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

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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 Quality of interhospital critical care transportation in the Euregion Meuse-Rhine (QUIT EMR) score, which focuses on the quality of the transport system, and secondarily the SEMROS (Simplified EMR outcome score) which detects changes in the 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 pretransport, intratransport and post-transport items of each patient case.

To be included, patients must be at least 18-years of age and should have been supervised by a physician during an interhospital transport which was started in the study region.

The quality of the QUIT EMR score will be assessed by comparing 3 predefined 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 hours 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 1 April 2015 until 31 December 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 randomised trial involving patients of various categories being randomly assigned to different levels of transportation system shall be conducted.

Strengths and limitations of this study

- Uniform web-based registration of critically ill patient transport cases creates a unique database to be used in the assessment of two newly developed scoring systems which will be introduced in research and clinical practice.
- Outcomes of this prospective study will provide an international multicentre 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.

Trial registration number: NTR4937.

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 a lack of sophisticated resuscitation equipment or absence of sufficiently qualified staff.[2–10] Within the group of patients requiring interhospital transportation, there are two subcategories: those necessitating urgent lifesaving intervention at an expert centre, and those who are dependent on

Table 1 Definitions of different levels of ground transport systems

	Minimum requirements of ambulance and equipment	Minimum requirements of first team member	Minimum requirements of second team member
System A (high)	MICU/ITW*	Intensivist†	ICU nurse IC paramedic‡
System B (medium)	IC ambulance§	ICU physician¶	Paramedic
System C (low)	Standard ambulance	Physician	Paramedic

*High volume ambulance equipped with: a boarding ramp, ICU ventilation equipment as well as standard ambulance equipment, a minimum of six 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 a ventilator/monitoring/defibrillation unit/suction unit and at least 6000 L of oxygen (or 6000 L of pressurised oxygen, if required by the particular ventilator system). The unit must also have a stand-alone capacity of at least 120 min.
†Board certified Intensivist.
‡Paramedic with additional intensive care qualification.
§Standard ambulance equipped with: a standard ambulance equipment, an ICU transport ventilator, a minimum of four infusion pumps, invasive monitoring equipment and 2000 L of oxygen. The unit must also have a stand-alone capacity of at least 60 min.
¶FCCS or a similarly trained physician with at least 6 months intensive care experience.
ECMO, extracorporeal membrane oxygenation; FCCS, fundamental critical care support; IABP, intra-aortic balloon pump; IC, intensive care; ICU, intensive care unit; ITW, Intensivtransportwagen; MICU, Mobile Intensive Care Units; NO, nitric oxide.

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 an 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.

Non-stop 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 (EMR) was 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 organisation 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 Sequential Organ Failure Assessment (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 which focuses on the quality of the transport system and SEMROS (Simplified EMR outcome score), which detects changes in the 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 multicentre study in which three 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).
Secondary Objectives:

A. To assess whether transportation outcome (as determined by the 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: Pretransport 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 multicentre cohort study. There will be no initiation of interventions, only analysis of anonymous data. The study is open for inclusion from 1 April 2015 until 31 December 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 the direct supervision of a physician within the study region.

Study parameters

Around 150 pretransport, intratransport 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. – Patient status obtained during the intake call
   – Patient status on arrival of the transportation team
   – Patient status at the end of the transportation
3. Interventions performed by the transportation team
4. Adverse events
5. Dispatch centre data
6. 24 hours follow-up

QUIT EMR and SEMROS score

The QUIT EMR Score is a dichotomised 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 on changes in physiological parameters, and 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 dichotomised to 0 or 1 accordingly.

All transport charts were then also assessed and scored 1 (positive judgement) or 0 (negative judgement) by four specialists from MUMC+ (anaesthesiologists 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 interobserver level of agreement of 85–92%.

The Simplified EMR Outcome Score (SEMROS) is a dichotomised score, where 1 indicates that a patient's status remained unchanged or was improved within 24 hours after transportation, and 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 an MICU. Of these 110 cases, 90 complete data sets were suitable for calculation of pretransport and post-transport SOFA score[20] and SEMROS. The SOFA score differs from 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 pretransport lower than SOFA score post-transport 0
- SOFA score pretransport equal to SOFA score post-transport 1
- SOFA score pretransport 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 organisations). 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 standardised set of demographic data, transportation system information, clinical data from 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: http://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 finalised, the level 1 user will have the opportunity to request a portable document format 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 centre will be noted.

Level 2 users

Twenty-four 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 authorisation in the web-based application with the use of personalised 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 the overview of transportation cases not yet finalised by level 1 users within their access region.
C. Enter transport codes and alarm times from patient charts.
D. Contact the responsible dispatch centre to obtain details of the patient (name, date of birth).
E. Twenty-four 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, finalise the case.

Following finalisation 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 personalised username/password combinations. A data set must be authorised by a level 3 user before it can be included in the final database. Unauthorised 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 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 data set will not be admitted to the final database.

Furthermore, this small group of the highest level of users will be authorised 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 authorisation by the coordinating investigator and the technical control staff.

Statistical analysis

Measured parameters will be represented by mean (SD) or median (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$\leq$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 the 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 χ^2 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 pretransport variable is an independent risk factor for 24 hours post-transportation mortality.

Data mining to identify the impact of other potentially important variables besides 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. 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 randomised trial involving patients of various categories being randomly assigned to different levels of the 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 score, laboratory value independent.

In the ongoing discussion of centralisation of healthcare 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 prioritises monitoring of quality, such as the cross-border collaboration, the EMR, is necessary.

Simply evaluating the number of critical events or the number of interventions 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 physiological 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 randomised 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 the use of scoring systems for quality and outcome monitoring. Such research would provide insight into how best transportation resources can be used.

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 optimising 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, since it is important that resources are efficiently used, there is a necessity for reliable pretransportation analysis of an individual patient's transportation needs, in combination with standardised quality monitoring. It is hypothesised that outcomes of this study will be able to be used to help create a more evidence-based organisation of interhospital transportation of critically ill patients.

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Ethics approval Ethics committee of UNiversity Medical Centre Maastricht and UNiversity Hospital of Aachen.

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