Muscle relaxants

Sedatives

Others, namely

E (Environmental Exposure)

Namely

Other

more than one option possible

- IABP
- ECMO
- Others, namely

Addendum database Part 4 Transport related adverse events

Section finished?

Adverse events

- Yes

No

Technical errors

Ambulance

Description

Outcome

Trolley

Ventilator

Infusion pump

Defibrillator

Suction unit

Monitoring

Others

Patient / treatment / team related events

SPO2 < 90%

Q1. Immediate Intervention?

Yes

No

Q2. Result

Recovery within 60 seconds

No recovery within 60 seconds

Q3. Outcome end of transport

Recovery

No recovery

Mean RR < 60 or RR syst < 80

New tachycardia (HF > 120/min)

☐ New bradycardia (HF < 40/min)

☐ VF/VT

☐ Asystolie/PEA

☐ Unintended extubation

Q1. Result

◉ Difficult airway

○ Direct reintubation

○ Oxygen supply

Q2. Outcome end of transport

◉ No SPO2 < 85%

○ SPO2 < 85% < 2 min

○ SPO2 < 85% > 2 min

☐ Loss IV access art lijn?

Q1. Immediate Intervention?

◉ Yes

○ No

Q2. Result

◉ CVC

○ Peripheral IV line

☐ Medication related complication

more than one option possible

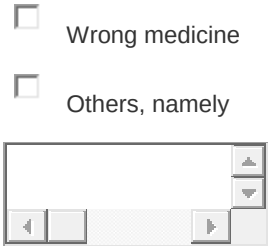
☐ Dose error

☐ Side effects

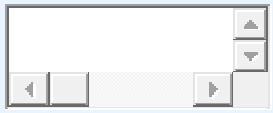
☐ Wrong access route

☐ Wrong medicine

☐ Others, namely



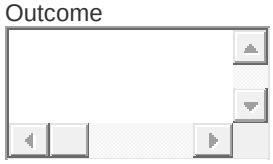
☐ Communication related complication



Others

Description

Outcome



Addendum database Part 5 Data dispatch centre

Section finished?	☐
Time of alarm	
Time of departure 1	
Time of arrival 1	
Time of departure 2	
Time of arrival 2	
Time end of transport	
Personal details	
Patient name	
Date of birth	

Addendum database Part 6 Follow-up post transport

Section finished?	☐
Patient is alive?	◉ Yes ○ No
ABG	☐ Data unknown pH PaO2 *kPa* *mmHg* PaCO2 *kPa* *mmHg* Lactat *mmol/L*
Not normal values	Hb *unit 1* *unit 2*
Intubation	☐
CPR	☐
Others	
Planned intervention	○ PTCA ○ Assist device ○ TIPPS ○ Operation ○ Others ○ None
Time of intervention	
Neurological status	
Pupil reaction	Left ○ Yes ○ No Right ○ Yes

	○ No
Pupil size	Left ○ Normal ○ Wide Right ○ Normal ○ Wide
Cardiac/hemodynamic status	
Rhythm	Frequency
Vasoactive medication	Systolic BP Diastolic BP
Pulmonary status	
SpO2	☐ Not measurable/unknown
Breathing frequency	
Ventilation	*Not ventilated* *Noninvasive ventilation FiO2 (in percent)* *Noninvasive ventilation PeeP* *Noninvasive ventilation Minute Volume* *Invasive ventilation FiO2 (in percent)* *Invasive ventilation PeeP* *Invasive ventilation Minute Volume*
Nefrologic status	
Diuresis	○ Data unknown ○ > 0,5 ml/kg/h ○ < 0,5ml/kg/h ○ Anurie / CVVH
Chronic RF	☐

Laboratory findings

☐ Data unknown

Time of collection

Hb *unit 1* *unit 2*

Thrombocytes *unit 1* *unit 2*

K *unit 1* *unit 2*

aptt/INR *unit 1* *unit 2*

Bilirubin *unit 1* *unit 2*

BMJ Open

QUIT EMR trial: a prospective, observational, multicentre study to evaluate quality and 24 hours post transport morbidity of interhospital critical care transportation- study protocol

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QUIT EMR trial:

a prospective, observational, multicentre study to evaluate quality and 24 hours post transport morbidity of interhospital critical care transportation – study protocol.

Ulrich Strauch*, Dennis CJJ Bergmans*, Joachim Habers, Jochen Jansen***, Bjorn Winkens ****, Dirk J Veldman #, Paul MHJ Roekaerts*, Stefan K Beckers##**

Ulrich Strauch *Corresponding author*
Maastricht University Medical Centre+, Department of Intensive Care *
P. Debyelaan 25 PO Box 5800, 6202 AZ Maastricht (The Netherlands)
Fone: 0031433876385 E mail: u.strauch@mumc.nl

Dennis CJJ Bergmans Maastricht University Medical Centre+, Department of Intensive Care *
P. Debyelaan 25 PO Box 5800,6202 AZ Maastricht (The Netherlands)
E mail: d.bergmans@mumc.nl

Joachim Habers Emergency Medical Service district of Aachen**
Zollernstrasse 20, 52070 Aachen (Germany)
E mail : aelrd_staedteregion-aachen@web.de

Jochen Jansen Emergency Medical Service South Limburg***
Geleenbeeklaan 2, 6166 GR Geleen (The Netherlands)
E Mail: j.jansen@ggdzl.nl

Bjorn Winkens Maastricht University, Department of Methodology and Statistics****
CAPHRI School for Public Health and Primary Care
PO Box 616, 6200 Maastricht, The Netherlands
E Mail: bjorn.winkens@maastrichtuniversity.nl

Dirk JVeldman Maastricht University, MEMIC Center for data and information management #
P. Debyeplein 1, Postbus 616, 6200 MD Maastricht, The Netherlands
E Mail: d.veldman@maastrichtuniversity.nl

Paul MHJ Roekaerts Maastricht University Medical Centre+, Department of Intensive Care *
P. Debyelaan 25 PO Box 5800,6202 AZ Maastricht (The Netherlands)
E mail: p.roekaerts@mumc.nl

Stefan Beckers Emergency Medical Service, Fire Department, City of Aachen##
Stolberger Str. 155, 52068 Aachen (Germany)
and Department of Anaesthesiology, University Hospital RWTH Aachen,
Pauwelsst. 30, 52074 Aachen (Germany) ##
E Mail: aelr@mail.aachen.de

Abstract

Introduction

Transportation (intra- and interhospital) of critically ill patients is a well known high risk procedure. Evidence based criteria to determine the quality of a transport system and the impact of transport on the patient's outcome are missing. Two scoring systems, one to monitor quality of the transport system (Quality of interhospital critical care transportation in the Euregion Meuse-Rhine: QUIT EMR Score) and the other to detect changes in patient's clinical condition 24 hours after transport (Simplified EMR outcome score: SEMROS) have been developed and validated retrospectively in our hospital. The primary objective of this study is to validate the QUIT EMR Score in a prospective, observational study. Secondary objective is to analyse whether negative transport outcome influences 24 hour post transport morbidity/mortality by using SEMROS and to detect predictive outcome parameters for 24 hours post transport mortality.

Methods and Analysis

About 150 pre, intra and post transport items of adult patients (age>18), undergoing interhospital transport supervised by a physician, with the departing hospital being located within the study region, will be documented in a web based application.

To validate the QUIT EMR score 3 pre-defined levels of transport facilities (high/medium/low standard) will be compared. Subsequently the effect of transport quality on 24 hours post transport morbidity will be determined using SEMROS.

The expected number of transports in the study region is about 3000/year. The study is open for inclusion from April 1st 2015 until December 31st 2017

Ethics and Dissemination

The trial was approved by the Ethics committees of the university hospitals Maastricht (NL) and Aachen (Germany). The results of the study will be published in a peer reviewed journal. Depending on the results a prospective randomised trial will be conducted with defined patient categories being randomised to different levels of transport systems.

Trial Registration: NTR4937

Keywords

Interhospital Transport, Mobile Intensive Care, Critical Care Transportation, Quality of critical care transportation

Strengths and limitations of the study

- Using a web based, uniform way of registration of interhospital transports of critically ill patients we will create an unique database that will enable us to introduce two new developed scoring systems into research and clinical practice
- A clinically relevant quality monitoring score will be validated in a prospective, international, multicentre trial setting
- The effect of transport quality on 24 hours post transport morbidity will be measured using a new developed and validated score
- Registration of transport data is voluntary and will be performed by transport teams, bias in registration of transports cannot be ruled out
- Follow up data might not be available for all transports, which can lead to registration bias

Introduction

Transportation of critically ill patients is well known high-risk procedure with a significant rate of adverse events [1]. Especially during interhospital transportation, the patient's safety can be compromised due to the absence of highly qualified staff and the lack of sophisticated resuscitation equipment [2-10]. Focusing on interhospital transportation there are two categories of patients with different needs in terms of transport facilities. On the one hand there are patients in need of urgent lifesaving intervention in an expertise center, on the other hand there are patients with the need for continued Intensive Care Unit (ICU) therapy including the use of extracorporeal devices during transport. In the daily German and Dutch practice different types of ground ambulances are available for the transport of critically ill patients, known as:
Standard ambulance, ICU ambulance, Mobile Intensive Care Unit / Intensivtransportwagen (MICU/ITW).
The transport teams usually consist of a paramedic and a physician, transports with a MICU/ITW are frequently accompanied by a physician and a nurse both trained and experienced in ICU therapy.
In general the responsible dispatch centre coordinates all transports, the decision with regard to the most appropriate available transport system is based on urgency and severity of illness. Providing 24/7 facilities for interhospital transport is resource intense, though, the cooperation of different regions seems useful.
Within in the Euregion Meuse Rhine a cross border (Netherland, Germany) project group developed a plan for cooperation with regard to emergency and MICU/ITW transportation. Facing substantial differences in organisation and legislation of interhospital transport in the two countries the project group stated that there is a need for a uniform manner of measuring quality of transport systems. Currently, parameters like adverse event rate, short term mortality, changes in SOFA score before and after transport are used to describe quality of transport systems [11-19].
As it is difficult to determine whether a deterioration of the patient's condition during or immediately after transport is due totransport related aspects or due to the natural course of the disease[15] the "Quality of interhospital critical care transportation in the Euregion Meuse-Rhine trial (QUIT EMR trial)" was initiated by the project group.
As a first step two scores were developed, one to determine transport system quality and one to detect relevant changes in the patient's clinical condition 24 hours after transport. The calculations of both scores are based on algorhythms and can be performed manually or in an automated way.

- The QUIT EMR Score is a dichotomized score with 1 indicating that there was no necessity for a transport team intervention or that adequate interventions were performed and 0 indicating that there were inadequate interventions or no interventions despite physiologic parameters beyond predefined thresholds. The used algorythm does not solely focus on changes in physiologic parameters, but combines changes with documented interventions being performed by the transport team. The used data can be found in the additional file "web application" at part 2.2, part 2.3 and part 3.
- The Simplified EMR Outcome Score (SEMROS) is a dichotomized score with 1 indicating that the patient's status remained unchanged or improved within 24 hours after transport and 0

indicating that the patient's condition deteriorated within 24 hours after transport. The used data to calculated SEMROS can be found in the additional file "web application" at part 2.1 and part 6.

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To validate the QUIT EMR score, 100 transport charts of the Mobile Intensive Care Unit (MICU) from Maastricht University Medical Centre+ (MUMC+) have been used to calculate the QUIT EMR score and accordingly dichotomise the score to 0 or 1 All these calculations have been done by the coordinating investigator. Then four experts (anaesthesiologists and/or intensivists) experienced in interhospital transport from MUMC+ revised the transport charts using the following criteria to score a transport 1 (positive judgement) or 0 (negative judgement):

- Stable situation during transport without intervention 1
- Stable situation with adequate intervention 1
- Unstable situation with adequate intervention 1
- Unstable situation or important physiologic parameters beyond threshold without adequate intervention or with inadequate intervention 0

The experts were free to define stable versus unstable situation, adequate versus inadequate intervention and to define thresholds for physiologic parameters. Finally, the results of the QUIT EMR score and those of the 4 experts have been compared, with a level of agreement of 84%-92% and an inter-observer level of agreement of 85.0% to 92.9%

Regarding SEMROS, a total of 110 MICU transports towards MUMC+ have been revised by the coordinating investigator. Of these, 90 complete datasets were available to calculate pre- and post-transport Sequential Organ failure score (SOFA score) [20] and SEMROS.
In the 90 cases, the observed level of agreement of the SOFA score and SEMROS was 88,9%.
This was the case for 2 different versions of the score, the first one including Bilirubin, lactate and pH and the second without these laboratory parameters.
The following definitions have been used regarding changes in the SOFA score:

1 (positive outcome) or 0 (negative outcome)

- SOFA score pre transport lower than SOFA score post transport 0
- SOFA score pre transport equal to SOFA score post transport 1
- SOFA score pre transport higher than SOFA score post transport 1

On this basis a web based application to register all necessary data has been developed by the centre for data and information management of Maastricht University. Specially designed algorithms for automatic calculation of the two scores will be implemented in the study web application.

Objectives

Primary Objective:

To validate the QUIT EMR score in a prospective multicentre study by comparing three, within the study region commonly used, transport systems.

Hypothesis:

Transports with high standard ground transport systems compared to medium and/or low standard ground transport systems (Table 1) will show significant differences in specific subgroups and trends in the whole population in

- *the recently developed QUIT EMR score and/or*
- *number and severity of adverse events*

	Minimum requirements ambulance/equipment	***Minimum requirements teammember 1***	***Minimum requirements teammember 2***
System A (high)	*MICU/ITW*[1]	*Intensivist*[2]	*ICU nurse* *IC Paramedic*[3]
System B (medium)	*IC ambulance*[4]	*ICU Physician*[5]	*Paramedic*
System C (low)	*Standard Ambulance*	*Physician*	*Paramedic*

Table 1: Definitions of different levels of ground transport systems

1) *High volume ambulance with boarding ramp, standard ambulance equipment and ICU equipment including ICU ventilator, minimum of 6 infusion pumps, invasive monitoring, ability to reach the patient from all sides, ability to transport patients with additional medical devices as ECMO, NO, IABP, back-up systems for ventilator/monitoring/defibrillation unit/ suction unit, minimum of 6,000 l Oxygen, if the ventilator is dependent on pressured air also 6,000 l of pressured air in the ambulance, stand-alone capacity 120 min,*
2) *Board certified Intensivist*
3) *Paramedic with Intensive Care qualification in addition*
4) *Standard ambulance with standard ambulance equipment and ICU transport ventilator, minimum of 4 infusion pumps, invasive monitoring, 2,000 l of oxygen in the ambulance, stand-alone capacity of 60 min*
5) *FCCS or FCCS like trained physician with at least 6 months Intensive Care experience*

Secondary Objectives:

a) To determine whether transportation outcome (as determined by QUIT EMR score) influences 24-hour post transport morbidity (as determinde by SEMROS).

Hypothesis:

Negative transport outcome leads to a higher 24-hour post transport morbidity.

b) To detect characteristics that define the patient's needs in terms of level of transportation facility.

Hypothesis:

Pre transport data that indicate a benefit of using a high standard transport system can be detected and defined.

c) To detect predictive outcome parameters concerning 24-hour post transport mortality

Hypothesis:

Pre transport data that indicate 24-hour post transport mortality will be detected and defined.

Methods/Design

Design

"Quality and efficacy of interhospital critical care transportation in the Euregion Meuse-Rhine" is an international, prospective, observational, multicentre cohort study. No intervention will be performed, only completely anonymised data will be analysed. The study is open for inclusion from April 1st 2015 until December 31st 2017.

Population/ inclusion criteria

Adult patients (18 years or older) undergoing interhospital transport supervised by a physician within the study region (MICU region Maastricht (NL), district of Aachen (D), City of Aachen (D), district of Heinsberg (D)). Momentary registration of these transports suggests, that up to 3000 interhospital transports per year take place under direct supervision of a physician within the study region.

Study parameters

About 150 pre, intra and post transport items will be scored, an overview of these data can be found in the extra file "web application". The main sections of registration are divided into

1	Demographics (patient related, equipment/ambulance/team related)
2.1	Patient status obtained during the intake call
2.2	Patient status on arrival of transport team
2.3	Patient status at the end of the transport
3	Interventions performed by the transport team
4	Adverse events
5	Data dispatch center
6	24-hours follow up

Data Registration

Web application

A web application has been developed to facilitate data registration. The initial registration will be performed by level 1 users (medical staff present during transport), whereas follow-up data will be obtained by level 2 users (research staff from the participating organisations). Logfiles of all changes will be stored in the audit layer.

Level 1 users

A standardized set of demographic data, transportation system information, clinical data at the moment of the intake call, arrival of the transportation team at the patient and at the end of transportation, interventions performed by the transportation team, and adverse events will be documented in the web based application (additional file part 1-4) by the responsible physician. The web application (URL: www.eumic.eu) will be accessible through general username/password combinations. Each participating hospital will receive one unique username/password combination. Alternatively, access will be possible using a global username/password combination for each ambulance, based on the cap codes of the vehicles.

After having finalized the case, the level 1 user gets the opportunity to receive a PDF file of the documented items. Furthermore, there will be a feedback link to send an e-mail comment directly to the coordinating investigator or to the technical support staff of MUMC+.

There will be no registration of personal data such as name or date of birth to ensure patient privacy. The unique transport code given by the responsible dispatch centre will be noted.

Level 2 users

Twenty-four hours after transportation, status information of the patient will be obtained by contacting the ICU in the accepting hospital.

To this end, a group of level 2 users will get access to the database via a personalised username/password combination. This group will be authorised to complete data sets and to visually inspect not yet finalized transportations in the region the level 2 user is authorised for. Level 2 users are not authorised to change items scored by level 1 users.

The workflow for level 2 users will be as follows:

a) Daily log-in to the database
b) Level 2 users will get an overview of transports being finalized by level 1 users in the region the level 2 user is authorised for
c) The Level 2 user will obtain the transport code and alarm time from the patient chart
d) Consequently, the responsible dispatch centre will be contacted to get patients identification (name, date of birth).
e) The Level 2 user will contact the ICU of the accepting hospital to get the standardised information about patient's status 24 hours after transport, this data will be documented in part 6 of the database
f) After completion of the registration, the level 2 user will finalize the case, after which the level 2 user will no longer be able to view the case.

Level 3 users

Level 3 users will perform weekly check-ups of data reliability. These are the regional study coordinators, who are granted access to the application given a personalised username/password combination.

All data sheets must be authorised by a level 3 user before entering the final database.

If a case is not authorised for entering the database, it will be stored in a separate database for unauthorized cases.

The level 3 users will get an overview of new cases divided in complete and incomplete cases. All incomplete cases will be opened and revised by the level 3 user who is authorised to add missing information or to overwrite incorrect data. If the registered data have missing values which do not allow calculation of at least the QUIT EMR score, the dataset will not be admitted to the final database. Furthermore, this small group of users will be authorised to view all open cases, and those that are stored in the databases.

After approval of a case for the final database, case identification data will be deleted to ensure that the data in the central database are completely anonymous.

Technical control

Next to the medical administrator group there will be continuous technical control and data safety monitoring done by a technical administrator group from Maastricht University. This group will work independently from the medical coordinators.

Access to the database will only be possible after authorization by the coordinating investigator and the technical control staff.

Statistical Analysis

Baseline characteristics will be presented by mean (SD), or median (interquartile range, IQR) when appropriate, for numerical variables, and by number (%) for categorical variables. All analyses will be performed using IBM SPSS Statistics for Windows. A p-value ≤ 0.05 will be considered statistically significant.

The difference in changes in QUIT EMR score and SEMROS, and the number of interventions between high and medium/low standard ground transport systems will be assessed using independent samples t-test or Mann-Whitney U-test where appropriate. The difference in proportion of adverse events between the transport systems will be tested using Chi-square or Fisher's exact test. To account for potential confounders, linear and logistic regression analysis will be performed for numerical and binary outcomes, respectively, where group (high versus medium/low standard ground transport system) and all baseline variables known to be related to the outcome are included in the model.

Logistic regression analysis will be performed to determine which pre transport variable is an independent risk factor for 24 hours post transport mortality.

In case the data set suits data mining to identify important variables, this will also be performed.

Ethics and dissemination

The study will be conducted according to the principles of the Declaration of Helsinki amended by the WMA General Assembly in October 2013.
Only anonymous data of adult patients undergoing interhospital transportation indicated to be supervised by a physician will be used for analysis. No interventions will be performed.
Therefore, the Medical Research Ethics Committees (METC) of the university hospitals Maastricht (The Netherlands) and Aachen (Germany) concluded that there is no need for obtaining patient's informed consent.
The study is registered in the Netherlands National Trial Registration: NTR4937
The available data of the validation process of both scores are in preparation for publication.
Depending on the results of this study, a prospective randomised trial will be conducted with defined patient categories being randomised to different levels of transportation systems.

Discussion

With this study a quality monitoring score is expected to be clinically validated, which then can be used for further research. Beside quality monitoring, the group of investigators is interested in clinical relevant effects of interhospital transportation on patients' morbidity 24 hours after transport. Therefore we introduce a clinical, laboratory value independent score.
In the on-going discussion of centralization of health care facilities, a reliable, efficient and proven safe transport modality which meets the individual patient needs is regarded the key factor for success in future developments in this field [21-25].
Actually, the logistic and financial burden of 24/7 coverage of transportation facilities remains high. Therefore, close cooperation within a regional network is necessary. Such a network might include, as in the Euregion Meuse Rhine, a cross border collaboration where a standardized quality monitoring is highly important. Using numbers of critical events during transport, or the number of parameters beyond defined thresholds does not necessarily reflect the quality of a transport system.[15] These events can take place due to the natural course of the patient's disease or due to transport related effects.
As an approach to determine whether patient related or transport related factors lead to a deterioration of the patient's condition, the presented QUIT EMR score combines performed interventions of the transport team with changes in the physiologic status of the patient.
Thus, a blood pressure drop beyond the defined threshold despite an increase in dosage of vasoactive medication will not lead to a negative judgement. To the best of our knowledge, such an approach to determine quality of interhospital transportation of critically ill patients has not been described.
The second point of interest in this study is whether a clinically relevant influence of transport quality on patient's 24 hours post transport morbidity and/or mortality can be detected. Available, validated ICU scores, like the SOFA score use laboratory values for instance bilirubin level and thrombocytes. Since these values usually are not available at the day of transport in case of an emergency transport we introduce a new score to determine whether the condition of the patient worsens 24 hours after transport or not.
Moreover, we expect to get enough information to create new, concrete hypothesis to conduct a randomised controlled non inferiority trial for transportations of certain patient categories with an ICU ambulance versus a Mobile Intensive Care Unit using the presented quality and outcome monitoring.

If we can detect a link between outcome and quality of transport systems for certain patient categories, a more rational use of resource intense systems like the MICU can be postulated.

Certainly, our study has limitations.

First, the transport data registration is voluntary, therefore bias in registration cannot be ruled out.

Second, all transport data are registered by the transportation team, no online data are available.

Third, the design of the web application is the result of a compromise between practical issues (how much time is necessary to complete the registration) and research questions, with the result that some aspects in the registration offer certain space for personal interpretation of the transportation team members.

Fourth, the logistic burden to obtain follow up information is high, therefore follow up data might not be available for all transportations.

In conclusion, there is a need for efficient resource utilisation, therefore a reliable pre-transport analysis of the needs of the individual patient in terms of transportation facility in combination with standardised quality monitoring is warranted. The authors believe that the current study can be an important step towards a more evidence based organisation of interhospital transportation of critically ill patients.

List of abbreviations

AE	Adverse event
ECMO	Extracorporeal membrane oxygenation
EMS	Emergency Medical Service
EUMIC	Euregional Mobile Intensive Care
FCCS	Fundamental Critical Care Support
IABP	Intra-aortic balloon pump
ICU	Intensive Care Unit
METC	Medisch-Etische Toetsings Commissie
MICU	Mobile Intensive Care Unit
MUMC+	Maastricht University Medical Centre +
NO	Nitric Oxide
SEMROS	Simplified Euregion Meuse Rhine Outcome Score
SD	Standard deviation
SOFA	Sequential Organ Failure Assessment
QUIT EMR	Quality and efficacy of interhospitall critical care transport in the Euregion Meuse-Rhine

Competing interests

The authors declare that they have no competing interests.

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Authors' contribution

US	is coordinating investigator, has been involved in the planning and drafted the manuscript
DB	has been involved in planning the study design and revised the manuscript
JH	has been involved in planning the study design and revised the manuscript
JJ	has been involved in planning the study design and revised the manuscript
BW	has been involved in planning the study design and revised the manuscript
DV	has been involved in planning the study design, is responsible for the web application and revised the manuscript
PR	has been involved in planning the study design and revised the manuscript
SB	has been involved in planning the study design, revised the manuscript and has given final approval

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Addendum/database Part 1 demographics

Part 1 General demographics

Section finished?	☐
Date	
Time of alarm	○ 08.00-17.00h ○ 17.00-23.00h ○ 23.00-08.00h
Transport unit	○ MICU / ITW ○ IC ambulance ○ Standard ambulance ○ Helicopter
Transport team	
First member	☐ EMT ☐ Intensivist / Anesthesiologist ☐ Internist ☐ Surgeon ☐ First aid specialist (SEH-arts) ☐ Trainee ICU / anesthesia ☐ Trainee internal medicine ☐ Trainee surgery ☐ EMS physician ☐ Others, namely
Second member	○ ICU nurse ○ Paramedic

	○ Others, namely
Third member	○ ICU nurse ○ Paramedic ○ Driver ○ Others, namely
Transport number (code)	
Responsible dispatch center	○ Aachen ○ Noord Limburg ○ Zuid Limburg ○ Zuidoost Brabant
Departing hospital	
Receiving hospital	
Year of birth (yyyy)	
Length (cm)	
Body weight (kg)	
Sex	○ Male ○ Female
Reason of transfer	○ Treatment in expertise centre ○ No ICU / IIMC bed available

- Return to patient's region
- Follow up treatment
- Others

Treatment in expertise centre

- Cardio vascular surgery
- Cardiologie
- General surgery
- ICU
- Neurosurgery
- Others, namely

Requested urgency of transport

- < 30 min
- 30-120 min
- > 120 min

Accomplished within urgency timespan?

- Yes
- No

Major diagnosis
more than one option possible

- Acute kidney injury
- Acute liver failure
- Cardiac diagnosis
- Multitrauma
- Neurological diagnosis (except neurotrauma)
- Neurotrauma
- Pulmonary diagnosis
- Sepsis
- Status after expertise treatment

	☐ Others, namely
	
Additional diagnosis *more than one option possible*	☐ Multitrauma ☐ Neurotrauma ☐ Scepsis ☐ Not applicable/None
Intervention planned within 24 hours *more than one option possible*	☐ Assist device ☐ Operation ☐ PTCA ☐ TIPPS ☐ Others, namely
	

Addendum Database Part 2.1 Patient status intake call

Section finished? ☐

Neurological status

- ○ Altered
- ○ Awake
- ◉ Comateus
- ○ Sedated

Pupil reaction

Left
- ○ Yes
- ○ No

Right
- ○ Yes
- ○ No

Pupil size

Left
- ○ Normal
- ○ Wide

Right
- ○ Normal
- ○ Wide

Cardiac/hemodynamic status

Rhythm
- ○ AF
- ○ Pacemaker
- ○ SR
- ○ Other

Frequency

Vasoactive medication
- ○ No iv vasoactive medication
- ○ 1 iv vasoactive medication
- ○ > 1 iv vasoactive medication

Systolic BP

Diastolic BP

Pulmonary status

SpO2 ☐ Not measurable/unknown

Breathing frequency

Ventilation

- Not ventilated
- Noninvasive ventilation
- Invasive ventilation

Not ventilated

- No oxygen
- Nasal oxygen
- Oxygen mask

Noninvasive ventilation FiO2 (in percent)

Noninvasive ventilation PeeP

Noninvasive ventilation Minute Volume

Invasive ventilation FiO2 (in percent)

Invasive ventilation PeeP

Invasive ventilation Minute Volume

ABG

☐ Data unknown

pH

PaO2 *kPa* *mmHg*

PaCO2 *kPa* *mmHg*

Lactat *mmol/L*

Nefrologic status

Diuresis

- Data unknown
- > 0,5 ml/kg/h
- < 0,5ml/kg/h
- Anurie / CVVH

Chronic RF	☐
Laboratory findings	☐ Data unknown
	Hb ____ *unit 1* ____ *unit 2* Thrombocytes ____ *unit 1* ____ *unit 2* K ____ *unit 1* ____ *unit 2* aptt/INR ____ *unit 1* ____ *unit 2* Bilirubin ____ *unit 1* ____ *unit 2*
Others	
Additional medical devices *more than one option possible*	☐ ECMO V-A ☐ ECMO V-A +IABP ☐ ECMO V-V ☐ IABP ☐ NO ☐ EECC02 ☐ Others, namely
Situation stable within last 2 hours before transport	○ Yes ○ No

Addendum database Part 2.2 Patient status at arrival

Section finished?	☐
Changes in status	◉ Yes ○ No
ABG measured within last 30 minutes	☐
ABG	☐ Data unknown pH ____ PaO2 ____ *kPa* ____ *mmHg* PaCO2 ____ *kPa* ____ *mmHg* Lactat ____ *mmol/L*
Neurological status	◉ Altered ○ Awake ○ Comateus ○ Sedated
Pupil reaction	Left ◉ Yes ○ No Right ◉ Yes ○ No
Pupil size	Left ◉ Normal ○ Wide Right ◉ Normal ○ Wide
Cardiac/hemodynamic status	

Rhythm	○ AF ○ Pacemaker ○ SR ◉ Other Frequency
Vasoactive medication	◉ No iv vasoactive medication ○ 1 iv vasoactive medication ○ > 1 iv vasoactive medication
	Systolic BP Diastolic BP
Pulmonary status	
SpO2	☐ Not measurable/unknown
Breathing frequency	
Ventilation	◉ Not ventilated ○ Noninvasive ventilation ○ Invasive ventilation
Not ventilated	○ No oxygen ○ Nasal oxygen ○ Oxygen mask
Noninvasive ventilation FiO2 (in percent)	
Noninvasive ventilation PeeP	
Noninvasive ventilation Minute Volume	
Invasive ventilation FiO2 (in percent)	
Invasive ventilation PeeP	
Invasive ventilation Minute Volume	

Other changes in status

Addendum database Part 2.3 Patient status end of transport

Section finished?	☐
Changes in status	◉ Yes ○ No
ABG measured within last 30 minutes	☐
ABG	☐ Data unknown pH ____ PaO2 ____ *kPa* ____ *mmHg* PaCO2 ____ *kPa* ____ *mmHg* Lactat ____ *mmol/L*
Neurological status	○ Altered ○ Awake ○ Comateus ◉ Sedated
Pupil reaction	Left ◉ Yes ○ No Right ◉ Yes ○ No
Pupil size	Left ◉ Normal ○ Wide Right ◉ Normal

	○ Wide
Cardiac/hemodynamic status	
Rhythm	○ AF ○ Pacemaker ○ SR ◉ Other Frequency
Vasoactive medication	◉ No iv vasoactive medication ○ 1 iv vasoactive medication ○ > 1 iv vasoactive medication
	Systolic BP Diastolic BP
Pulmonary status	
SpO2	☐ Not measurable/unknown
Breathing frequency	
Ventilation	◉ Not ventilated ○ Noninvasive ventilation ○ Invasive ventilation
	Not ventilated ○ No oxygen ○ Nasal oxygen ○ Oxygen mask *Noninvasive ventilation FiO2 (in percent)* *Noninvasive ventilation PeeP* *Noninvasive ventilation Minute Volume* *Invasive ventilation FiO2 (in percent)*

	Invasive ventilation PeeP	
	Invasive ventilation Minute Volume	
Other changes in status		

Addendum database Part 3 Transport team interventions

Section finished? ☐

Intervention done
- ◉ Yes
- ○ No

Situation stable during transport
- ◉ Yes
- ○ No

A (Airway)

Intubation ☐

Alternative airway ☐

Others

B (Breathing)

Changes in ventilator settings

☐ PeeP
- ○ Increase
- ○ Decrease

☐ Tidal volume/ inspiratory pressure
- ○ Increase
- ○ Decrease

☐ FiO2 (in percent)
- ○ Increase

Decrease

C (Circulation)

CPR

Volume therapy

No additional volume

500 ml extra volume

500-1000 ml extra volume

> 1000 ml extra volume

Bleeding control

Others

D (Disability)

Medication

Changes in vasoactive medication

Increase in dosage

Decrease in dosage

IV Bolus application

more than one option possible

Adrenaline

Analgetics

Atropine

Muscle relaxants

Sedatives

Others, namely

E (Environmental Exposure)

Namely

Other

more than one option possible

- IABP
- ECMO
- Others, namely

Addendum database Part 4 Transport related adverse events

Section finished?

Adverse events

- Yes

No

Technical errors

Ambulance

Description

Outcome

Trolley

Ventilator

Infusion pump

Defibrillator

Suction unit

Monitoring

Others

Patient / treatment / team related events

SPO2 < 90%

Q1. Immediate Intervention?

Yes

No

Q2. Result

Recovery within 60 seconds

No recovery within 60 seconds

Q3. Outcome end of transport

Recovery

No recovery

Mean RR < 60 or RR syst < 80

New tachycardia (HF > 120/min)

☐ New bradycardia (HF < 40/min)

☐ VF/VT

☐ Asystolie/PEA

☐ Unintended extubation

Q1. Result

◉ Difficult airway

○ Direct reintubation

○ Oxygen supply

Q2. Outcome end of transport

◉ No SPO2 < 85%

○ SPO2 < 85% < 2 min

○ SPO2 < 85% > 2 min

☐ Loss IV access art lijn?

Q1. Immediate Intervention?

◉ Yes

○ No

Q2. Result

◉ CVC

○ Peripheral IV line

☐ Medication related complication

more than one option possible

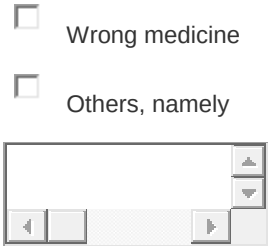
☐ Dose error

☐ Side effects

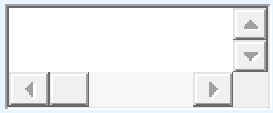
☐ Wrong access route

☐ Wrong medicine

☐ Others, namely



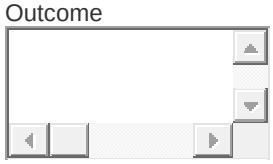
☐ Communication related complication



Others

Description

Outcome



Addendum database Part 5 Data dispatch centre

Section finished?	☐
Time of alarm	
Time of departure 1	
Time of arrival 1	
Time of departure 2	
Time of arrival 2	
Time end of transport	
Personal details	
Patient name	
Date of birth	

Addendum database Part 6 Follow-up post transport

Section finished?	☐
Patient is alive?	◉ Yes ○ No
ABG	☐ Data unknown pH PaO2 *kPa* *mmHg* PaCO2 *kPa* *mmHg* Lactat *mmol/L*
Not normal values	Hb *unit 1* *unit 2*
Intubation	☐
CPR	☐
Others	
Planned intervention	○ PTCA ○ Assist device ○ TIPPS ○ Operation ○ Others ○ None
Time of intervention	
Neurological status	
Pupil reaction	Left ○ Yes ○ No Right ○ Yes

	○ No
Pupil size	Left ○ Normal ○ Wide Right ○ Normal ○ Wide
Cardiac/hemodynamic status	
Rhythm	Frequency
Vasoactive medication	Systolic BP Diastolic BP
Pulmonary status	
SpO2	☐ Not measurable/unknown
Breathing frequency	
Ventilation	*Not ventilated* *Noninvasive ventilation FiO2 (in percent)* *Noninvasive ventilation PeeP* *Noninvasive ventilation Minute Volume* *Invasive ventilation FiO2 (in percent)* *Invasive ventilation PeeP* *Invasive ventilation Minute Volume*
Nefrologic status	
Diuresis	○ Data unknown ○ > 0,5 ml/kg/h ○ < 0,5ml/kg/h ○ Anurie / CVVH
Chronic RF	☐

Laboratory findings

☐ Data unknown

Time of collection

Hb *unit 1* *unit 2*

Thrombocytes *unit 1* *unit 2*

K *unit 1* *unit 2*

aptt/INR *unit 1* *unit 2*

Bilirubin *unit 1* *unit 2*

BMJ Open

QUIT EMR trial: a prospective, observational, multicentre study to evaluate quality and 24 hours post transport morbidity of interhospital critical care transportation- study protocol

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QUIT EMR trial: a prospective, observational, multicenter study to evaluate quality and 24 hours post transport morbidity of interhospital transportation of critically ill patients - *study protocol*

Ulrich Strauch*, Dennis CJJ Bergmans*, Joachim Habers, Jochen Jansen***, Bjorn Winkens ****, Dirk J Veldman #, Paul MHJ Roekaerts*, Stefan K Beckers##**

Ulrich Strauch *Corresponding author*
Maastricht University Medical Centre+, Department of Intensive Care *
P. Debyelaan 25 PO Box 5800, 6202 AZ Maastricht (The Netherlands)
Phone: 0031433876385 E mail: u.strauch@mumc.nl

Dennis CJJ Bergmans Maastricht University Medical Centre+, Department of Intensive Care *
P. Debyelaan 25 PO Box 5800,6202 AZ Maastricht (The Netherlands)
E mail: d.bergmans@mumc.nl

Joachim Habers Emergency Medical Service district of Aachen**
Zollernstrasse 20, 52070 Aachen (Germany)
E mail : aelrd_staedteregion-aachen@web.de

Jochen Jansen Emergency Medical Service South Limburg***
Geleenbeeklaan 2, 6166 GR Geleen (The Netherlands)
E Mail: j.jansen@ggdzl.nl

Bjorn Winkens Maastricht University, Department of Methodology and Statistics****
CAPHRI School for Public Health and Primary Care
PO Box 616, 6200 Maastricht, The Netherlands
E Mail: bjorn.winkens@maastrichtuniversity.nl

Dirk JVeldman Maastricht University, MEMIC Center for data and information management #
P. Debyeplein 1, Postbus 616, 6200 MD Maastricht, The Netherlands
E Mail: d.veldman@maastrichtuniversity.nl

Paul MHJ Roekaerts Maastricht University Medical Centre+, Department of Intensive Care *
P. Debyelaan 25 PO Box 5800,6202 AZ Maastricht (The Netherlands)
E mail: p.roekaerts@mumc.nl

Stefan Beckers Emergency Medical Service, Fire Department, City of Aachen##
Stolberger Str. 155, 52068 Aachen (Germany)
and Department of Anaesthesiology, University Hospital RWTH Aachen,
Pauwelsst. 30, 52074 Aachen (Germany) ##
E Mail: aelr@mail.aachen.de

Abstract

Introduction

It is widely accepted that transportation of critically ill patients is high risk. Unfortunately, however there are currently no evidence based criteria with which to determine the quality of various interhospital transport systems and their impact on the outcomes for patients. We aim to rectify this, by assessing 2 scores which were developed in our hospital in a prospective, observational study. Primarily we will be examining the QUIT EMR score (Quality of interhospital critical care transportation in the Euregion Meuse-Rhine), which focuses on the quality of the transport system, and secondarily the SEMROS (Simplified EMR outcome score) which detects changes in patient's clinical condition in the 24 hours following their transportation.

Methods and Analysis

A web based application will be used to document around 150 pre-, intra-, and post transport items of each patient case.

To be included patients must be at least 18 year of age and have been supervised by a physician during an interhospital transport started in the study region.

The quality of the QUIT EMR score will be assessed by comparing 3 pre-defined levels of transport facilities; the high, medium, and low standards. Subsequently SEMROS will be used to determine the effect of transport quality on the morbidity 24 after transportation.

It is estimated that there will be roughly 3000 appropriate cases suitable for inclusion in this study per year. Cases shall be collected from April 1st 2015 until December 31st 2017.

Ethics and Dissemination

This trial was approved by the Ethics committees of the university hospitals of Maastricht (Netherlands) and Aachen (Germany). The study results will be published in a peer reviewed journal. Results of this study will determine if a prospective randomized trial involving patients of various categories being randomly assigned to different levels of transportation system shall be conducted.

Trial Registration: NTR4937

Keywords

Interhospital Transport, Mobile Intensive Care, Critical Care Transportation, Quality of critical care transportation

Study strengths and limitations

- Uniform web based registration of critically ill patient transport cases creates a unique database to be used in the assessment of 2 newly developed scoring systems which will be introduced in research and clinical practice.
- Outcomes of this prospective study will provide an international, multicenter focused evaluation of a clinically relevant quality monitoring score.
- With the use of a recently evaluated scoring system, this study will provide insight into the effects of different modes of transport on patient mortality 24 hours following transportation.
- Voluntary registration of transport data provided by transportation teams means that the possibility of registration bias cannot be excluded.
- Potential registration bias may be intensified by occasional unavailability of follow up data.

Introduction

It is widely accepted that transportation of critically ill patients is high risk, resulting in a significant rate of adverse events [1]. Patient safety can be compromised particularly during interhospital transportation as a result of lack of sophisticated resuscitation equipment or absence of sufficiently qualified staff [2 - 10]. Within the group of patients requiring interhospital transportation there are 2 subcategories; those necessitating urgent lifesaving intervention at an expert center, and those who are dependent on continuous Intensive Care Unit (ICU) therapy, including the use of extracorporeal devices. In daily practice in Germany and the Netherlands there are multiple varieties of ground ambulances available for use in transporting critically ill patients. These include standard ambulances, ICU ambulances, and Mobile Intensive Care Units/Intensivtransportwagen (MICU/ITW). Transportation teams usually include a paramedic and a physician, and teams working within a MICU/ITW often include a physician and nurse trained and experienced with ICU therapy. Typically, the dispatch centre coordinates the transportation, and the type of mode used is often based on the urgency and severity of the patient's illness.

Nonstop provision of interhospital transport demands a large amount of resources, however it has been observed that regional cooperation and support has been useful in making this more manageable. A group within the Euregion Meuse Rhine formed over the Dutch-German border in order to attempt to develop a plan of cooperation to improve emergency and MICU/ITW transportation. Substantial differences in organization and legislation regarding interhospital transport in the different countries of the project group were discovered, prompting the group to express the necessity for development of a uniform manner of measuring quality of transport systems. Currently, parameters such as adverse event rate, short term mortality, and changes in SOFA score before and after transport are used to describe quality of transport systems [11-19]. To combat difficulties in determination of whether a deterioration of a patient's condition during or immediately after transport is attributable to aspects of the transportation, or due to the natural course of the disease [15], the project group has initiated the "Quality of interhospital critical care transportation in the Euregion Meuse-Rhine trial (QUIT EMR trial)".

The initial step of the trial was development of 2 scores; the QUIT EMR score (Quality of interhospital critical care transportation in the Euregion Meuse-Rhine), which focuses on the quality of the transport system, and SEMROS (Simplified EMR outcome score) which detects changes in patient's clinical condition in the 24 hours following their transportation. Scores can be both systematically and manually calculated.

Objectives

Primary Objective: To assess the QUIT EMR score by means of a prospective multicenter study in which 3 different transport systems, commonly used within the study region, are compared.
Hypothesis: The QUIT EMR score will be demonstrated as being reliable and accurate, and shall show that there is a difference in number and severity of adverse events between groups of patients transported with high, medium, or low standard ground transport systems (table 1).

	Minimum requirements of ambulance and equipment	***Minimum requirements of first team member***	***Minimum requirements of second team member***
System A (high)	*MICU/ITW*[1]	*Intensivist*[2]	*ICU nurse* *IC Paramedic*[3]
System B (medium)	*IC ambulance*[4]	*ICU Physician*[5]	*Paramedic*
System C (low)	*Standard Ambulance*	*Physician*	*Paramedic*

Table 1: Definitions of different levels of ground transport systems

1) *High volume ambulance equipped with: a boarding ramp, ICU ventilation equipment as well as standard ambulance equipment, a minimum of 6 infusion pumps, invasive monitoring equipment, the ability to reach the patient from all sides, the ability to transport patients with additional medical devices (such as ECMO, NO, IABP), back-up systems for ventilator/monitoring/defibrillation unit/ suction unit, and at least 6000L of oxygen (or 6000L of pressurized oxygen, if required by the particular ventilator system). The unit must also have a stand-alone capacity of at least 120 minutes.*
2) *Board certified Intensivist.*
3) *Paramedic with additional Intensive Care qualification.*
4) *Standard ambulance equipped with: standard ambulance equipment, an ICU transport ventilator, a minimum of 4 infusion pumps, invasive monitoring equipment, and 2000L of oxygen. The unit must also have a stand-alone capacity of at least 60 minutes.*
5) *FCCS or similarly trained physician with at least 6 months Intensive Care experience*

Secondary Objectives:

a) To assess whether transportation outcome (as determined by QUIT EMR score) influences 24-hour post transport morbidity (as determined by SEMROS).
Hypothesis: Negative transport outcome will lead to a higher 24-hour post transportation morbidity.

b) To examine if it is possible to identify and define characteristics which can be used in determination of the necessary transportation variety for a patient.
Hypothesis: It will be possible to identify and define characteristics which can be used in determination of the necessary transportation variety for a patient.

c) To identify predictive outcome parameters concerning 24-hour post transport mortality.
Hypothesis: Pre-transport parameters indicating 24-hour post transport mortality will be identified and defined.

Methods

Design

"Quality and efficacy of interhospital critical care transportation in the Euregion Meuse-Rhine" is an international, prospective, observational, multicenter cohort study. There will be no initiation of interventions, only analysis of anonymous data. The study is open for inclusion from April 1st2015 until December 31st 2017.

Population/Inclusion criteria

All cases included shall be of patients who are over 18 years of age and who undergo interhospital transportation within the MICU region of Maastricht (Netherlands), district of Aachen (Germany), City of Aachen (Germany), or district of Heinsberg (Germany). Current transportation data suggest that up to 3000 cases of interhospital transportations per year take place under direct supervision of a physician within the study region.

Study parameters

Around 150 pre-, intra-, and post transport parameters will be scored. Details of these data will be available in the extra file "web application". The largest registration categories include:

1 Demographics (patient, equipment, ambulance, and transportation team related)
2.1 Patient status obtained during the intake call
2.2 Patient status on arrival of transportation team
2.3 Patient status at the end of the transportation
3 Interventions performed by the transportation team
4 Adverse events
5 Dispatch center data
6 24-hours follow up

QUIT EMR and SEMROS score

The QUIT EMR Score is a dichotomized scoring system. A score of 1 indicates that there was no necessity for intervention by the transportation team, or that the transport team provided adequate interventions, and a score of 0 indicates that interventions from the transportation team were either insufficient or not performed despite indication. The applied algorithm focuses not only changes in physiologic parameters, but also combines changes with documented interventions being performed by the transport team. Used data can be found in the additional file “web application” under part 2.2, part 2.3, and part 3.

The QUIT EMR score has been assessed by means of score calculation of 100 transport charts of the Maastricht University Medical Centre+ (MUMC+) Mobile Intensive Care Unit (MICU). These scores were then subsequently dichotomized to 0 or 1 accordingly.

All transport charts were then also assessed and scored 1 (positive judgement) or 0 (negative judgement) by 4 specialists from MUMC+ (anesthesiologists and/or intensivists) experienced in interhospital transport. These specialist scores were calculated using the following criteria:

- Stable situation during transportation without intervention 1
- Stable situation with adequate intervention 1
- Unstable situation with adequate intervention 1
- Unstable situation or changes in crucial physiological parameters indicating necessary intervention without intervention or with inadequate intervention 0

Specialists were free to define whether a situation was stable or not as well as whether or not intervention was adequate. Finally, the QUIT EMR scores and the specialist scores were compared, and an agreement level between 84% and 92% was found, as well as an inter-observer level of agreement of 85.0% to 92.9%.

The Simplified EMR Outcome Score (SEMROS) is a dichotomized score, whereby 1 indicates that a patient’s status remained unchanged or was improved within 24 hours after transportation, and where 0 indicates that a patient’s condition deteriorated within the 24 hours following transportation. Data used for calculation of SEMROS is accessible in the web application additional files under parts 2.1 and 6.

Data used to assess this score were 110 cases of patient transportation towards MUMC+, with the use of a MICU. Of these 110 cases, 90 complete datasets were suitable for calculation of pre- and post-transport Sequential Organ failure score (SOFA score) [20] and SEMROS. The SOFA score differs from the SEMROS in that it requires multiple laboratory values, which in clinically practice may not always be available, for calculation. Using these 90 cases, an observed level of agreement between the SOFA score and SEMROS of 88.9% was calculated.

The following definitions were used regarding the SOFA score: 1 (positive outcome) or 0 (negative outcome)

- SOFA score pre-transport lower than SOFA score post transport 0
- SOFA score pre-transport equal to SOFA score post transport 1
- SOFA score pre-transport higher than SOFA score post transport 1

A web based application for registration of necessary data has been developed by the center for data and information management of Maastricht University. Specially designed algorithms for automatic calculation of the two scores will be implemented in the study web application.

Data Registration

Web application

A web application has been developed to facilitate data registration. Level 1 users (medical staff present during patient transportation) will perform the initial registration, while follow-up data will be obtained by level 2 users (research staff from the participating organizations). An audit layer of the application will track and store information of all changes.

Level 1 users

For each case, the physician concerned will document in additional files 1 through 4 of the web application: a standardized set of demographic data, transportation system information, clinical data from at the time of the intake call, time of arrival of the transportation team at the patient and at time at the end of transportation, interventions performed by the transportation team, and adverse events. The web application (URL: www.eumic.eu) will be accessible through general username/password combinations. Each participating hospital will receive one unique username/password combination. Alternatively, access will be possible using a global username/password combination for each ambulance, based on the cap codes of the vehicles.

Once a case is finalized, the level 1 user will have the opportunity to request a PDF file of the documented data. Furthermore, a link will become available for the user to send a comment via email directly to the coordinating investigator or to the technical support staff of MUMC+.

There will be no registration of personal data such as name or date of birth to ensure patient privacy. The unique transport code given by the responsible dispatch center will be noted.

Level 2 users

24 hours after completion of patient transportation, further details will be obtained by level 2 users directly contacting the ICU of the receiving hospital. These users will be able to access and ultimately complete data sets from their area of authorization in the web based application with use of personalized username/password combinations. These users will be unable to alter any data entered previously by level 1 workers.

The procedure for level 2 users will be as follows:

a) Login to the database.
b) Observe overview of transportation cases not yet finalized by level 1 users within their access region.
c) Enter transport codes and alarm times from patient charts.
d) Contact the responsible dispatch center to obtain details of the patient (name, date of birth).
e) 24 hours after patient transportation, contact the ICU of the accepting hospital for details of the patient's status, and add these details to the system.
f) Once registration of all details is complete, finalize the case.

Following finalization of a case, users will have no further access to review the input data.

Level 3 users

Level 3 users, typically the regional study coordinators, will perform weekly check-ups of data reliability within the system using their personalized username/password combinations. A data set must be authorized by a level 3 user before it can be included in the final database. Unauthorized cases will be stored in a separate database.

The level 3 users will have overviews of complete and incomplete cases. Incomplete cases will be opened and revised by the level 3 user, who will be authorized to add missing information or to overwrite incorrect data. If the registered data have missing values which do not allow calculation of at least the QUIT EMR score, the dataset will not be admitted to the final database.

Furthermore, this small group of the highest level of users will be authorized to view all open cases, as well as those which are stored in the complete cases and incomplete cases databases.

After approval of a case for the final database, case identification data will be erased to ensure that the data in the central database are entirely anonymous.

Technical control

Alongside the groups of medical administrators, continuous technical control and data safety monitoring will be carried out by a technical administrator group from Maastricht University. The work of this group will be independent from that of the medical administrators.

Access to the database will only be possible after authorization by the coordinating investigator and the technical control staff.

Statistical Analysis

Measured parameters will be represented by mean (SD) or median (interquartile range, IQR) when variables are numerical, and by number (%) when variables are categorical. All analyses will be performed using IBM SPSS Statistics for Windows. P-values ≤ 0.05 will be considered statistically significant. Where appropriate, Independent sample Mann-Whitney U tests or t-tests will be used to assess changes in QUIT EMR score, changes in SEMROS, or differences in the number of interventions performed between groups of patients who were transported with high or low/medium

standard ground transportation systems. Differences in proportion of adverse events between the levels of transportation systems will be tested using Chi-square or Fisher's exact test. To account for potential confounders, linear and logistic regression analysis will be performed for numerical and binary outcomes respectively, in a model including groups of high and low/medium standard ground transportation systems and all baseline variables known to be related to the outcome. Logistic regression analysis will be performed in order to be able to determine which pre-transport variable is an independent risk factor for 24 hours post transportation mortality.

Data mining to identify impact of other potentially important variables beside type of transportation system shall be performed where appropriate.

Ethics and dissemination

The study will be conducted in line with the principles of the Declaration of Helsinki amended by the WMA General Assembly in October 2013. Only anonymous data from cases of adult patients undergoing physician supervised interhospital transportation will be used for analysis. As no interventions as part of the study shall be performed, it was decided by the Medical Research Ethics Committees (METC) of the university hospitals in Maastricht (Netherlands) and Aachen (Germany) that obtaining informed consent from patients was unnecessary. The study is registered in the Netherlands National Trial Registration: NTR4937. The current data pertaining to the assessment process of both scores are in preparation for publication. Results of this study will determine if a prospective randomized trial involving patients of various categories being randomly assigned to different levels of transportation system shall be conducted.

Discussion

Outcomes of this study will be useful for future research, by means of assessing a quality monitoring scoring system, and clinically relevant, by taking into consideration the clinical outcomes of patients who were transported with different varieties of vehicles. Therefore, we introduce a clinical, laboratory value independent, score.

In the on-going discussion of centralization of health care facilities, a reliable, efficient, and proven safe transport modality which meets the individual patient needs is regarded as the key factor for success in future developments in this field [21-25].

In clinical practice, the logistic and financial burden of 24/7 provision of transportation facilities remains high. To reduce these pressures, close cooperation within a regional network which prioritizes monitoring of quality, such as the cross-border collaboration, the Euregion Meuse Rhine, is necessary. Simply evaluating the number of critical events or the number of intervention requiring physiological parameter changes during transportation cases cannot provide reliable assessment of the quality of a transportation system [15]. This is because such events can occur as a result of the natural course of a patient's illness. To overcome this, the QUIT EMR score combines performed interventions of the transportation team with changes in physiologic status of the patient. Therefore, events such as a dramatic decrease in blood pressure requiring intervention, which is then adequately treated would not result in a negative judgement. To the best of our knowledge, such an approach to determine quality of interhospital transportation has yet to be described.

Secondarily this study examines the possibility of identifying clinically relevant factors which might potentially aid in prediction of 24-hour post-transportation morbidity or mortality.

Currently available and validated scoring systems, such as the SOFA score, require laboratory values which are not always available at the time of transportation. The scoring systems assessed within this study provide a means to calculate the likelihood that a patient's condition will be worse 24 hours after they have been transported, when laboratory values are unavailable.

Moreover, it is expected that sufficient information will be collected to create a new, concrete hypothesis for a randomized controlled non-inferiority trial examining the difference in outcomes of transportation of particular patient categories with either an ICU ambulance or MICU/ITW. This research can be conducted with use of the scoring systems for quality and outcome monitoring. Such research would provide insight into how best transportation resources can be utilized.

Certainly, the study is not without limitations. Potentially the greatest limitation is that registration of transport data is voluntary, which may result in a registration bias. Moreover, the registration of transportation data is completed by the concerned transportation team, meaning that no online data are available. In an attempt to create an appropriate compromise between optimizing data collected, and keeping the registration procedure practical and manageable, it is possible that some aspects of the registration process are unclear which could result in personal interpretation, and discrepancies within collected data. Finally, there is a high logistic burden involved in following up all data, therefore it might not always be available for all cases.

In conclusion, because it is important that resources are efficiently utilized, there is a necessity for reliable pre-transportation analysis of an individual patient's transportation needs, in combination with standardized quality monitoring. It is hypothesized that outcomes of this study will be able to be used to help create a more evidence based organization of interhospital transportation of critically ill patients.

List of abbreviations

AE	Adverse event
ECMO	Extracorporeal membrane oxygenation
EMS	Emergency Medical Service
EUMIC	Euregional Mobile Intensive Care
FCCS	Fundamental Critical Care Support
IABP	Intra-aortic balloon pump
ICU	Intensive Care Unit
METC	Medisch-Etische Toetsings Commissie
MICU	Mobile Intensive Care Unit
MUMC+	Maastricht University Medical Centre+
NO	Nitric Oxide
SEMROS	Simplified Euregion Meuse Rhine Outcome Score
SD	Standard deviation
SOFA	Sequential Organ Failure Assessment
QUIT EMR	Quality and efficacy of interhospital critical care transport in Euregion Meuse-Rhine

Conflicitng interests

The authors declare that they have no conflicting interests.

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Authors' contribution

US	coordinating investigator, involved in planning, drafting the original manuscript.
DB	involvement in study planning, manuscript revision.
JH	involvement in study planning, manuscript revision.
JJ	involvement in study planning, manuscript revision.
BW	involvement in study planning, manuscript revision.
DV	involvement in study planning, manuscript revision, and creation of the web application.
PR	involvement in study planning, manuscript revision.
SB	involvement in study planning, manuscript revision, providing final approval.

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Addendum/database Part 1 demographics

Part 1 General demographics

Section finished?	☐
Date	
Time of alarm	○ 08.00-17.00h ○ 17.00-23.00h ○ 23.00-08.00h
Transport unit	○ MICU / ITW ○ IC ambulance ○ Standard ambulance ○ Helicopter
Transport team	
First member	☐ EMT ☐ Intensivist / Anesthesiologist ☐ Internist ☐ Surgeon ☐ First aid specialist (SEH-arts) ☐ Trainee ICU / anesthesia ☐ Trainee internal medicine ☐ Trainee surgery ☐ EMS physician ☐ Others, namely
Second member	○ ICU nurse ○ Paramedic

	○ Others, namely
Third member	○ ICU nurse ○ Paramedic ○ Driver ○ Others, namely
Transport number (code)	
Responsible dispatch center	○ Aachen ○ Noord Limburg ○ Zuid Limburg ○ Zuidoost Brabant
Departing hospital	
Receiving hospital	
Year of birth (yyyy)	
Length (cm)	
Body weight (kg)	
Sex	○ Male ○ Female
Reason of transfer	○ Treatment in expertise centre ○ No ICU / IIMC bed available

- Return to patient's region
- Follow up treatment
- Others

Treatment in expertise centre

- Cardio vascular surgery
- Cardiologie
- General surgery
- ICU
- Neurosurgery
- Others, namely

Requested urgency of transport

- < 30 min
- 30-120 min
- > 120 min

Accomplished within urgency timespan?

- Yes
- No

Major diagnosis
more than one option possible

- Acute kidney injury
- Acute liver failure
- Cardiac diagnosis
- Multitrauma
- Neurological diagnosis (except neurotrauma)
- Neurotrauma
- Pulmonary diagnosis
- Sepsis
- Status after expertise treatment

	☐ Others, namely
Additional diagnosis *more than one option possible*	☐ Multitrauma ☐ Neurotrauma ☐ Scepsis ☐ Not applicable/None
Intervention planned within 24 hours *more than one option possible*	☐ Assist device ☐ Operation ☐ PTCA ☐ TIPPS ☐ Others, namely

Addendum Database Part 2.1 Patient status intake call

Section finished? ☐

Neurological status

- ○ Altered
- ○ Awake
- ◉ Comateus
- ○ Sedated

Pupil reaction

Left
- ○ Yes
- ○ No

Right
- ○ Yes
- ○ No

Pupil size

Left
- ○ Normal
- ○ Wide

Right
- ○ Normal
- ○ Wide

Cardiac/hemodynamic status

Rhythm
- ○ AF
- ○ Pacemaker
- ○ SR
- ○ Other

Frequency

Vasoactive medication
- ○ No iv vasoactive medication
- ○ 1 iv vasoactive medication
- ○ > 1 iv vasoactive medication

Systolic BP

Diastolic BP

Pulmonary status

SpO2 ☐ Not measurable/unknown

Breathing frequency

Ventilation

- Not ventilated
- Noninvasive ventilation
- Invasive ventilation

Not ventilated

- No oxygen
- Nasal oxygen
- Oxygen mask

Noninvasive ventilation FiO2 (in percent)

Noninvasive ventilation PeeP

Noninvasive ventilation Minute Volume

Invasive ventilation FiO2 (in percent)

Invasive ventilation PeeP

Invasive ventilation Minute Volume

ABG

☐ Data unknown

pH

PaO2 *kPa* *mmHg*

PaCO2 *kPa* *mmHg*

Lactat *mmol/L*

Nefrologic status

Diuresis

- Data unknown
- > 0,5 ml/kg/h
- < 0,5ml/kg/h
- Anurie / CVVH

Chronic RF	☐
Laboratory findings	☐ Data unknown
	Hb ____ *unit 1* ____ *unit 2*
	Thrombocytes ____ *unit 1* ____ *unit 2*
	K ____ *unit 1* ____ *unit 2*
	aptt/INR ____ *unit 1* ____ *unit 2*
	Bilirubin ____ *unit 1* ____ *unit 2*
Others	
Additional medical devices *more than one option possible*	☐ ECMO V-A ☐ ECMO V-A +IABP ☐ ECMO V-V ☐ IABP ☐ NO ☐ EECC02 ☐ Others, namely
Situation stable within last 2 hours before transport	○ Yes ○ No

Addendum database Part 2.2 Patient status at arrival

Section finished?	☐
Changes in status	◉ Yes ○ No
ABG measured within last 30 minutes	☐
ABG	☐ Data unknown pH PaO2 *kPa* *mmHg* PaCO2 *kPa* *mmHg* Lactat *mmol/L*
Neurological status	◉ Altered ○ Awake ○ Comateus ○ Sedated
Pupil reaction	Left ◉ Yes ○ No Right ◉ Yes ○ No
Pupil size	Left ◉ Normal ○ Wide Right ◉ Normal ○ Wide
Cardiac/hemodynamic status	

Rhythm	○ AF ○ Pacemaker ○ SR ◉ Other Frequency
Vasoactive medication	◉ No iv vasoactive medication ○ 1 iv vasoactive medication ○ > 1 iv vasoactive medication
	Systolic BP Diastolic BP
Pulmonary status	
SpO2	☐ Not measurable/unknown
Breathing frequency	
Ventilation	◉ Not ventilated ○ Noninvasive ventilation ○ Invasive ventilation
Not ventilated	○ No oxygen ○ Nasal oxygen ○ Oxygen mask
Noninvasive ventilation FiO2 (in percent)	
Noninvasive ventilation PeeP	
Noninvasive ventilation Minute Volume	
Invasive ventilation FiO2 (in percent)	
Invasive ventilation PeeP	
Invasive ventilation Minute Volume	

Other changes in status

Addendum database Part 2.3 Patient status end of transport

Section finished?	☐
Changes in status	◉ Yes ○ No
ABG measured within last 30 minutes	☐
ABG	☐ Data unknown pH ____ PaO2 ____ *kPa* ____ *mmHg* PaCO2 ____ *kPa* ____ *mmHg* Lactat ____ *mmol/L*
Neurological status	○ Altered ○ Awake ○ Comateus ◉ Sedated
Pupil reaction	Left ◉ Yes ○ No Right ◉ Yes ○ No
Pupil size	Left ◉ Normal ○ Wide Right ◉ Normal

	○ Wide
Cardiac/hemodynamic status	
Rhythm	○ AF ○ Pacemaker ○ SR ◉ Other Frequency
Vasoactive medication	◉ No iv vasoactive medication ○ 1 iv vasoactive medication ○ > 1 iv vasoactive medication
	Systolic BP Diastolic BP
Pulmonary status	
SpO2	☐ Not measurable/unknown
Breathing frequency	
Ventilation	◉ Not ventilated ○ Noninvasive ventilation ○ Invasive ventilation
	Not ventilated ○ No oxygen ○ Nasal oxygen ○ Oxygen mask *Noninvasive ventilation FiO2 (in percent)* *Noninvasive ventilation PeeP* *Noninvasive ventilation Minute Volume* *Invasive ventilation FiO2 (in percent)*

	Invasive ventilation PeeP	
	Invasive ventilation Minute Volume	
Other changes in status		

Addendum database Part 3 Transport team interventions

Section finished? ☐

Intervention done
- ◉ Yes
- ○ No

Situation stable during transport
- ◉ Yes
- ○ No

A (Airway)

Intubation ☐

Alternative airway ☐

Others

B (Breathing)

Changes in ventilator settings

☐ PeeP
- ○ Increase
- ○ Decrease

☐ Tidal volume/ inspiratory pressure
- ○ Increase
- ○ Decrease

☐ FiO2 (in percent)
- ○ Increase

Decrease

C (Circulation)

CPR

Volume therapy

No additional volume

500 ml extra volume

500-1000 ml extra volume

> 1000 ml extra volume

Bleeding control

Others

D (Disability)

Medication

Changes in vasoactive medication

Increase in dosage

Decrease in dosage

IV Bolus application

more than one option possible

Adrenaline

Analgetics

Atropine

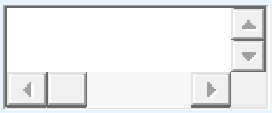
Muscle relaxants

Sedatives

Others, namely

E (Environmental Exposure)

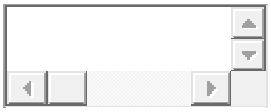
Namely



Other

more than one option possible

- ☐ IABP
- ☐ ECMO
- ☐ Others, namely



Addendum database Part 4 Transport related adverse events

Section finished? ☐

Adverse events

◉ Yes

No

Technical errors

Ambulance

Description

Outcome

Trolley

Ventilator

Infusion pump

Defibrillator

Suction unit

Monitoring

Others

Patient / treatment / team related events

SPO2 < 90%

Q1. Immediate Intervention?

Yes

No

Q2. Result

Recovery within 60 seconds

No recovery within 60 seconds

Q3. Outcome end of transport

Recovery

No recovery

Mean RR < 60 or RR syst < 80

New tachycardia (HF > 120/min)

☐ New bradycardia (HF < 40/min)

☐ VF/VT

☐ Asystolie/PEA

☐ Unintended extubation

Q1. Result

◉ Difficult airway

○ Direct reintubation

○ Oxygen supply

Q2. Outcome end of transport

◉ No SPO2 < 85%

○ SPO2 < 85% < 2 min

○ SPO2 < 85% > 2 min

☐ Loss IV access art lijn?

Q1. Immediate Intervention?

◉ Yes

○ No

Q2. Result

◉ CVC

○ Peripheral IV line

☐ Medication related complication

more than one option possible

☐ Dose error

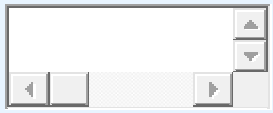
☐ Side effects

☐ Wrong access route

☐ Wrong medicine

☐ Others, namely

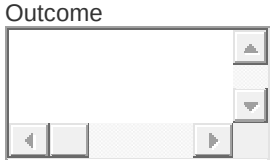
☐ Communication related complication



Others

Description

Outcome



Addendum database Part 5 Data dispatch centre

Section finished?	☐
Time of alarm	
Time of departure 1	
Time of arrival 1	
Time of departure 2	
Time of arrival 2	
Time end of transport	
Personal details	
Patient name	
Date of birth	

Addendum database Part 6 Follow-up post transport

Section finished?	☐
Patient is alive?	◉ Yes ○ No
ABG	☐ Data unknown pH PaO2 *kPa* *mmHg* PaCO2 *kPa* *mmHg* Lactat *mmol/L*
Not normal values	Hb *unit 1* *unit 2*
Intubation	☐
CPR	☐
Others	
Planned intervention	○ PTCA ○ Assist device ○ TIPPS ○ Operation ○ Others ○ None
Time of intervention	
Neurological status	
Pupil reaction	Left ○ Yes ○ No Right ○ Yes

	○ No
Pupil size	Left ○ Normal ○ Wide Right ○ Normal ○ Wide
Cardiac/hemodynamic status	
Rhythm	Frequency
Vasoactive medication	Systolic BP Diastolic BP
Pulmonary status	
SpO2	☐ Not measurable/unknown
Breathing frequency	
Ventilation	*Not ventilated* *Noninvasive ventilation FiO2 (in percent)* *Noninvasive ventilation PeeP* *Noninvasive ventilation Minute Volume* *Invasive ventilation FiO2 (in percent)* *Invasive ventilation PeeP* *Invasive ventilation Minute Volume*
Nefrologic status	
Diuresis	○ Data unknown ○ > 0,5 ml/kg/h ○ < 0,5ml/kg/h ○ Anurie / CVVH
Chronic RF	☐

Laboratory findings

☐ Data unknown

Time of collection

Hb *unit 1* *unit 2*

Thrombocytes *unit 1* *unit 2*

K *unit 1* *unit 2*

aptt/INR *unit 1* *unit 2*

Bilirubin *unit 1* *unit 2*