Defining core data for continuous benchmarking in pre-hospital critical care

by

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Without data you're just another person with an opinion

W. Edwards Deming

Scientific environment

This PhD project is the result of cooperation between several institutions.

The work started in collaboration with my first principal supervisor, Professor Hans Morten Lossius at University of Stavanger and Norwegian Air Ambulance Foundation. Due to practical challenges the role as principal supervisor was changed to Assoc. Professor Marius Rehn from University of Stavanger and Norwegian Air Ambulance Foundation in 2015. My co-supervisors have been Dr. Andreas Jørstad Krüger at Department of Emergency Medicine and Pre-Hospital Services at St. Olav's Hospital, Trondheim and Dr. Kjetil Gorseth Ringdal at Department of Anaesthesiology at Vestfold Hospital Trust, Tønsberg. Professor Jo Røislien from University of Stavanger and Norwegian Air Ambulance Foundation provided statistical supervision and advice.

The studies have been carried out at Stavanger University Hospital and the Norwegian Air Ambulance bases in Stavanger, Bergen, Trondheim and Ålesund. We have also collaborated with the Helicopter Emergency Medical Services (HEMS) in Finland (FinnHEMS).

The Research Department at Stavanger University Hospital has provided the necessary research facilities at "Forskningens Hus" and "Forskertua". I have been affiliated to the Faculty of Health Sciences at the University of Stavanger (UiS).

I have received financial support for this project as an employee at the Department of Research, Norwegian Air Ambulance Foundation, Oslo.

Preface with acknowledgements

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Summary of papers

The aim of medical research is to improve patient care through evidence-based practice. Currently, the evidence base in physician-staffed emergency medical services (p-EMS) is weak and we remain uncertain for which patients p-EMS assistance is essential to and for which patients p-EMS is not needed. To increase the evidence base of p-EMS and to evaluate its potential effects, high quality data is pivotal. Currently, data is not reported uniformly, thereby complicating research. Furthermore, we should make better use of routinely collected data as these are readily available, thereby facilitating research.

The aim of this thesis was to increase the quality of routinely reported data in p-EMS by focusing on accuracy and completeness. We did this through the following objectives:

1. Explore the feasibility of collecting template data according to a predefined template

2. Explore whether pre-hospital physicians can score a reliable pre-event American Society of Anesthesiologists Physical Scale (ASA-PS) on-scene

3. Describe the quality of reported Glasgow Coma Score (GCS) and Systolic Blood Pressure (SBP) data in studies depicting p-EMS

4. Revise and update a template for reporting in p-EMS

We conducted four studies; one feasibility study, one prospective observational study, one systematic literature review and one qualitative consensus project. Accuracy and completeness are two important attributes describing quality in medical research. Without accurate data, research will be inaccurate and erroneous conclusions can be drawn. Furthermore, high completeness rates are always preferable to incomplete data.

Based on the four studies we can conclude that the use of a template is feasible in p-EMS, that the quality of reported GCS and SBP is variable and that a reliable pre-event ASA-PS can be scored on-scene. We also created an updated template for reporting in p-EMS.

The findings are important because highlighting the varying quality of reporting in p-EMS may increase awareness which may further increase both accuracy and completeness. Furthermore, we argue for incorporation of a full pre-event ASA-PS when reporting from p-EMS, thereby enabling us to take comorbidity into account in p-EMS research. By reporting according to the updated template, we may, in the future, enable comparisons and further development of p-EMS.

List of papers

This thesis is based on the following papers:

I. Tønsager K, Rehn M, Ringdal KG, Lossius HM, Virkkunen I, Østerås Ø, Røislien J, Krüger AJ; *Collecting core data in physician-staffed pre-hospital helicopter emergency medical services using a consensus-based template: international multicentre feasibility study in Finland and Norway.* BMC Health Serv Res. 2019 Mar 8;19(1):151.

II. Tønsager K, Rehn M, Krüger AJ, Røislien J, Ringdal KG; *Assignment of pre-event ASA physical status classification by pre-hospital physicians: a prospective inter-rater reliability study.* BMC Anesthesiol. Jul 9;20(1):167.

III. Tønsager K, Krüger AJ, Ringdal KG, Rehn M; *Data quality of Glasgow Coma Scale and Systolic Blood Pressure in scientific studies involving physician-staffed emergency medical services: systematic review.* Acta Anaesthesiol Scand. 2020 Aug;64(7):888-909.

IV. Tønsager K, Krüger AJ, Ringdal KG, Rehn M and the P-EMS Template Collaborating Group; *Template for documenting and reporting data in physician-staffed pre-hospital services: a consensus-based update.* Scand J Trauma Resusc Emerg Med. 2020 Apr 3;28(1):25.

Abbreviations

κ_w	–	Quadratic weighted Cohen's kappa
AD	–	Anno Domini
ASA-PS	–	American Society of Anesthesiologists Physical Scale
CPR	–	Cardiopulmonary Resuscitation
DC	–	Defibrillator Cardioversion
ECG	–	Electrocardiogram
ECMO	–	Extracorporeal Membrane Oxygenation
ED	–	Emergency Department
EMS	–	Emergency Medical Services
EU	–	European Union
FinnHEMS	–	Finland's Helicopter Emergency Medical Services
GCS	–	Glasgow Coma Scale
GDPR	–	General Data Protection Regulation
GRRAS	–	Guidelines for Reporting Reliability and Agreement Studies
HEMS	–	Helicopter Emergency Medical Service
IDoc	–	In-hospital physician
LAD artery	–	Left Anterior Descending artery
MEES	–	Mainz Emergency Evaluation Score
NAAF	–	The Norwegian Air Ambulance Foundation
NGT	–	Nominal Group Technique
OR	–	Odds Ratio
P-Doc	–	Pre-hospital physician
P-EMS	–	Physician-staffed Emergency Medical Services
P-HEMS	–	Physician-staffed Helicopter Emergency Medical Services

PICO	–	Population Intervention Comparison Outcome
PRISMA	–	Preferred Reporting Items for Systematic reviews and Meta-Analyses
RCT	–	Randomized Controlled Trial
REBOA	–	Resuscitative Endovascular Balloon Occlusion of the Aorta
RECORD	–	REporting of studies Conducted using Observational Routinely collected Data
REK	–	Regional Committee for Medical and Health Research Ethics
RTS	–	Revised Trauma Score
SBP	–	Systolic Blood Pressure
SQUIRE	–	Standards for QUality Improvement Reporting Excellence
STEMI	–	ST-Elevation Myocardial Infarction
STROBE	–	STrengthening the Reporting of OBservational studies in Epidemiology
TBI	–	Traumatic Brain Injury
US	–	United States
WHO	–	World Health Organization

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1 Introduction

1.1 General introduction

Pre-hospital emergency medical services (EMS) are heterogeneously implemented through the world. EMS systems range from simple systems offering basic care to highly specialized systems providing critical care on-scene [1-6]. There is a continuous demand on all pre-hospital care, carrying an impetus to continuously strive for optimal resource expenditure. Accordingly, it is essential to early identify the appropriate level of pre-hospital care for each patient. Furthermore, there is an ongoing process of centralization of critical care for specific diseases in developed countries [7]. This has led to an increased demand for high-quality EMS because specialized hospital resources are only available at certain locations. EMS must increasingly be able to triage patients to the correct level of care and provide high quality treatment en-route. Also, centralization of hospital care increases the need for inter-facility transports, requiring high-quality EMS for secure patient transfer. In Europe and Australasia, pre-hospital physician-staffed emergency medical services (p-EMS) are common [1, 2]. These high-quality services are particularly resource demanding and we should therefore have extensive knowledge of their effects.

1.2 Development of Helicopter Emergency Medical Services (HEMS)

Transport of patients has been reported since around 900 AD when horse carriages were used to transport psychiatric patients. Emergency medical transports originates from the need of ferrying wounded soldiers to hospitals during war times [8]. The first known record of an emergency ambulance transport took place in 1487 by Spanish forces during the siege of Málaga. Modern EMS is said to have started with Napoleon's chief surgeon, Dominique Jean Larrey, who during the 17th century

acknowledged the importance of rapid transport of wounded soldiers to surgical care [9]. During the Civil War (1861-1865) in the United States (US), the Union Army developed an organized system to evacuate soldiers from the field [10]. Lessons learned during the Civil War were applied as civilian EMS systems formed in the US during the late 1800s.

In 1938, an experienced German trauma surgeon stated that "It is not the emergency patient who should be taken to the hospital to be seen by the doctor, but the hospital doctor should go out and see and treat the emergency patient at the scene of an accident" [11]. This has since been referred to as the beginning of p-EMS.

The first patient transport by air took place in 1870, when 160 wounded French soldiers from Paris were evacuated by hot air balloons [12]. Helicopters for evacuation were introduced during the World War II, where helicopters used their winch to rescue downed pilots from the jungle. To be evacuated, the pilots had to be able to connect themselves to the winch and the method was thus poorly suited for severely injured persons [13]. The first reported successful trauma evacuation by helicopter took place in the jungle of Burma in 1945 [8]. The operation took two weeks to complete.

The use of helicopters for evacuation accelerated during the Korean War (1950-1953) and the Vietnam War (1964-1969), where the challenging topography made ground ambulances impractical [14]. In Korea, patients were transported outside the fuselage and any medical treatment during transport was impossible [15]. In Vietnam, larger helicopters were available, and patients and caregivers were transported inside the aircraft body [15]. For the first time, patient treatment could be provided en-route.

Based on the military experiences, civilian air medical services developed during the late 1950s. In 1958, the first civilian air medical service was established in Etna, California. The service transported patients to the only available physician in town and delivered

medications during emergencies. During the 1960s, helicopters were increasingly used to transport road traffic casualties in the US [16]. In Europe, the first civilian physician-staffed air ambulance was established in Germany during the 1960s [12]. Since then, helicopters have increasingly been used for transport of severely sick or injured patients. Today, helicopters are integrated in the health care system worldwide, particularly in high-income countries in Europe, North America and Australasia [13].

1.3 P-EMS

1.3.1 Norway

In Norway, patients have been transported by air since Viggo Widerøe performed the first patient transport in 1932 [17]. After World War II, small civilian seaplanes were increasingly used to transport patients in the western and northern parts of Norway. During these transports, no medical service was provided [17].

The first p-EMS in Norway was a physician-staffed ambulance established in Oslo in the 1960s.

In 1966, a passenger ferry sank on its way from Kristiansand (Norway) to Hirtshals (Denmark). All the 144 passengers on board were rescued by a Danish rescue helicopter. Norway had no rescue helicopter available at the time.

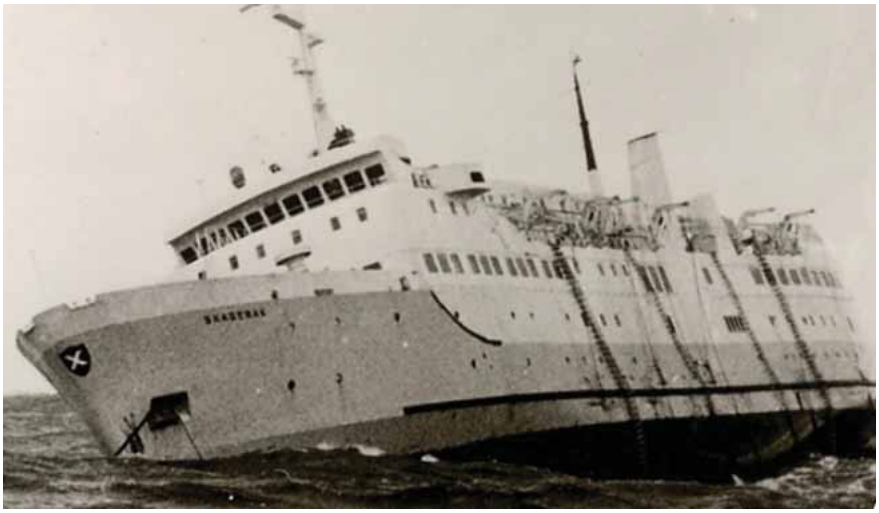

Photo: MS Skagerrak who sank in 1966 on its way from Kristiansand to Hirtshals. From M/S Museet for søfart, Denmark. Re-printed with permission.

Following the ferry accident, the Norwegian Government acknowledged the importance of having rescue helicopters available and acquired 10 Westland Sea King MK43B helicopters. Since May 1973, the 330 Squadron of the Royal Norwegian Air Force have operated the Sea King helicopters and provided a Search and Rescue (SAR) service. During the first years, conscript physicians were on-board when considered necessary. From 1988, specially trained anaesthesiologists have been permanent members of the Sea King crew for all missions and the service is embedded in the national air ambulance system. The medical capacity equals the smaller ambulance helicopters [17].

Inspired by Germany, the concept of civilian physician-staffed air ambulance helicopters was introduced in Norway by the physician Jens Moe in 1978 [17]. The service was founded as an ideal, non-profit organisation (today known as the Norwegian Air Ambulance Foundation (NAAF)) and the first mission was performed on the 3rd of June 1978. In 1988, the Norwegian National Air Ambulance Service was established, funded by the government. All helicopters were staffed with

anaesthesiologists. Their main task was to provide advanced emergency medical treatment on-scene and to transport the patient directly to the correct level of care [17]. Since 2002 the Regional Health Authorities have been responsible for the air ambulance service. Nine air ambulance airplanes staffed with a mix of specially trained nurses and anaesthesiologists and thirteen air ambulance helicopters staffed with specially trained anaesthesiologists are available 24/7. There are seven SAR bases (six bases on the mainland and one at Svalbard) carrying an anaesthesiologist on-board. The SAR helicopters are available 24/7 and provide both SAR and ambulance missions. Except from Svalbard, all SAR bases and all helicopter bases have a rapid response car available. Additionally, several hospitals have their own anaesthesiologist-staffed rapid response car for selected missions.

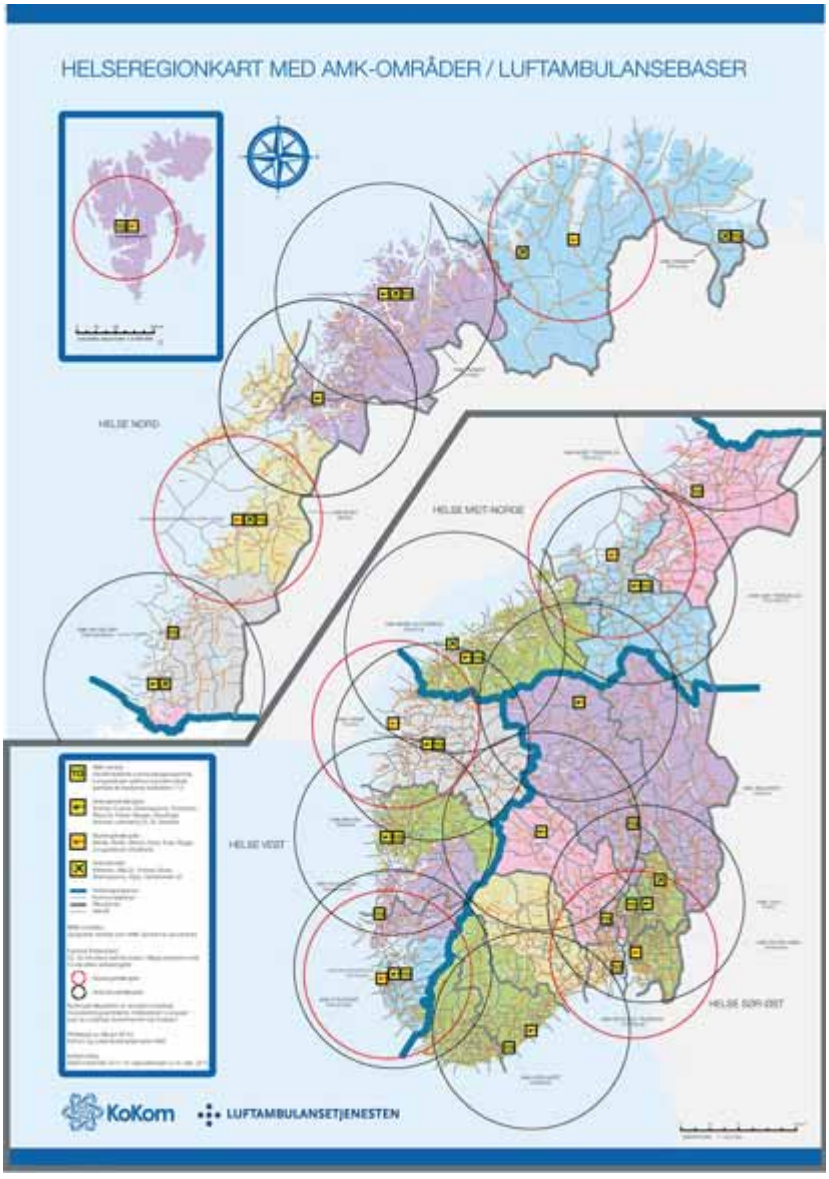

Figure 1 – The Norwegian air ambulance bases
Illustration: Luftambulansetjenesten. Re-printed with permission.

1.3.2 The Nordic countries

The Nordic countries share many similarities; the culture and populations are fairly homogeneous, and the health care system is governmentally funded. Free, equal and fair access to emergency care is in principle available for all residents, regardless of socioeconomic status or location [2, 18]. Despite subarctic climatic conditions and a challenging topography, the p-EMS provide highly advanced care on-scene, thereby aligning with the principle of equity of access [18]. P-EMS are dispatched by dedicated regional dispatch centres [19] and except from on Iceland, all p-EMS physicians in the Nordic countries are anaesthesiologists.

Denmark has since the 1980s had p-EMS operating rapid response cars. A governmentally funded national HEMS was established in 2014, aiming to make physician-led pre-hospital care available for all patients regardless of location [20]. Today, p-EMS in Denmark consist of four physician-staffed HEMS bases and physician-staffed rapid response cars covering the whole Danish population. All p-EMS physicians are anaesthesiologists.

Finland introduced their first physician-staffed rapid response car in Helsinki in 1973. During the 1980s, a charity-funded physician-staffed HEMS program was established. The HEMS in Finland (FinnHEMS) re-organized and became governmentally funded in 2011. Today, there are six FinnHEMS bases providing national coverage.

In Sweden, the first pre-hospital physician-staffed units were introduced in the 1970s. Sweden is the only Scandinavian country without a national governed p-EMS and the services are heterogeneous compared to the other Scandinavian countries. The Swedish p-EMS have developed regionally, and each county is responsible for staffing their helicopters. There are currently nine HEMS bases. Six of the regions deploy pre-hospital anaesthesiologists for all missions and further two regions can have an anaesthesiologist on-board dependent on the type of mission. In

Stockholm, a nurse anaesthetist is on board. There are also five fixed-wing aircrafts available for long distance medical transports and some county councils have access to five SAR helicopters which can be staffed with medical crew if considered necessary [19].

Iceland has an EMS system which is mostly governmentally funded; 85 percent of cost is covered by the government and 15 percent of cost is charged to the individual [19]. Air transport is mainly by fixed-wing aircrafts (85% of air transport missions). Physicians are general practitioners, anaesthesiologists or medical residents and attend the service for about 40% of missions. A HEMS and SAR service staffed with an emergency physician or an anaesthesiologist is also available (15% of air transport missions) [19].

1.3.3 Europe

The first physician-staffed HEMS units were established in Germany during the 1960s. Since then, p-EMS have become widespread in Europe. P-EMS are present in most of Europe, but operational concepts and staffing differ. Some services use a physician for all missions, while others use physicians only for selected missions (e.g., trauma). The common feature of European p-EMS is the deployment of a dedicated, specially trained physician for pre-hospital management of the critically ill or injured patient. Physicians have their background from several specialties, e.g., anaesthesiology, emergency medicine, surgery, orthopaedics or internal medicine. P-EMS are available in Finland, Denmark, Sweden, Norway, Iceland, Germany, France, Italy, Spain, The Netherlands, Hungary, The United Kingdom, Switzerland, The Czech Republic, Belgium, Scotland, Austria, Greece, Portugal, Luxembourg, Poland, Romania, Croatia, Slovenia and Slovakia [14].

1.3.4 America, Asia, Australia and Africa

EMS systems are heterogeneously developed worldwide. By 1960 a patchwork of unregulated systems developed in the US, provided by hospitals, fire departments, volunteer groups or undertakers [9]. Physicians staffed some of the ambulances, while other ambulance services had minimally trained or untrained personnel. Between 1967 and 1973, a more structured EMS system developed [9]. Today, most pre-hospital services in the US are staffed with paramedics but some services also carry a physician on-board.

EMS in South America are highly varying. Commonly, urban areas have a mixture of public and private EMS. Highly developed, high-quality private EMS are available in urban areas, but are generally subscription-based. Available resources in rural and remote areas may be scarce and of varying quality. Pre-hospital physicians are common, especially for the private subscription-based EMS [21, 22].

There is a substantial variance in Asian EMS [23], ranging from systems providing basic care to advanced physician-staffed systems and HEMS. The most developed countries have the most advanced EMS.

A governmentally funded ambulance service staffed with paramedics constitutes the backbone of the Australian EMS. Due to long distances and large wilderness areas, a network of fixed-wing aircrafts and helicopters staffed with nurses or physicians has developed [24].

In Africa, EMS exist in one third of the countries and only 9% of African citizens have EMS coverage [4]. Eight African countries have a p-EMS (Angola. Botswana, Cameroon, Libya, Nigeria, South Africa, North Sudan and Zambia), covering certain parts of the countries. Background of the physicians and the service provided remain unknown [4].

1.4 P-EMS versus EMS

Ordinary EMS are commonly staffed with paramedics and emergency medical technicians. Pre-hospital care is constantly developing and to enable new, advanced diagnostic and therapeutic interventions to be applied on-scene, some EMS systems, especially in developed countries in Europe and Australasia, have integrated specially trained physicians in their EMS systems [6, 25]. Physicians have their background from anaesthesiology, surgery, orthopaedics, internal medicine or as emergency physicians. Units carrying a physician are commonly referred to as p-EMS. P-EMS can use all different available means of transportation and are not restricted to the use of helicopters.

1.5 P-EMS versus HEMS

The “H” in HEMS stands for “helicopter”. HEMS are EMS units utilizing helicopters as means of transportation and are not always synonymous with p-EMS. The crew composition of HEMS differs. Some services include a specially trained physician in the crew for all missions, others use physicians for selected missions, while yet others do not include physicians in their missions at all [26]. Specially trained HEMS physicians commonly have their background from anaesthesiology, surgery, orthopaedics, internal medicine or as emergency physicians. HEMS crews without physicians consist of different combinations of nurses and paramedics. The term HEMS is often used alternately with p-EMS and is synonymous if the helicopter crew includes a physician. When comparing EMS systems, it is crucial to separate the effect of the physician from that of the means of transportation and information on staffing of HEMS should always be provided.

1.6 The complexity of p-EMS

A constructed patient case is presented below to depict the complexity of a p-EMS helicopter mission (based on personal experience, several key elements are changed to ensure anonymity).

> *A 53-year-old male suffered acute chest pain when he arrived at work. Half an hour earlier, he had been training at the local fitness centre. His colleagues immediately realized something was wrong and called the emergency number. An ambulance unit arrived on site after 6 minutes and the electrocardiogram (ECG) showed that the patient had a ST-Elevation Myocardial Infarction (STEMI), suspecting an occluded Left Anterior Descending (LAD) artery. The nearest HEMS unit was dispatched to transfer the patient directly to a Percutaneous Coronary Intervention centre. Flight time was estimated to be 12 minutes.*
>
> *The weather was challenging, with rain and patches of fog. When HEMS landed, the patient suffered severe chest pain and limited effect of the morphine he had received from the EMS. The HEMS physician gave more morphine and the patient was transferred to the helicopter. Documentation on the paper form carried by the HEMS physician was not possible due to heavy rain. Inside the helicopter, the patient was monitored with defibrillation pads, non-invasive blood pressure and a pulse oximeter. The initial blood pressure was 88/50. The patient was still awake, but the HEMS physician realised they had to prioritise rapid transport to hospital to get the LAD re-opened. After take-off the patient vomited all over the cabin. He was restless and constantly moving and tried to loosen the seat belt. The HEMS physician administered additional morphine, but the patient was still restless and in severe pain. The ECG started to show different arrythmias. Due to constantly bumping conditions because of the wind, the HEMS physician had to stay restrained to the cabin seat. Six minutes after take-off the patient had a ventricular*

fibrillation. At that time, the helicopter was flying over water and the nearest lading spot was at the hospital six minutes away. The HEMS physician immediately started CPR. Despite several DC-shocks, the ventricular fibrillation remained refractory. Six minutes later they landed at the helipad of the hospital. The patient stretcher was transferred to a trolley and brought immediately to the emergency department (ED) with ongoing resuscitation. The transfer from the helicopter to the ED took four minutes. In the ED the cardiac arrest team continued the resuscitation. The HEMS physician had no written information to deliver during handoff and had to rely on her memory regarding physiological parameters and time points. When she tried to take a monitor printout, she realized that it was not possible because in-hospital personnel had turned off the monitor. She stayed in the ED and completed the patient paper form with the information she remembered.

The patient case presented is representative of a real-life situation and illustrates the complexity of a HEMS mission. Humans interact with technology and helicopter operating conditions influence critical care decisions. Patient care must always be prioritized, making documentation (on paper) challenging.

Furthermore, identical interventions can be appropriate in one situation and inappropriate in another. E.g., if a patient with a traumatic brain injury (TBI) has a Glasgow Coma Scale (GCS) of 10 and is five minutes away from hospital by ambulance, the patient may be transported in a lateral position while monitoring the airways and the consciousness [27]. If the GCS score decreases or there are airway problems, the patient can be intubated en-route. If the same patient is 40 minutes away from hospital by helicopter, the patient may be intubated prior to transport. The interior space of a helicopter for patient transport is limited, complicating intubation en-route. It is not always possible to land a helicopter immediately, especially when flying over water. Also,

monitoring of vital functions may be difficult in environments dominated by noise, vibrations and darkness.

1.7 Status of documentation in p-EMS

Documentation in p-EMS has clinical, legal, financial and operational implications [28]. Firstly, pre-hospital documentation has a clinical purpose. It describes the patient's signs and symptoms, the interventions provided on-scene and the patient's response to the interventions. This information forms the basis for further treatment at the receiving facility. Furthermore, the pre-hospital documentation is included in the continuum of care and information captured is important for quality improvement and assessment initiatives [28].

Secondly, documentation is required by law and there are directions for mandatory and optional variables [29]. If the patient is injured or dies, all documentation is potentially reviewed and scrutinized. Also, documenting whether the service operates in adherence with legal requirements (e.g., performance requirements and staffing) is important.

Thirdly, documentation reflects the medical costs associated with the cases and may serve as a driver for grants from financial authorities and policy makers [28].

Pre-hospital documentation of care has several operational implications [28]; data serves as a basis for EMS system development, e.g., staffing, deployment and system utilization. Data regarding performance of the EMS system (e.g., response time, on-scene time, number of cases etc.) may influence hospital management decisions and further development of the system to fulfil legal and organisational requirements.

EMS and p-EMS systems have developed through local and regional initiatives and documentation does not seem to have had a main focus. Already in 2005, the World Health Organization (WHO) acknowledged

that documentation of key variables is a prerequisite for creating a high-quality pre-hospital system [30] and recommended systematic data collection on all EMS levels. Furthermore, they highlighted the importance of formatting the data to be in consistence with national and international norms [30]. This is pertinent to p-EMS as well and has resulted in publication of several templates for standardized documentation [31-35]. Some of these templates are readily implemented while others are not. There are currently no uniformly, internationally recognized standard for p-EMS documentation and each individual country may decide their own variables to collect.

Automated data capture is common in hospitals, e.g., in the operating theatres. Although technology exists, similar solutions are not readily available out-of-hospital. During a p-EMS mission, medical and operational data are frequently documented on a paper form and subsequently manually entered into an electronic file at a later stage [36]. Furthermore, as illustrated by the former patient case, data is often registered in retrospect, thereby introducing recall bias and inaccuracy. The human mind often underestimates how long it takes to complete a task and this influences retrospective registration of time variables [37].

1.8 What is quality in health care?

Quality in health care is a term with multiple definitions [38, 39]. When aiming to improve or assess quality one must start by having some understanding of the term "quality". A working definition by WHO define quality to consist of six areas or dimensions [39]. These dimensions require that health care be:

1. Effective (evidence-based health care which improves health outcome for individuals and communities, based on need)
2. Efficient (deliverance of health care in a manner which maximizes resource use and avoids waste)

3. Accessible (health care that is timely, geographically reasonable and provided in a setting that is adapted to medical needs)
4. Acceptable/patient-centred (health care adapted to the preferences and local culture of users)
5. Equitable (health care of equal quality, regardless of gender, race, ethnicity, geographical location or socioeconomic status)
6. Safe (health care which minimizes risks and harms to users)

1.9 P-EMS quality

Traditionally, quality assessment in EMS has been directed towards increasing quality to reach a certain minimum. This process is described as quality assurance rather than quality improvement and typically focuses on the individual [40]. As long as an individual performs better than a defined lower limit, quality is judged satisfactory. Quality improvement, on the other hand, aims to increase performance of all parts of a system rather than solely focusing on each individual. The difference between quality assurance and quality improvement is described visually below (Fig.2) [40].

Figure 2 – Quality assurance versus quality approval. Institute for healthcare improvement; Dr. Scoville, Dr. Lloyd. Permission for reprint granted.

P-EMS have become more widespread, but services are resource demanding and critics frequently question the added value of the pre-hospital physician. Health budgets are limited, thereby carrying a strong

focus on making the right priorities. In order to optimize resources and to make the right strategic choices for development of p-EMS, focus should be shifted from quality assurance to quality improvement [40]. To meet the needs for reporting and improving quality in p-EMS, a set of quality indicators for p-EMS have been developed [41]. The quality indicators measure quality of both p-EMS responses and system structures. High-quality data is a prerequisite for enabling documentation of these indicators.

1.10 Data quality

There is no uniform definition of data quality and the descriptions varies [42-45]. In the context of a medical registry, data quality has been defined as "The totality of features and characteristics of a data set, that bear on its ability to satisfy the needs that results from the intended use of data." [42] Another definition of data quality is "Data that are fit for use by data consumers." [44]. Different dimensions of data quality are described in the literature, but definitions are ambiguous and inconsistent [42].

To claim that we improve quality, we must clearly define what we mean by the term "quality". Quality is often described as composed of several attributes. The most cited data quality attributes in literature are accuracy and completeness [42] and we consider these also to be relevant for p-EMS. Accuracy and completeness, as defined by O'Reilly, are considered attributes to describe quality in p-EMS for the present thesis [45]:

Accuracy: The extent to which registered data are in conformity with the truth.

Completeness: The extent to which all necessary data have been registered on registered cases.

1.11 Why study data quality in p-EMS?

Although the evidence is increasing for the effect of p-EMS, the literature reports conflicting results [7, 46-51]. Some studies attribute the effects of p-EMS to rapid transport (e.g., helicopters) to definitive care, while others attribute the effects to the presence of a physician on-scene [49, 52, 53]. To increase our knowledge base of p-EMS effects and produce high-quality research, we need high-quality data. We need to know for which patients p-EMS are beneficial and which patients do not need a p-EMS. Routinely collected data may contribute to increase the knowledge of p-EMS effects. Using routine data in research is often complicated by inconsistent reporting and efforts to increase data quality should be made. This thesis aims to increase quality of routine data reported in p-EMS.

1.12 What is the problem?

Pre-hospital care has developed through local and regional initiatives. Resources and health budgets are limited and to establish and operate a p-EMS is a resource intensive task.

Pre-hospital treatment is part of a continuum of patient care, but currently, we do not have sufficient knowledge to identify patients for which p-EMS is most beneficial and for whom pre-hospital care can be provided by other professionals with similar results (e.g., ordinary EMS, general practitioners on-call) [54, 55]. Furthermore, we do not know which pre-hospital advanced interventions are essential to improve outcome [54, 55].

Outcome research for pre-hospital interventions is needed to increase our knowledge of the effects of p-EMS. To perform high-quality research, we need high-quality data [56]. Data is usually collected on paper and later converted to digital data [36]. This conversion is challenging for data capture and potentially produces data of variable quality. Most studies in p-EMS are observational and data variables are not uniform.

A high rate of missing data is commonly reported [57-61]. Research from the trauma field points out that only a small proportion of data are similar and comparable [59-61]. To increase data quality, we need uniform and transportable data and focus on strategies to increase accuracy and completeness.

Randomized controlled trials (RCTs) remain the reference standard for evidence-based medical research and is often able to generate high-quality data. However, RCTs are so far limited in p-EMS, due to ethical, legal and practical aspects [62]. A critically ill patient is per definition not able to give consent [62] and randomization in different operational situations may be difficult. Furthermore, conducting RCTs is resource demanding and results are not automatically generalizable [63]. As such, supplementing RCTs with other research methods have the potential to generate a broader evidence-base and is valuable.

Data is already being collected for all p-EMS cases regardless of research, and we should make better use of the data collected. However, most of the routinely collected p-EMS data is of variable quality and not adapted to research. If we increase the quality and relevance of routinely collected p-EMS data, we may increase the data quality for observational studies. Furthermore, high-quality routinely collected data may facilitate feasibility studies, generation of hypotheses, clinical audits, quality improvement initiatives, system developments and activity reporting.

2 Aims

The overall aim of this project was to increase the quality of routinely reported data in p-EMS. This was done by focusing on two attributes describing quality:

1. Accuracy (the extent to which registered data are in conformity with the truth)
2. Completeness (the extent to which all necessary data have been registered on registered cases)

These attributes are important in p-EMS because complete data always outperform incomplete data and accuracy of variables are needed to be able to perform high-quality research. The specific research questions or aims were:

Study I

What is the feasibility of pre-hospital physicians to collect patient and system level data by using the original template for uniform reporting of data in p-EMS? What proportion of the requested template data was possible to document? Which factors affected data capture?

Study II

Can pre-hospital physicians score a reliable pre-event ASA-PS already while on-scene?

Study III

What is the quality of reported GCS and SBP data in studies depicting p-EMS?

Study IV

To revise and update the original template for documenting and reporting in p-EMS by use of an expert consensus process.

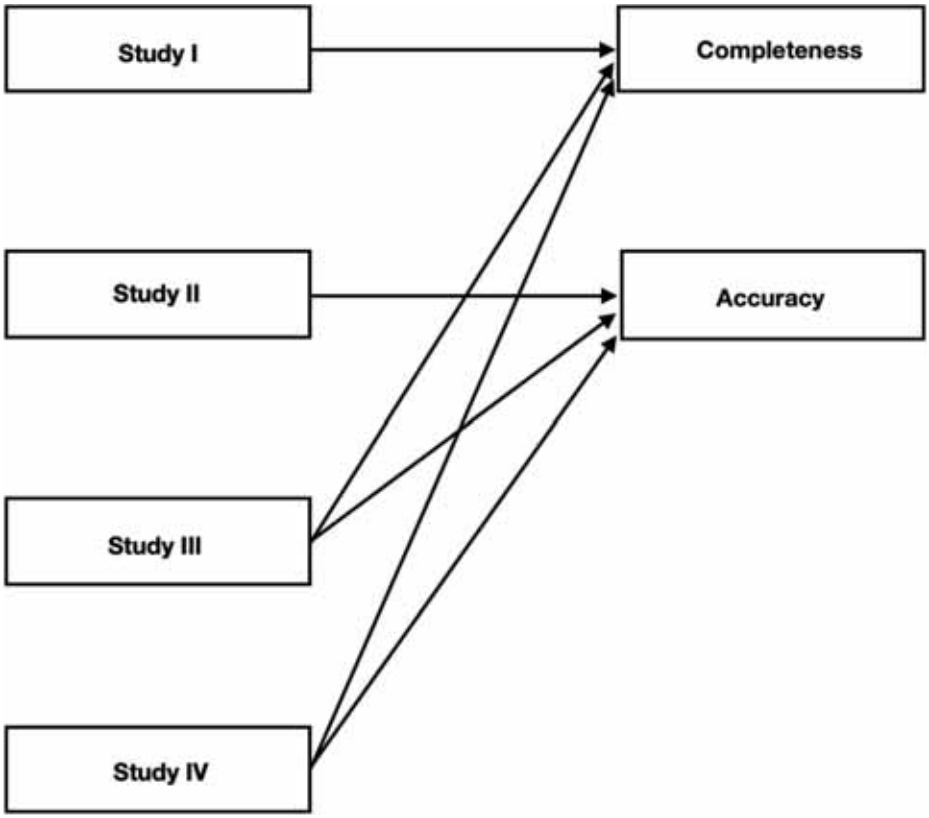

Figure 3 – How each study relates to the attributes used to describe quality
Study I describes completeness rates. Study II describes accuracy of pre-event ASA-PS reported on-scene. Study III describes both accuracy and completeness for GCS and SBP reported in the literature. Study IV provides a framework enabling increased accuracy and completeness of reported data in the future.

3 Methodological considerations

Different methods have been used in each study and thus methodological considerations will be described consecutively.

3.1 Study I: Feasibility of collecting data according to a template

Several templates created by expert consensus are available in p-EMS [31, 34, 64, 65], but feasibility of their use should be tested. If a variable included in a template is unfeasible to collect, then the variable should be modified or removed. A template for documenting and reporting of core data in p-EMS was developed [65]. To assess feasibility of collecting p-EMS data, we explored the completeness rates of variables collected using this template.

Different factors have the potential to influence completeness rates when implementing a template, e.g., template design, provider motivation, training and perceived relevance [66-68]. To explore both how motivation and the template design influenced data collection, we assessed the feasibility of using the p-EMS template in two similar systems, but in different settings. We compared completeness rates when physicians collected data in a routine manner (standard data collection method) with data collection when physicians were highly motivated (focused data collection method). By studying these two data collection methods, we were able to describe how motivational factors and template design influenced data collection and the relevance of this when aiming to increase completeness rates of variables.

We included p-EMS in Finland and Norway due to system and setting similarities [2]. Both services operate 24/7 and are staffed with specially trained anaesthesiologists, mostly consultants. Both operate in a subarctic climate with potentially long distances to definitive care. Both

services handle a mixed patient population, including medical, surgical and trauma patients of all ages. The services are dispatched through a dedicated emergency medical communication centre. Differences between the services also exists. In Finland, the EMS paramedics must consult a p-EMS physician before medications can be administered on-scene. This results in a significant volume of remote medical directions for the Finnish p-EMS compared to Norwegian services. In Norway, many ordinary EMS services can, due to a set of predefined delegations, administer certain medications on-scene according to criteria without consulting a physician and the rate of medical directions is low. Despite the abovementioned differences, the services were considered comparable.

3.1.1 Participants

Finland is the only country where the original template is fully implemented, and all FinnHEMS bases use the template for routine data collection. The data is transferred to a national database. FinnHEMS facilitated extraction of routinely collected template data from their database.

Focused data collection involved 16 selected physicians from four Norwegian p-EMS bases (Trondheim, Ålesund, Bergen and Stavanger). The physicians were chosen by the investigators, based on knowledge of their motivation for participating in research.

From our clinical experience we acknowledge that complete data collection of template data is often regarded as time consuming, boring or irrelevant. E.g., measuring blood pressure twice on a stable patient with an isolated ankle fracture seems irrelevant. We aimed for maximal template data collection by establishing the focused data collection. This involved recruiting physicians who would document also the seemingly irrelevant variables to prove that they were possible to capture. The data collection period was kept short (six weeks) to avoid documentation

fatigue. The selected physicians were instructed to collect complete template data regardless of clinical relevance. This might be compared to creating an "ideal condition" in a lab, whereas in a real-world situation, the condition is usually far from ideal. Accordingly, we compared data collected under "ideal" conditions with data collected on an every-day basis by physicians unaware of being studied (standard data collection).

The Hawthorne effect [69], which means that individuals modify their response or behaviour when they are aware of being observed, is evident in the focused data collection part of the study. However, we wanted the participants to change their behaviour by increasing their completeness rates of reporting data. Thus; the Hawthorne effect is a desired consequence. To take advantage of this effect in the future, the importance of documentation rates should constantly be highlighted, e.g., by regular clinical audits.

3.1.2 Data collection and analyses

The focused data collection required extensive effort, making the registration period as short as possible to prevent physicians from lowering their completeness rates because of documentation fatigue. All data variables were collected on paper forms and later digitized by the investigators (Appendix 1).

Data from FinnHEMS was exported from their database and to exclude the influence of seasonal variations on completeness rates, data from one year was extracted.

In Finland, thirteen variables were mandatory (all process mapping variables) and completeness rates for these variables were therefore 100%. Physicians were not able to complete their registration forms without registering these variables. Mandatory variables may give

complete data but must be carefully selected to avoid false registrations when completing registration forms.

Before analysing data from the two cohorts, data had to go through a resource intensive merge, complicated by different data formats.

Data was analysed using descriptive statistics to identify and compare completeness rates for the two sites. Because we hypothesized that several factors, e.g., patient diagnosis, time available and transportation method would influence completeness rates, we performed separate analyses for a set of predefined situations. Chi-square was used for categorical data and Mann-Whitney U Test was used for continuous data to identify differences in completeness rates for different clinical situations.

3.2 Study II: Inter-rater reliability of pre-event ASA-PS scoring on-scene

Comorbidity is an important risk adjustment factor when evaluating pre-hospital interventions and is important for predicting patient outcome [70, 71], but we do not know whether the information available on-scene is sufficient to score a reliable pre-event ASA-PS. In templates, pre-event ASA-PS scores are often dichotomized, thereby providing a non-specific measure of comorbidity. Although P-EMS have limited access to patient journals, stratification on comorbidity is equally important on-scene to tailor therapy, medication and monitoring to each patient [72].

We aimed to investigate whether pre-hospital physicians were able to score a reliable full-scale pre-event ASA-PS already while on-scene with the information they had available. We defined the on-scene period as from when p-EMS arrived at patient site until delivering of the patient to the receiving facility.

Information used to score a pre-event ASA-PS is usually found in hospital journals. Pre-hospital physicians deliver patients to several

hospitals and in-hospital data are often unavailable for pre-hospital physicians due to legal restrictions of data access. Because knowledge of comorbidity is relevant for p-EMS it was important to assess whether a reliable pre-event ASA-PS could be scored on-scene.

To explore whether differences in pre-event ASA-PS scores were related to different availability of data or to each pre-hospital physician we designed a two-step prospective inter-rater reliability study. Inter-rater agreement between pre- and in-hospital physicians scoring pre-event ASA-PS on the same patients, but under different conditions and with different data access, was assessed. Following the first step, a second step exploring inter-rater reliability when pre- and in-hospital physicians had access to the same data was performed.

There is no consensus on reporting comorbidities in pre-hospital critical care and several methods exists [73-75]. ASA-PS is readily available and widely used by anaesthesiologists. All pre-hospital physicians in our system are anaesthesiologists. ASA-PS was originally designed to allow statistical analyses of outcomes and to standardize terminology [76] and describes the physiological base of a patient. Originally, the ASA-PS did not attempt to describe operative risk [77], but the scale has shown to correlate well with overall surgical mortality [76]. Furthermore, pre-event ASA-PS is shown to be an independent predictor of mortality after trauma [75, 78, 79] and is included in several p-EMS templates [64, 65]. We therefore used ASA-PS as comorbidity measure in this study.

In the present study we reported pre-event ASA-PS. The distinction between pre-event ASA-PS and ASA-PS is of relevance. We are interested in the physiological base of a patient before an event to assess how it affects the outcome of the event. The original in-hospital ASA-PS score represents the physiologic base before anaesthesia and surgery which is of interest when aiming to appraise the impact on outcome after surgery. In this case, the "event" is the upcoming anaesthesia or surgery. In the case of pre-event ASA-PS, the event is a trauma or illness. Thus,

pre-event ASA-PS aims to describe the physiological base of a patient before a trauma or illness occurs. If we include the present illness or injury in the ASA-PS score, we have a description of the current state after an event, not the physiological base of the patient before the event occurred. If a former healthy person without any known comorbidities sustains a head injury resulting from trauma, pre-event ASA-PS will be 1. If this person is brought to the hospital and needs surgery, the in-hospital ASA-PS score will take the recent trauma into account and ASA-PS will be rated ≥2.

Guidelines for Reporting Reliability and Agreement Studies (GRRAS) [80] was used for reporting in this study.

3.2.1 Participants

In this study we included experienced pre-hospital physicians working in high-activity Norwegian p-EMS bases (Stavanger and Trondheim) Both services admit patients mainly to one university hospital. This was of relevance for the in-hospital part of the study, where in-hospital physicians required access to patient journals to score included patients.

The three in-hospital physicians at each site were chosen by the authors based on personal knowledge, research experience and willingness to participate. The physicians were both experienced registrars and consultants.

3.2.2 Data collection and analysis

The rationale for the two steps in this study is described below.

Step 1

Several studies have compared ASA-PS scores against a reference standard [79]. For this to be a viable approach, such a reference standard must indeed exist or be straightforward to create. However, when two or

more raters score ASA-PS, their scores are never identical, not even for in-hospital physicians. To take this into account when exploring inter-rater agreement between pre- and in-hospital physicians, we compared not only pre-hospital physicians against each in-hospital physician, but also the three in-hospital physicians against each other (Fig.4). The rationale for this was that if the difference between pre- and in-hospital scores did not differ more than the scores between the in-hospital physicians against each other, then the pre-hospital scores were equally valid and could be used accordingly. This is in line with the image analysis literature, where it has been pointed out that if an automatic method is to be considered equally good as radiologists, it must be indistinguishable from them [81]. That means that if a machine shall be considered as "seeing" the same as trained radiologists, the results produced by the machine and trained radiologists must be equal [82].

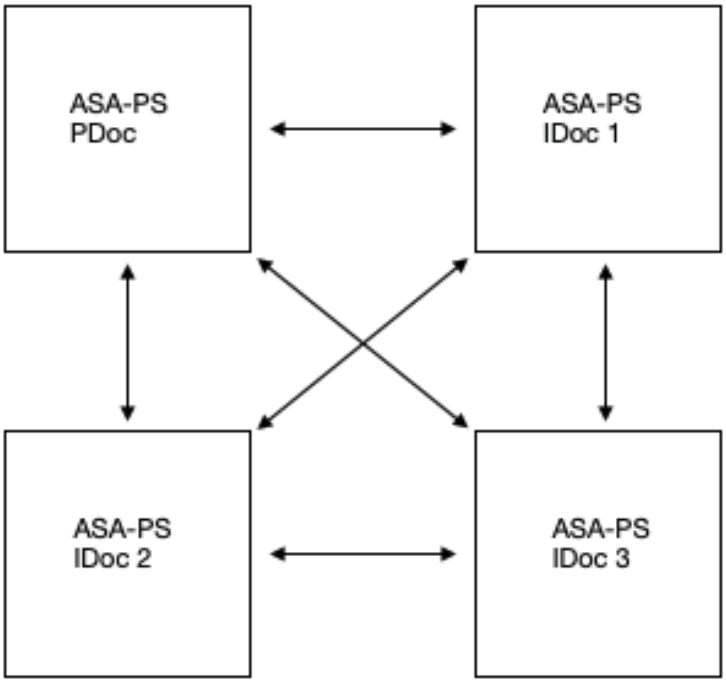

Figure 4 – Comparisons of pre-event ASA-PS scores
Pre-hospital pre-event ASA-PS scores (ASA-PS PDoc) were compared with pre-event ASA-PS scores by each in-hospital physician (ASA-PS IDoc 1-3). In-hospital physicians were also compared with each other.

In Stavanger, data collection was on a case report form (Appendix 2). In Trondheim, the pre-event ASA-PS was already implemented in daily reporting and the variable was therefore digitally reported. For each case, the pre-hospital physicians also reported how difficult pre-event ASA-PS was to score and from where they got information enabling them to score a pre-event ASA-PS. If pre-event ASA-PS could not be scored, the reason for this was reported.

The period of reporting pre-event ASA-PS was kept as short as reasonable. In order to perform sample size calculations some information on the variation of the phenomenon under study is needed. However, we were unable to identify any studies reporting pre-event ASA-PS in a pre-hospital real time setting. Without prior empirical

information on the variation of the phenomenon under study a sample size calculation could not be performed [83, 84]. Depending on the research question, a sample size between 10 to 50 is reported as a requested minimum in literature [85]. For the present study, we aimed for a sample size of 20 scores per pre-hospital physician (Step 1). If no agreement between pre- and in-hospital physicians for 20 patients could be established, we considered the pre-hospital scores to be irrelevant. Based on activity data from the bases we considered an inclusion period of three months to be sufficient. However, not all pre-hospital physicians scored 20 patients. In retrospect we acknowledge that the inclusion period could have been extended to allow more robust results.

Assessing agreement of a categorical scale between two raters is done using kappa statistics [86, 87]. Kappa statistics quantify the level of agreement (inter-rater reliability) between categorical variables by different raters, taking agreement expected to occur by chance into account [86], resulting in a number between 0 and 1. Given our ordinal outcome, the quadratic weighted Cohen's kappa was applied in our analyses: Quadratic weighted Cohen's kappa (κ_w) is a modification that also accounts for the magnitude of disagreement [87]. κ_w is a number between 0 and 1. There is no uniform interpretation of Cohen's Kappa in the literature. We used the classification described by Shrout [88] (Table 1):

Table 1 – Interpretation of the Cohen's Kappa (Shrout et al. [88])

Value of κ_w	Inter-rater reliability
≤0.10	None
0.11 – 0.40	Slight
0.41 – 0.60	Fair
0.61 – 0.80	Moderate
0.81 – 1.0	Substantial

Because different interpretations and semantic descriptions of the numeric Cohen's Kappa values exists [86, 89], one should always refer the numeric kappa values and which interpretation was used when reporting the data.

Step 2

Usually, when assessing inter-rater reliability, raters have access to the same information. In this study, access to information was different because pre-hospital physicians did not have access to the patient journal and thus had less information available when performing the pre-event ASA-PS scoring. Thus; after the first step we were left with the unanswered question of whether the observed difference in scores were due to either different physicians performing the scoring (pre- versus in-hospital) or different availability of patient information. We investigated this further in a follow-up study. Here we gave all the pre-hospital physicians access to the full patient journal for 20 of the included patients. The patients were randomly selected and re-scored by all pre-hospital physicians.

The inner agreement structure of the dataset was explored using minimax hierarchical agglomerative clustering and visualized in dendrograms [82]. This approach allows for not only providing average values, but also demonstrate the variation in the dataset. This allows us to align with the sufficiency principle [90] which highlights how both the central tendency and the variation are equally important in order to summarize a dataset without loss of information.

Traditional statistical tests are all developed for assessing a statistically significant difference in the data, e.g. between groups. The absence of a statistically significant difference does however not mean there isn't a difference: such a negative result could be due merely to too low statistical power. Exploring agreement, on the other hand, is about assessing non-difference. For this, standard statistical tests are thus inapplicable. Performing a statistical test on the difference in agreement

values is not a straightforward task. Although assessing the difference in agreement values through a statistical test is theoretically possible, and some methodological publications on the matter exist [82], no such test is readily available in any software. Because implementing such a test is quite a substantial programming task, we did not implement it in our analyses.

3.3 Study III: Systematic review depicting quality of reporting of GCS and SBP in literature

To increase quality of reporting we need to understand the current state of reporting. An increasing number of scientific papers reporting from p-EMS are published annually. To describe the reporting quality of all p-EMS documentation is complicated due to the number of scientific papers and variables reported. We therefore limited the assessment of reporting quality in p-EMS to include two variables; GCS and SBP. We chose these variables because GCS and SBP are considered core variables for reporting in p-EMS and are included in outcome prediction models [32, 35, 70, 91-93]. Furthermore, we wanted to explore if there were major differences between provider assessment data (GCS) and monitor data (SBP).

As amount of scientific papers have increased, a growing need of synthesizing evidence has evolved [94]. Previously, experts were nominated to write review articles to synthesize existing evidence [94]. These reviews were non-transparent on authors subjective influence, posing a high risk for biased results.

Because of a growing need for a method to minimize systematic (bias) and random error (imprecision), the systematic review methodology evolved. A systematic review collects and synthesizes data relevant to a predefined research question in a systematic and reproducible way [95]. The search criteria are explicit, well defined and studies are included based on predefined eligibility criteria [95]. Validity and risk of bias are

evaluated, and results are synthesized and presented systematically. We aimed to get an overview of the current knowledge of the reporting quality of GCS and SBP and performed a systematic review.

3.3.1 Search strategy and study selection

We applied the following inclusion criteria:

1. Original articles where any data on GCS or SBP were captured and reported by a p-EMS
2. At least one value for SBP or GCS had to be reported
3. P-EMS had to be present on scene
4. If a study reported data from both p-EMS and ordinary EMS, cases handled by p-EMS had to be reported separately
5. Articles published between 2001 Jan 1st and 2019 Aug 9th
6. Articles describing both primary and secondary (transfer) missions

The main challenge was to decide if the article reported from a p-EMS or not and to extract p-EMS cases when a study reported both EMS and p-EMS data. The description of the participants or study subjects was often not clear, making decision about inclusion difficult. We used a wide search strategy to increase sensitivity and to compensate for substandard indexing of studies.

The Covidence screening and data extraction tool was used for study selection [96]. This is a digital tool for management of systematic reviews, designed to make the systematic review process more efficient. Collaborating researchers can screen and make their own judgements about studies and later compare their judgements with the other participants when including studies in a review. In the present study, the first author screened all the abstracts and excluded literature that clearly did not comply with the inclusion criteria. To increase validity, this process could have been performed by two authors. Because uncertain

articles were derived in full text and later screened by two authors, we considered one author to be sufficient for initial article screening.

The articles remaining after the first screening were derived in full-text and screened by two authors. The first author screened all articles in pairs with one of the co-authors. The reason for excluding articles at this stage was mainly that the article did not report from a p-EMS.

3.3.2 Information sources

We searched CINAHL, Cochrane, Embase, Medline, Norart, Scopus, SweMed+ and Web of Science in our search. We assumed that the number of included articles would be high and similar studies have described that inclusion of grey literature has been of minor importance [97]. Therefore, we omitted to search the grey literature.

3.3.3 Data collection

The data collection process for a systematic review relies on a well-defined PICO. A PICO is a framework aiming to clearly specify your research question. The mnemonic stands for population (P), intervention (I), comparisons (C) and outcomes (O). The "I" can be interchanged with an "E" (Exposure). In our study we defined the PI(E)CO as follows:

Population

Specially trained physicians working in a p-EMS. All categories of missions.

Interventions/Exposures

Documentation of GCS and/or SBP during the pre-hospital treatment interval for all patients. Identification and quality appraisal of accuracy, completeness and capture of GCS and SBP in studies depicting p-EMS.

Comparisons

GCS:

Was GCS reported according to the original method for reporting GCS? How was GCS reported (e.g., as a sum score, as individual components (eye-verbal-motor scores reported separately) or as categories)? When was GCS documented (before or after interventions, e.g., sedation or intubation)?

SBP:

How was SBP reported (e.g., as continuous invasive measurements, as repeated non-invasive measurements, as single non-invasive measurement or as palpation of pulses)? When was SBP documented (before or after interventions e.g., administration of vasoactive medications to raise blood pressure)?

Outcomes

GCS:

Types of deviations from original method for reporting of GCS.

Completeness rates. Missing cases (cases not included in the study). How was GCS documented after interventions (e.g., sedation or intubation)?

SBP:

Types of deviations from "gold standard" (continuous invasive measurement). Completeness rates. Missing cases (cases not included in the study).

To be valid and reliable, the data extraction must be pre-specified, reproducible and explicit. We predefined our data extraction and all information was registered in PROSPERO [98], an international prospective register of systematic reviews.

3.3.4 Quality appraisal

Items for depicting external and internal validity were chosen by the authors and are thus subject for selection bias and discussion. Quality appraisal was performed by one author, but uncertainties were discussed

with another author. Ideally two authors should have assessed all items on all included papers. However, the threshold for involving a second author was low, thereby reducing the risk of selection bias.

3.3.5 Meta-analyses

A meta-analysis combines results from studies addressing a similar clinical question by using statistical techniques. In the systematic review the studies and the results were heterogeneous, and we did not have data to proceed with a meta-analysis.

3.4 Study IV: Delphi method

Consensus development methods are increasingly used in health care, aiming to reach agreement on a certain topic. A group may together have a wider range of experience and knowledge than a single person. Furthermore, interactions between group members may generate new ideas and stimulate considerations of a wider range of options [99].

To take advantage of the knowledge of experts within our field, we used a Delphi method to create an updated version of the template for documenting and reporting in p-EMS [65]. The original template was published in 2011. Since then, new methods (e.g., REBOA [100] and ECMO [101]), medications (e.g., Tranexamic acid [102, 103]), therapeutic options (e.g., pre-hospital balanced transfusion protocols [104, 105]) and diagnostic tools (e.g., ultrasound [106]) have been commonly implemented in p-EMS. Precise reporting of these new methods, medications, therapeutic and diagnostic options was not available within the original template. Furthermore, implementation of the original template has not been as widespread as hoped for. Currently the original template is only implemented in Finland. Also, the feasibility study (Study I) showed clear areas for improvement of the template. We aimed to update the template and make it an even more relevant tool for data capture.

3.4.1 Choice of method

There are different methods available for reaching formal consensus, each with benefits and limitations. Three main approaches are common in the field of healthcare; the Delphi method, the nominal group technique (NGT) and the consensus development conference [99]. A fourth method; named the modified nominal group technique (m-NGT) has evolved during the past decade. This method is a combination of the Delphi technique and the NGT [62].

The Delphi method origins from the 1960s and was developed to obtain consensus in a systematic manner on a certain topic from a group of experts in a given field [107]. The method uses multiple rounds of questionnaires to collect data from a defined group of participants. At least two, but often more, rounds are needed to reach consensus, dependent of the topic. Feedback from previous rounds are given to participants in each round. All communication is through (e-)mail and there is no meeting or physical interaction between participants. The Delphi technique is advantageous when a large number of participants is desired and is more cost-effective than methods involving a physical meeting.

The NGT is a structured group meeting originating from the government, education, industry and social sciences since the 1960s [107]. The NGT typically gather a group of 10-15 experts in a given field who meet face-to-face to reach agreement on a certain topic. The meeting is led by a moderator and is commonly divided into separate rounds where experts propose, rate, discuss, re-rate and agree on variables or questions [62].

The consensus development conference was developed from a need to make decisions in a public forum [99]. Commonly a group of about ten people is brought together to constitute a decision-making group and to reach consensus. Evidence is presented to the decision-making group by various interest groups or experts. The decision-making group then retire

and try to reach consensus on a topic based on the evidence and information presented. All parts of the process are led by a chairman.

The m-NGT combines the Delphi and the NGT [62]. The method consists of four steps. The first two steps use the Delphi methodology to generate data variables. The third step is a physical consensus meeting where the experts can discuss their views in a structured way and conclude on e.g., which variables to include in a template. The process is led by a moderator. In the fourth step a coordinator edits a final proposal to agree upon, based on the conclusions from the consensus meeting. The final proposal is sent to the participating experts for approval.

The original template was developed by use of m-NGT. This method is proven efficient and is described for development of several templates [62]. However, the method is both expensive and time consuming because the experts have to meet physically. Furthermore, the results may be influenced by extrovert experts on behalf of more introvert participants. We wanted to explore whether an updated template could be created with a method that is more time- and cost efficient than the m-NGT. We also considered a physical meeting to be unnecessary because we did not expect all variables to be new. We already had some knowledge of which variables to implement (from the original template) and decided to use the Delphi technique. In the digital era, the Delphi technique has become readily available. Another important advantage with the Delphi technique, which we considered advantageous for our purpose, is that because all answers can be anonymized, we can avoid favouring certain responses. By using a coordinator for all interactions with the experts, all responses were anonymized to the researchers in the present study. Also, with increasing demand for social distancing and travel restrictions because of the Covid-19 pandemic, it is favourable to use a method not involving physical contact.

3.4.2 Choice of experts

There are no exact criteria for selection of participants for a Delphi study. Because experts do not physically meet, a Delphi study can have a substantial number of participants.

The original template had its origin in a joint Scandinavian project (The ScanDoc project [108]) and recruited three representatives from Scandinavia per one from other European services [65]. In the template update, we broadened to include European services. Many European countries share similarities regarding organization of their health care services and operate p-EMS similar to those in Scandinavia. To increase the relevance of the template also outside Scandinavia, we invited experts from the most active p-EMS in Europe, including Scandinavia, to participate. Furthermore, because the study was an update of a former published template, we decided to use the same criteria for expert recruitment as in the original template. These included:

1. Clinical experience by working in p-EMS
2. Scientific and/or substantial leadership responsibilities in pre-hospital care
3. Ability to communicate in English

Clinical experience from p-EMS was important to ensure that the participants had insight into the operational context of p-EMS, to make the template relevant for its intended use. Scientific or leadership responsibilities were important to potentially increase methodology compliance.

The number of participants in a Delphi study is a trade-off between what is ideal and what is acceptable. A large group could potentially have increased reliability of the resultant template compared to a smaller group. Ideally, the number of participants could have been higher in our study. However, Waggoner et al. concluded that on basis of the current literature, a panel size of 5 to 11 members is most beneficial across all

consensus methods described [109] and Nair et al. concluded that reliability of consensus recommendations declines when number of participants falls below six [107]. When number of participants is above 12, improvement of reliability is not substantial [107]. In our study, we invited 30 experts, of which 15 agreed to participate. Of these, 11 participants responded in the first round and nine participants responded in all rounds. The most common reason for rejecting participation was lack of time. We were successful in recruiting experts from high-activity p-EMS services in Europe (Germany, Switzerland, The Netherlands, Hungary, Spain, UK, Denmark, Finland and Norway) in our expert group. Thus; we considered the group to be representative for its purpose. Also, according to the literature, the number of participants was acceptable [107, 109].

3.4.3 Consensus

To define what is meant by consensus is a crucial part of a Delphi process, but currently no exact definition of consensus exists. Nair et al. described three methods for reaching consensus; a final vote determining percent agreement among participants, a rating scale (e.g., 1-5) where a predefined mean rating must be achieved for inclusion or that a majority of participants must give a topic a certain rating for inclusion [107]. For the present study we decided to refine the method for defining agreement compared to similar consensus processes in critical care. We defined consensus as when >70% of the participants rated a variable ≥4. This definition of consensus is transparent and clearly defined. Variables who were rated ≥4 by 50-70% of the participants were re-rated. Before the re-rating, the already included variables were presented to the participants. Re-rating reduced the risk of excluding variables relevant for inclusion.

3.4.4 Stages in the Delphi process

Stage 1

We wanted the template to be an update of the original template and distributed the original template to all experts [65]. To increase feasibility of data capture, similar variables should have identical definitions in different templates and be interchangeable. This prevents documentation fatigue. To encourage similar wording and definitions of variables, we therefore sent published templates from other areas in pre-hospital critical care to the experts [34, 41, 64, 110]. We highlighted that it was not mandatory to copy the definitions used in existing templates.

The experts suggested ten variables they considered most important for reporting in p-EMS within each of five predefined sections (Fixed system variables, Event operational descriptors, Patient descriptors, Process mapping variables and Outcome and quality indicators). The predefined sections were identical with the sections from the original template [65]. We also included an optional sixth section for proposal of variables that did not fit into one of five predefined sections. In total, 194 unique main variables were suggested. Several of the main variables had sub-variables.

Stage 2

The 194 unique variables suggested were structured in a worksheet. All the variables from the original template were among the suggested variables. The variables were sent back to the experts for rating from 1 (totally disagree) to 5 (totally agree) based on perceived relevance.

Stage 3

The first round of rating resulted in 68 included main variables. Thirty-five main variables and 32 sub-variables rated were rated ≥4 by 50-70% of experts and were returned for re-rating.

Stage 4

After re-rating, additionally 5 main variables were included. The final template included 73 main variables.

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4 Results

4.1 Summary Paper I

In Paper I we explored the feasibility of the original template reporting from p-EMS by assessing completeness rates [65]. Templates can generate a substantial amount of data, facilitating research [62]. However, the original template for reporting in p-EMS has not been readily implemented. A step towards increased implementation is to test feasibility. If suggested variables are not possible to document, then they should be revised or removed. This study was a first step in increasing the relevance, and implementation, of a p-EMS template.

We applied a standard (Finland) and a focused (Norway) data collection method. The main finding is that high completeness rates are achievable in p-EMS. Overall, we documented 73% of data with the standard data collection method and 90% of data with the focused data collection method. When efforts were optimized (focused data collection), rate of documentation did not differ between severely ill or injured (93%) and not severely ill or injured (87%) patients (p-value 0.94). We interpreted this as that the operational context has less impact on the degree of completeness than we hypothesized. Motivation and focus on documentation appear to have major impact on completeness rates, indicating that human factors are important and should be emphasized when aiming to increase completeness rates.

Physiological variables are reported to be frequently missing variables in p-EMS [111, 112], and this is consistent with our findings. Reporting of physiological variables almost doubled when comparing the focused (88%) to the standard (45%) documentation.

Time of day had no impact on completeness rates either for the focused or the standard data collection method.

For all variables with repeated documentation (physiological variables) the last value was less complete than the first. In Finland, the documentation rates for the first and last variables were 59% and 31% respectively. In Norway the first and last variables were documented in 90% and 86% of cases respectively. Repeated documentation of physiological variables is important to capture trends and changes in patient state and to reveal the effects of treatment.

For short missions (<20 minutes from alarm to patient is delivered at the receiving medical facility), we found a reduced documentation rate ($p < 0{,}001$ and $p < 0{,}009$ in Finland and Norway respectively when compared to missions >20 minutes). Documentation rate improved further when missions were >40 minutes. These findings were as expected. For the shortest missions there is not always time to prioritize data capture. Automated data capture from monitors may increase documentation rates for short missions.

Completeness rates for two variables were particularly affected by the template design. For the variables reporting diagnostic procedures performed and which breathing procedures were used, there was no option recording "none" or "not relevant". When none of the procedures were performed, the template did not allow to register this and only 41% and 36% of the data (focused data collection) was documented respectively. Thus, template design affected completeness rates and must be carefully considered when designing templates for reporting.

This study adheres to the overall aim by identifying that high completeness rates are achievable in p-EMS. In p-EMS in Finland and Norway, the operational contexts do not lead to substandard completeness rates. Efforts to increase implementation and motivation, but also template design must be highlighted.

4.2 Summary Paper II

Paper II explored whether pre-hospital physicians can score a reliable pre-event ASA-PS with the information available on-scene. Information necessary to score a full pre-event ASA-PS is considered not readily available in p-EMS because access to in-hospital journals is restricted. Having the full pre-event ASA-PS available in p-EMS facilitates p-EMS research, outcome prediction, quality assurance and triaging on-scene. Whether pre-hospital pre-event ASA-PS scores are equivalent with in-hospital scores are therefore of interest.

We used a two-stepped prospective inter-rater reliability method to explore whether a reliable pre-event ASA-PS could be scored on-scene. Pre-event ASA-PS was scored by pre-hospital physicians, based on information available on-scene. Information was mostly sought from the patient or next of kin. Three hundred and one patients were included. Five patients could not be scored due to unconsciousness or inability to communicate. Physicians reported that information was easy to obtain in 76% of the cases. In-hospital physicians scored pre-event ASA-PS based on information from hospital journals.

Using Shrout's interpretation of Cohen's Kappa [88], we found that inter-rater reliability of pre-event ASA-PS scores between pre-and in-hospital physicians was moderate to substantial (κ_w 0,47 - 0,89) when data access was different (Step 1). Inter-rater reliability was higher between the in-hospital physicians (κ_w 0,77 - 0.85). When all physicians had access to the same data (Step 2), the agreement increased (κ_w 0,65 - 0,93).

When data access was different (Step 1), pre- and in-hospital physicians had identical pre-event ASA-PS scores in 63% of cases. In 35% of cases scores were within one ASA-PS class from each other and in 2% of cases scores were more than one ASA-PS class from each other. When scores

were not identical pre-hospital scores were lower than in-hospital scores in 76% of cases.

The results above show that agreement between pre- and in-hospital physicians was somewhat lower than agreement among in-hospital physicians. Although the scores differ, we consider agreement between pre-and in-hospital scores as adequate. We concluded that the pre-hospital scores can be used as a comorbidity measure for pre-hospital patients, and we recommended application of the full pre-event ASA-PS classification system for documentation of comorbidity in p-EMS.

In this study we showed that p-EMS can score an adequate full pre-event ASA-PS on-scene. Quality of routinely reported data is increased because reporting the full pre-event ASA-PS scale increase discriminatory capability compared with dichotomized pre-event ASA-PS data.

4.3 Summary Paper III

Paper III explored the quality of reporting of GCS and SBP in scientific papers depicting p-EMS. We did this through a systematic review of the literature. A systematic literature search from January 2001 to August 2019 was performed in relevant databases and data on accuracy of reporting, completeness and capture were extracted. Assessment of external and internal validity was performed.

The search identified 5 530 records. We included 137 articles of which 111 reported GCS and 105 reported SBP. Seventy-nine articles reported both variables. The methodologies used in the included papers were heterogeneous. Nineteen studies were registry studies and six studies were interventional. Most studies were observational studies.

The main findings were that quality of reporting of GCS and SBP was varying and that most of the predefined variables for reporting external and internal validity were not reported (27% and 26% of external validity

data and 31% and 45% of internal validity data were reported for GCS and SBP respectively).

GCS was often reported as heterogeneous and unvalidated categories. There was no standard method for categorization and 15 different categorization methods were found. Reporting of GCS when functions were impaired due to illness, injuries or medical treatment (sedation/intubation) were poorly described and there was no clear strategy for reporting in such situations.

Repeated measures are important to follow the patient's physiology but were commonly not described. Completeness rates for GCS and SBP were reported in 40% and 45% of cases respectively.

Reporting of key variables in scientific papers is of varying quality and mandates increased focus on standardized reporting.

This study adheres to the overall aim of this thesis by highlighting the variable quality of reporting of GCS and SBP. Initiatives are needed to increase the quality of reporting. Describing the current situation was the first step in this process.

4.4 Summary Paper IV

Paper IV aimed to revise and update the original template for documenting and reporting in p-EMS through expert consensus.

Consensus can be reached through different methods and we applied a Delphi process with experts from the most active p-EMS in Europe, creating an updated template. We found that using a Delphi method to update a template was feasible. Efforts to increase implementation is crucial for the updated template to succeed and a data dictionary is under construction. The updated template was expanded by 42 variables, but the increase can in part be explained by different numbering of variables.

The “Fixed system variables” and “Outcome variables and quality indicators” sections increased the most.

We believe that a wide implementation rate is achievable given the involvement of experts from the most active p-EMS in Europe in developing this template.

This study adheres to the overall aim of this thesis by providing a feasible tool to generate uniform data.

5 Discussion

5.1 Summary of the answers to the questions asked

This thesis established that it is feasible to use a template for reporting in p-EMS and that template design and human factors affect completeness rates of template variables. Furthermore, we found that a reliable pre-event ASA-PS can be reported already on-scene. We discovered that GCS and SBP are heterogeneously described in the literature and pointed out how this influences quality of reporting and comparative research. We also updated the template for standardized reporting in p-EMS.

P-EMS is a limited resource, emphasizing the relevance of optimal use. Physiology is influenced immediately after a trauma or illness has occurred, not upon entering the hospital. Treatment and diagnostics should therefore be of high quality already on-scene. Because pre-hospital assessment and interventions on-scene are part of the continuum of care, data from p-EMS is important for documentation of the complete patient course and should be integrated with in-hospital data.

5.1.1 Data quality in p-EMS

Our main aim was to increase the quality of routinely reported data in p-EMS and through the different papers included in this thesis, we have assessed the data quality dimensions accuracy and completeness. Quality of reported data variables matter, because high quality data is a prerequisite for high quality research [56]. Most studies in p-EMS are based on retrospectively collected data from registries or medical records [62]. The data reported are of various quality, and incomplete and unclear reporting is common [113, 114]. This is worrying, but consistent with our findings (Paper III).

Ringdal et al. explored the comparability of Scandinavian trauma registries and found that although more than 200 different data points were collected, most lacked precise definitions and only 16 data points could be considered as similar enough to perform reliable comparisons of the quality of patient care [59]. Furthermore, inclusion criteria were not uniform [59]. Scandinavian p-EMS are quite similar [2], and collaboration is feasible, but the diversity of variables demonstrated by Ringdal et al. [59] complicates joint research of routinely collected data.

Precise definitions of variables increase accuracy and allow comparisons [59]. If routine data could be collected in a rigorous manner, with high compliance and high completeness rates, quality of retrospective studies could be increased. In Paper I, we found the use of a template to be feasible in p-EMS and argue for using a template for data collection to increase quality of retrospective data. However, to increase the feasibility of a template, a clearly defined data dictionary is needed, and efforts must be emphasized on motivation and implementation to increase completeness rates.

P-EMS provide goal-directed advanced therapy in a challenging environment [54]. Treatment and diagnostic options in p-EMS are increasing [100, 104, 105, 115-119] and to identify interventions that improve outcome when performed on-scene is important. Equally important is to find out which interventions should not be performed on-scene because the risk of complications is too high or because outcome is significantly improved by fast transport to definitive care [54]. Various scientific methods are needed to increase the evidence base in p-EMS [120]. RCTs are often described as gold standard, but few studies are randomized in p-EMS [121]. Randomization is challenging due to the nature of the emergency care and studies are often resource demanding. Also, the external validity of RCTs may be low [120]. Due to treatment, legal and governmental requirements, data is already reported for all missions, but this data is usually not adapted to research. To increase research possibilities, we should utilize routinely reported data to a

greater extent. However, the data must be clearly defined and customized to fit its purpose.

Initiatives to increase quality of health research also involves the use of, and adherence to, reporting guidelines as described by the Equator network (e.g., STROBE, PRISMA, SQUIRE, RECORD etc.) [122]. Adhering to such guidelines is also relevant for p-EMS research and reporting in accordance with the guidelines should be demanded by scientific journals in order to increase the quality of reporting.

5.1.2 Accuracy

We have defined accuracy as "the extent to which registered data are in conformity to the truth." [45]. This emphasize that decisions based on inaccurate data, involve a risk for erroneous conclusions to be drawn.

We addressed accuracy through Paper II and Paper III. It was important to reveal whether a reliable pre-event ASA-PS can be reported already on-scene because comorbidity information is not readily available in p-EMS. The findings in Paper II showed that we can use the pre-hospital pre-event ASA-PS for reporting comorbidity in p-EMS. However, assessment of pre-event ASA-PS for unconscious patients remain challenging. Ideally, p-EMS should have access to patient journals on-scene. Several countries have introduced summary care records (SCRs) which are electronic records providing access to important patient information [123, 124]. Access to SCRs may increase precision of pre-event ASA-PS scores and enable reliable scores of unconscious patients. However, access to SCRs is still not readily available in p-EMS.

The presence of comorbidities affects outcome in critical care [125, 126] and comorbidities are important for risk adjustment when evaluating pre-hospital interventions [70, 71, 75, 78, 127]. When comparing patients without comorbidities (ASA-PS 1) to patients with comorbidities (ASA-PS 2 or ASA-PS 3-4) a study found that unadjusted odds ratio (OR) for

death increased (OR 2,11 and 5,69 respectively) [128]. To include an accurate measure of comorbidity may allow better outcome prediction for p-EMS patients, thereby aiding decisions and research. A patient with pre-event ASA-PS 4 has a different physiological base than a patient with a pre-event ASA-PS 1. Recognition of comorbidity may aid triage decisions and determine threshold for, and timing of, interventions and physiological targets [75, 129]. E.g., threshold for invasive monitoring on-scene should be lower for fragile patients with a high comorbidity burden [129].

Tailored treatment is common in hospitals and stratification on comorbidity for individualized treatment is equally relevant in p-EMS [72, 125, 130]. Different comorbidity measures exist [131], but no comorbidity measure is agreed upon as standard in p-EMS. We chose to include the pre-event ASA-PS as a comorbidity measure because the scale is well known and already included in p-EMS templates [64, 65]. The ASA-PS is a subjective index of a patient's overall health status, not based on specific diagnoses. The scale was originally designed for statistical analyses and to standardize terminology [76, 77]. Other comorbidity indices, e.g., Charlson Comorbidity Index [132] and Elixhauser score [133] are based on age and a set of predefined diagnoses. Because access to hospital journals is restricted in p-EMS, scores based on defined diagnoses are considered unfeasible in p-EMS.

The ASA-PS did not originally attempt to describe operative risk, but the scale has been shown to correlate well with overall surgical mortality and mortality after trauma [75, 78, 79]. We have used the pre-event ASA-PS in a mixed p-EMS, with both medical and trauma cases. Whether pre-event ASA-PS correlates with mortality in a mixed p-EMS population is not known and must be explored.

Paper III focused on the accuracy, completeness and capture of reporting of GCS and SBP, aiming to depict the quality of GCS and SBP reporting in p-EMS studies. GCS and SBP are core physiological variables

commonly reported [114]. We concluded that that reporting of GCS and SBP in scientific papers was heterogeneous and of substandard quality. Inaccurately reported variables complicate comparisons and may affect the accuracy of research results.

Repeated measures of vital parameters in p-EMS are important because they may allow for understanding of the physiological changes and responses to treatment for each patient. Physiological changes may also serve as a surrogate measure for p-EMS performance [25]. Scoring systems such as the Mainz Emergency Evaluation Score (MEES) can quantify physiologic changes [92]. The MEES scoring system consists of seven variables (GCS, heart rate, hearth rhythm, SBP, respiratory rate, arterial oxygen saturation and pain). When reported at two different time points, changes in MEES (ΔMEES) can be calculated and describe whether the patient physiology has improved ($\Delta MEES \geq 2$), deteriorated ($\Delta MEES \leq 2$) or remain unchanged (ΔMEES -1 to +1). Thus, using the MEES scoring system provides an objective measure of physiological changes, facilitating outcome research [25]. We emphasized this in the updated template (Paper IV) by requesting physiological measurements at two different time points; when physicians arrive at patient side and at handover to the receiving medical facility.

Interventions performed on-scene will influence both GCS and SBP and to rationally decide whether study results are comparable, we need precise descriptions of the variables. This also applies to categorization of patients within a study. E.g., if vasoactive medication was administered, we need to know whether the SBP was measured before or after this intervention, as timing of measurement may yield significantly different results. To be useful for research purposes, the timing of measurements must be standardized. In the systematic review (Paper III), we found that timing of measurements was often not reported. One example includes whether GCS and SBP were reported before or after interventions. This was reported in 29% and 48% of

studies respectively. When timing of measurements is not known, or inconsistently reported, comparisons are difficult.

Reporting an accurate GCS is particular challenging when a patient is sedated or intubated because some or all components of the scale are untestable. A standard method for reporting GCS for sedated or intubated patients is not yet agreed upon in p-EMS. To enable accurate comparisons, regardless of method applied, the method selected must be reported. Most studies did not describe how GCS was reported when a patient was sedated or intubated (Paper III). Changes in GCS are important to evaluate effect of treatment and deterioration of patient state. Teasdale et al. recommend reporting each of the three GCS components (eye-verbal-motor) separately and assign the designation "not testable" listed with reason for all untestable components [134]. This approach will allow for comparisons of the GCS components possible to assess and we consider the method reasonable because it facilitates a reliable comparison of patients. However, regardless of how assessment of GCS is handled after sedation and intubation, the documentation approach must be reported.

5.1.3 Completeness

We defined completeness as "the extent to which all necessary data have been registered on registered cases" [45]. Complete data is not always present and different techniques for handling of missing data (e.g., complete case analysis, imputation) exists. However, complete data always outperform incomplete data and we should continuously strive to increase completeness rates [135, 136].

We assessed completeness in paper I and paper III and we found varying completeness rates reported in the literature (range 35-100%) (Paper III). More than half of the studies reporting GCS and SBP in p-EMS failed to report completeness rates (59% and 56% respectively).

A common objection to complete p-EMS data is the complexity of collecting complete data in an operational p-EMS context. This is in contrast to our findings (Paper I). We assessed different operational contexts to explore which factors affected data capture the most and except from short missions (missions with a duration of less than 20 minutes), completeness rates were high for all operational contexts. Especially missions with severely sick or injured patients are often reported to have missing data, explained by the assumption that physicians do not have time for data collection. We found high completeness rates for severely sick or injured patients when a focused data collection method was used (Paper I). Furthermore, physiological variables are reported to be the most missing variables in scientific papers [111, 112]. We found that rate of documented physiological variables in p-EMS almost doubled when a focused data collection was used (from 46% with a standard documentation method to 88% with focused documentation) (Paper I). The findings point towards motivation and training as main reasons for low completeness rates, not mainly operational issues. Training may increase adherence to guidelines and awareness of reporting [67, 137]. Motivational efforts are often closely related to an understanding of why a task is important and what we get out of it. This requires continuous feedback and highlighting of results that describe how we can use the documentation to improve patient care. Research and quality improvement initiatives of local data may increase motivation. Thus, efforts to increase motivation and training are maybe the most effective methods to increase completeness rates.

The updated template increased the number of variables compared with the original template (Paper IV). This may have implications for the completeness rates. Although we, based on the lessons learned from the feasibility testing of the original template, consider high completeness rates to be achievable also for the updated template, an increased number of variables may induce documentation fatigue. Part of the increased number of variables can be explained by different numbering. E.g., in

the updated template, breathing-related procedures and circulation-related procedures have their own main variable number while in the original template these variables are reported as sub-variables to a joint main variable. The first section, "Fixed system variables" was increased from 9 to 25, but the variables are intended for annual reporting and will thus not increase the workload during a mission. The following sections (2-5) have increased the number of variables from 22 to 48 thereby increasing the workload. Although they are possible to report, not all variables seem relevant for every mission. E.g., to collect all physiological variables at two time points for search and rescue missions, when a person is found in a good condition, may not be relevant. This has been taken into account by enable reporting "not recorded" for all physiological variables. To report "not recorded" will not give complete physiological data but can give a high "pseudo-completeness". Ideally, the reason for reporting "not recorded" (e.g., not relevant, not time to measure, forgot to measure) should also be recorded to identify how documentation can be improved. For other variables, such as whether a procedure was performed or not, it is highly relevant to include "none" or "not relevant" to increase completeness rates. The original template (Paper I) did not enable reporting of "none or "not relevant" for two variables, resulting in low completeness rates unable to distinguish between whether a procedure was not performed or not reported. Such "flaws" in template design must be monitored, e.g., by feasibility studies who can reveal such design impacts. Templates must be modified accordingly.

To increase completeness rates, it is possible to make reporting of variables mandatory. In Finland, mandatory documentation was introduced for some of the event operational descriptors and for all process mapping variables (Paper I). Physicians were not able to end registration of the case before the mandatory variables were reported. This strategy increases completeness rates and may be valuable in p-EMS. However, using mandatory variables requires selecting the right

variables. Physiological variables and time variables are not suitable for mandatory reporting because if you have forgotten to measure e.g., a blood pressure, you will have to report a false value to end registration. Such data fabrication will have the potential to introduce reporting bias. Mandatory reporting should rather be used for e.g., documenting whether procedures were performed or not, to describe the structure of a system or the competence of a crew. For selected data, mandatory reporting may be valuable.

5.1.4 The use of templates for documentation

Development of p-EMS has been an uncoordinated process and services have been developed through local initiatives. Furthermore, all p-EMS are adapted to national needs, resources and guidelines. This has created a myriad of different p-EMS variations, regarding operational issues, staffing and medical treatment available. However, patients are suffering from similar diseases or traumas regardless of location. Patient physiology follows similar pathways after trauma or disease regardless of where the patient is situated. Because several diseases and traumas are relatively rare, we argue that cooperation between services and countries is necessary to capture enough cases and data to generate research with enough power to conclude. However, when p-EMS systems are heterogeneous, we must minimize or exclude the effects of organizational and operational issues to determine what gives the best outcome for the patient. To use a template for reporting data may enable us to take into account the differences between services when comparing them and templates for reporting uniform data are therefore valuable. We therefore believe that the updated template (Paper IV) is relevant and of interest for most p-EMS.

Scientific papers often conclude that comparisons were difficult due to differences in data variables [59, 60]. The diversity of variables reported is comparable to our findings (Paper III), and the absence of unambiguous definitions complicates joint research [57, 59, 60, 138].

The use of templates does not guarantee uniform variables because of local adaptions [57, 138]. When we compared data from Finland and Norway (Paper I), a work-intensive job was needed to standardize categories because of local adaptions and differences in data formats. To allow accurate and rapid comparisons, variables must be unambiguously defined and registered in the same data format for easy export. This is achievable, but it requires strict adherence to variable definitions. Furthermore, a comprehensive data dictionary is mandatory to enable precise and accurate registrations. A common objection by professionals and stakeholders for the use of templates is that they do not find all variables relevant and they want other or additional variables included. We argue that this does not contradict the use of templates. As long as all template variables are uniformly reported, additional variables can be freely added and reported locally if desired.

5.1.5 Automated data capture

Today, paper registrations which are digitized in retrospect are common in p-EMS [36]. This method for documentation of the patient course can affect the data quality in several ways.

Firstly, documentation on paper is challenging because of weather conditions. Rain and snow restrict documentation on paper on-site. Secondly, operational conditions can impact documentation. E.g., patients at remote locations may need to be carried on a stretcher before being loaded into the helicopter. During the stretcher transport, the patient is often monitored or even ventilated, but documenting at the same time is often not possible because the physician also must help to carry the stretcher. Thirdly, severely ill patients pose a huge workload on physicians during transport and sometimes patient care must be given priority over documentation.

As described earlier, physiological variables are among the most missing variables in p-EMS [111, 112]. Automated data capture may potentially

increase both accuracy and completeness of physiological variables [25]. Automated data capture is common in the operating room and technology for using it in p-EMS exist. Automated data capture from monitors may decrease the workload, but custom tools for data collection are needed. We must also be aware of erroneous registrations, e.g., vibrations may affect measurements en-route.

The need for custom tools and automated data capture has been actualized by the Covid-19 pandemic. Pens and paper used for data capture, while the physician is simultaneously performing patient care, increases the risk for contamination of the documentation tools. An electronic device with automated data capture from monitors, which can be disinfected after each mission, could both increase data quality and reduce the risk for spread of infection.

5.2 Limitations

The studies included in this thesis have used different methods and different limitations adhere to each method. A limitation to Paper I is the low number of cases reported by some of the physicians. The registered cases ranged from 4 to 40 per physician, on average 8 cases were registered per physician. Because the physicians were evaluated as a group (not individually) we argue that the number of cases remain acceptable. To better depict reasons for missing data, we could have included a questionnaire exploring this.

Specific limitation to Paper II is the selection of participants. We did not quantify the effort each pre-hospital physician put into data capture for the pre-event ASA-PS scores. For some of the participants, the number of assigned scores were low and this may have influenced their kappa scores inducing inaccurate results. The study was performed in an anaesthesiologist-staffed p-EMS, but it remains unknown whether the results can be transferred to a non-anaesthesiologist p-EMS. Furthermore, patients who died prior to hospital arrival were excluded.

These patients are among the most severely sick or injured patients and they may have a substantial comorbidity burden. Omitting these patients may have overestimated the rate of agreement in this study.

Selection bias is a possible limitation to Paper III, e.g., erroneous exclusion or inclusion of studies in the systematic review. Likely, we failed to identify all relevant studies through our search strategy. This was demonstrated when performing the review; five studies were identified by chance. We attributed this to indexing of studies, but it may also be due to the search terms chosen. The quality appraisal items were defined by the authors and their transportability may be questioned. Information from the studies was subjectively interpreted, this can have introduced reporting bias.

Limitations to Paper IV include selection of participants. Our inherent tendency to recruit experts similar to ourselves may have introduced a selection bias. Furthermore, the number of participants (9 to 11 experts) was low. There is no agreement in the literature regarding participants in a Delphi study [139, 140], but a panel size of 6-11 has been suggested [107, 109]. We therefore considered 9 to 11 experts as acceptable. The risk of selection bias due to favouring of certain proposals were minimized as all responses from participants were handled by a coordinator and de-identified.

5.3 What is new and interesting with this work?

This thesis indicates that it is feasible to use a template for documentation in p-EMS, thereby challenging the conception that completeness rates are low in p-EMS due to operational conditions. We identified template design and motivation to be important factors for high completeness rates. Furthermore, the thesis highlights the importance of clear variable definitions and training to maintain high completeness rates over time.

This thesis also indicates that a reliable pre-event ASA-PS can be scored already on-scene. To our knowledge, this has never been described earlier. We therefore believe that the full-scale ASA-PS should be implemented for reporting of comorbidity in p-EMS, thereby potentially improving p-EMS outcome research.

We have also highlighted that documentation in scientific papers are variable and often substandard, complicating joint research and comparison of results. We have updated a template for reporting in p-EMS which we believe, if widely implemented, may generate uniform data and facilitate future research.

5.4 Who is this work useful to?

Most importantly, this work is relevant for the p-EMS patients. By providing a fundament for high quality data collection, quality of documentation may increase. Improved documentation quality may further increase quality of research and enable us to increase the evidence base for how to improve patient outcome. To continuously strive for improved patient outcome should always guide priorities in health care. Awareness among health care professionals (e.g., p-EMS physicians) of the importance of documentation can further increase documentation quality.

The work is also useful for p-EMS themselves to ensure deliverance of appropriate care, adherence to predefined standards, fulfilment of medicolegal requirements and development of procedures and medical capacities. Furthermore, high quality documentation is a backbone for operational issues in the delivery of p-EMS. For medical directors or stakeholders, high quality documentation can serve as a driver for important system decisions regarding staffing, operating hours, p-EMS deployment, disaster response etc. This has implications for the entire community regarding time to treatment and the capacity of p-EMS.

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6 Ethical considerations

The Norwegian Regional Committee for Medical and Health research ruled that Study I did not need formal approval (REK 2013/397b). In Finland all data was fully anonymized, and due to national regulations, no approval was needed. Each hospital district gave individual permission for data collection at each base in Finland (ID 85/2015, R16502, J4/16).

Study II was approved by the Regional Committee for Medical and Health Research Ethics in Western Norway (ID 2016/556). The committee ruled that no formal consent was necessary and exemption of consent for all patients was approved.

Study III was a systematic review and no approval was needed. The study was registered in PROSPERO prior to conducting the literature search (ID: CRD42016040031).

Study IV was a consensus process with experts who agreed to participate. The Regional Committee for Medical and Health Research Ethics in Western Norway (REK 2017/2498) considered the study protocol. They ruled that no ethical approval was needed. The Privacy Ombudsman (NSD 58762) considered the project not to include personal information and thus, there was no duty of notification and no approval was needed.

6.1 Ethical issues and dilemmas

In Study I we maximized data collection in Norway. Because all physiological data are commonly not collected twice for all patients there was a slight possibility that we by measurements would reveal pathology that we normally would not have found. This was particularly relevant for ECG findings. To handle incidental pathological findings, we instructed the physicians to follow up eventual findings by referral to a

relevant specialist for further investigations. No incidental pathological findings were identified during the study period.

In Study II, exemption of consent was approved for all patients. The general rule is that patients included in research shall give their consent to participate. In p-EMS this is usually not possible to achieve because the patient is severely ill or injured and thus unable to provide an informed consent. Studies involving the p-EMS population must always consider the potential disadvantage the study poses on their participants. In this study, three in-hospital anaesthesiologists had access to patient information to score pre-event ASA-PS. Regardless of this study, the anaesthesiologists have a duty of confidentiality and information about patients will never be shared. The disadvantage of being included was thus minimal. The Regional Committee for Medical and Health Research Ethics considered the disadvantage of being included in this study as negligible for each patient.

To protect the anonymity of the participating experts in Study IV, we used a coordinator for communication with the experts. The researchers did not at any time know which participant gave which answer. If participants have controversial opinions or opinions that differ from the majority, this can sometimes be difficult to a claim because participants are afraid of judgement. Anonymity ensures honest feedback.

6.2 Data sharing

6.2.1 General Data Protection Regulation (GDPR)

The European Union (EU) started their work with the GDPR [141] in 2012. Their aim was to create uniform regulations for person data in the whole Europe, e.g., to ensure that citizens had easier access to their own data and the right to have data deleted. The regulations were introduced in 2018. Unfortunately, the EU failed to agree on a common framework for the processing of personal data for research. Currently, researchers

must be aware that there may be differences between regulations among different countries. To succeed with joint research, a substantial work to adhere to the current and local regulations are needed. How this will impact the implementation of the updated template is currently not known but should be addressed.

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7 Conclusions, implications, further perspectives

7.1 Main conclusions

In this thesis we found that high completeness rates are available for reporting in p-EMS and that a reliable pre-event ASA-PS can be scored already on-scene. Furthermore, we found reporting of GCS and SBP to be heterogeneous in scientific studies. We have created an updated template for reporting in p-EMS. The updated template is a relevant framework capable of achieving our main aim; to increase quality of routinely reported data in p-EMS.

Pre-hospital critical care is a continuum, not a separate part of the patient course. A robust information system must be able to include data from several sources and to implement them to describe the complete patient course [142]. Uniform data collection and standardized evaluation is a prerequisite for high-quality outcome research, and we should continuously strive for improvements. However, the data collected should be linked with in-hospital and outcome data to get a detailed description of the complete patient course.

7.2 Future perspectives

Additional objectives for this project include creating a data dictionary and then work for implementation of the updated template in Norway, followed by implementation in all Scandinavian countries. Later, we will work for implementation of the updated template in Europe and creation of a common register for all p-EMS patients in Europe. Currently, no such register exists, and each national service manages its own data. If automated data capture from monitors could be directly imported into a common database, this would provide an unique opportunity for research and possibly enable us to answer the question of which advanced

interventions are essential on-scene. However, substantial work to adhere to the current regulations is needed to succeed. Furthermore, we should increase number of epidemiological studies by use of template data. We still lack knowledge of organizational and operational issues for most p-EMS.

A recently published systematic review describing number of trauma related research papers in the Nordic countries showed that only 40/844 (5%) of papers were collaborative studies across borders [121]. Because Scandinavian countries have many similarities, implementation of a common template with unambiguously defined variables may increase joint research. This may further increase knowledge of p-EMS effects and increase quality of care.

The updated template requests physiological data from two different time points; when arriving the patient and when the patient is handed over to the next level of care. In addition, the lowest SBP and SpO2 values are included for registrations. In TBI research, a SBP under 90 is correlated with worsened outcome for patients with brain injury [143] and it can be argued that the "dose" or time period with low blood pressure matters. Measurements at two time points is an improvement over single measurements, but ideally continuous measurements should be standard to depict a trend. In the field of new-born resuscitation, researchers revealed the normal heart rate during the first five minutes of life due to early, continuous measurements [144]. The findings changed the guidelines for resuscitation of new-borns. P-EMS are able to measure physiological variables at an earlier time point after trauma than in-hospital physicians. Documenting every single measurement within the patient course with early, automated data capture in p-EMS may enable us to study continuous physiological developments as early as possible after a trauma. Early measurements may increase the understanding of the patient course. The feasibility of automated data capture in p-EMS should be further explored.

Since the first Utstein template for cardiac arrest was created in 1991[33], several templates for other areas in critical care have been developed [31, 34, 64, 145]. Each template has been developed through separate expert consensus processes without any overall thought, cooperation or control. To make all the templates more relevant they should be combined, with uniform variables and definitions across templates. Not all variables are relevant for all cases, but technology selecting relevant variables when entering a preliminary diagnosis into a digitized registration form is available. When combined, the added value may be substantial and documentation fatigue will be minimized.

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Paper I

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RESEARCH ARTICLE Open Access

Collecting core data in physician-staffed pre-hospital helicopter emergency medical services using a consensus-based template: international multicentre feasibility study in Finland and Norway

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Abstract

Background: Comparison of services and identification of factors important for favourable patient outcomes in emergency medical services (EMS) is challenging due to different organization and quality of data. The purpose of the present study was to evaluate the feasibility of physician-staffed EMS (p-EMS) to collect patient and system level data by using a consensus-based template.

Methods: The study was an international multicentre observational study. Data were collected according to a template for uniform reporting of data from p-EMS using two different data collection methods; a standard and a focused data collection method. For the standard data collection, data were extracted retrospectively for one year from all FinnHEMS bases and for the focused data collection, data were collected prospectively for six weeks from four selected Norwegian p-EMS bases. Completeness rates for the two data collection methods were then compared and factors affecting completeness rates and template feasibility were evaluated. Standard Chi-Square, Fisher's Exact Test and Mann-Whitney U Test were used for group comparison of categorical and continuous data, respectively, and Kolomogorov-Smirnov test for comparison of distributional properties.

Results: All missions with patient encounters were included, leaving 4437 Finnish and 128 Norwegian missions eligible for analysis. Variable completeness rates indicated that physiological variables were least documented. Information on pain and respiratory rate were the most frequently missing variables with a standard data collection method and systolic blood pressure was the most missing variable with a focused data collection method. Completeness rates were similar or higher when patients were considered severely ill or injured but were lower for missions with short patient encounter. When a focused data collection method was used, completeness rates were higher compared to a standard data collection method.

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Conclusions: We found that a focused data collection method increased data capture compared to a standard data collection method. The concept of using a template for documentation of p-EMS data is feasible in physician-staffed services in Finland and Norway. The greatest deficiencies in completeness rates were evident for physiological parameters. Short missions were associated with lower completeness rates whereas severe illness or injury did not result in reduced data capture.

Keywords: Critical care, Emergency medical services, Pre-hospital emergency care, Feasibility studies, Documentation, Data collection,

Background

Systems for pre-hospital critical care exist worldwide, but emergency medical service (EMS) systems differ in resources, organizational and operational models; from simple systems providing basic life support to sophisticated systems providing critical care [1–10].

Treatment and diagnostic options in pre-hospital care are increasing and several in-hospital techniques are currently being applied in the pre-hospital setting [10–14]. To enable more point-of-care diagnostics and increase in advanced interventions, some EMS systems, especially in Europe and Australasia, have introduced helicopters and rapid-response cars staffed with specially trained physicians [10, 15]. The effect of physician-staffed EMS (p-EMS) is debated and studies report contradicting results [16–28]. A substantial challenge to assess quality of health care is lack of uniform documentation, this is also pertinent to p-EMS [29, 30].

The concept of consensus-developed condition-specific datasets has proven useful for research and quality assessment in several areas of critical care [30–33]. To evaluate the effect and efficiency of p-EMS, a template for uniform reporting of data from p-EMS was published [34]. However, to implement a template for documentation, feasibility of the template to collect the requested data in the context intended should be demonstrated [29, 35–39].

In Scandinavia, p-EMS is well established, and services are relatively similar, thus joint research efforts may be valuable [5, 34]. Finland is currently the only country where the template for documenting and reporting from p-EMS is implemented, thus the only country able to provide routinely collected template data. To evaluate template feasibility, we wanted to compare two different data collection methods in two similar systems. P-EMS in Finland and Norway employ the same operational and medical concept and differences between services are mainly seen in time variables, patient volume and service area [5]. We considered comparison of Finland and Norway to be feasible; thus, we decided to include these two countries for the present study.

The aim of the present study was to evaluate the feasibility of pre-hospital physicians to collect patient and system level data by using the template for uniform reporting of data from p-EMS [34], comparing data collection from a standard to a focused data collection method.

Methods

Study design

The study was an international multicentre feasibility study including two physician-staffed pre-hospital services. As the aim of the study was to examine the feasibility of collecting template data in a standard operational pre-hospital context, we designed a two-method collection protocol. We hypothesized that by using a dedicated and motivated group of physicians (focused data collection method), we would achieve a robust indication of whether the template data were possible to collect in general. By comparing data collected with the focused collection method to routinely collected data (standard data collection method) we could assess whether both methods were feasible, or if data collection was feasible for specially dedicated physicians only.

For the standard data collection method, data from the five p-EMS bases administered by FinnHEMS (the national operator of p-EMS in Finland), covering a total population of 3.7 million inhabitants, were extracted from their database for a period of 12 months (March 2013 through February 2014). The physicians were not informed that data were extracted, thus completeness rates represents routinely collected data for FinnHEMS.

For the focused data collection method, template data were collected prospectively for six weeks in Norway (January through March 2014) by 16 physicians from four p-EMS bases, covering a total population of 1.75 million inhabitants. Each participating physician was asked to collect template data as complete as possible on a predefined form and all physicians were informed that this was a study of completeness rates. Emphasis was on keeping the data collection period short to avoid study-fatigue. Data were placed in standardized categories and data sets from Finland and Norway were then merged.

Feasibility of the two data collection methods were assessed by comparing completeness rates on several variables. Variables that proved difficult to collect were

identified and reasons for different completeness rates were sought by comparing completeness rates for different patient groups and operational settings. Data were stratified according to medical problem, p-EMS escort to hospital, severity of the patient's condition, patient age, time from p-EMS arrival on scene to delivery at hospital and mode of transportation.

Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) [40] and Standards for Quality Improvement Reporting Excellence (SQUIRE) [41] guidelines were consulted when drafting the manuscript.

Data variables

The template for data collection consists of five main sections [34]. The first section, "Fixed system variables" contain data about service area, organization and activation criteria and is identical to all missions for each base, hence this section was not included in the study. The second section, "Event operational descriptors", contain time data, data on dispatch and type of transportation. The third section, "Patient descriptors", contain patient data, data on patient physiology and medical problem. The fourth section, "Process mapping data", contain data on medication and procedures performed during the mission and the fifth section, "Outcome measures", contain data on mission outcome. A full description of all variables is provided in Additional file 1. Physicians in Norway were instructed to register event operational and patient descriptors, process mapping and outcome measures. In total 33 variables were registered. Information on gender was omitted to de-identify patients. Further, the outcome measure "Physiological improvement" was also omitted, as this is a proposed quality indicator yet to be validated. The corresponding variables were extracted from the FinnHEMS database. For the standard data collection method, all process mapping data and data on unit arrival at scene, type and result of dispatch, comorbidity and medical problem were mandatory to register to complete patient records. For the focused data collection method, no variable was mandatory.

Statistical analysis

The two data collection methods were compared by comparing completeness rates on several variables. Variables that proved difficult to collect were identified and reasons for different completeness rates were sought by comparing completeness rates for different patient groups and operational settings. Data were stratified according to medical problem, p-EMS escort to hospital, severity of the patient's condition, patient age, time from p-EMS arrival on scene to delivery at hospital and mode of transportation. Categorical data are presented as counts (n) and proportions (%) while continuous data are presented as median and interquartile range (IQR). Standard Chi-Square, Fisher's Exact Test and Mann-Whitney U Test were used for group comparison of categorical and continuous data. Kolomogorov-Smirnov test [42] was used for comparison of distributional properties. Data were analyzed using IBM SPSS statistics version 22 and R 3.1.0.

Results

Study material

FinnHEMS submitted data from 12,486 missions. Of these, 8049 (64%) missions were excluded due to no patient encounter (supervision or advice only or due to a concurrent mission, weather or technical conditions), leaving 4437 (36%) missions eligible for further analyses. Norwegian p-EMS submitted data from 177 missions. Of these, 49 (28%) missions were excluded because of no patient encounter (due to weather or technical conditions), leaving 128 (72%) missions eligible for further analyses. The physicians in Norway registered on average 8 forms each, which is 1–2 forms per shift.

Patient and mission characteristics

Patient and mission characteristics are summarized in Table 1. In both countries the majority of dispatches were for medical missions. Finland had more trauma dispatches than Norway but fewer inter-hospital transfers. In both countries, trauma was the single most common medical problem, followed by cardiac arrest in Finland and chest pain in Norway. In Finland, p-EMS physicians were transported to the scene by helicopter, but most patients were transported to the hospital by ground ambulances accompanied by the p-EMS physician. Most Norwegian patients were transported to the hospital by helicopter. Finland had significantly longer median on-scene time and median time from origin call to patient arriving hospital compared with Norway, but there was no difference in transport time or time from when call was received at the emergency medical communication centres to p-EMS arrival at scene. Significantly more advanced procedures were performed in Finland compared to Norway, but there was no difference in the number of patients receiving medication.

Completeness of patient-level core data

With the standard data collection method, all 13 mandatory variables were 100% complete (Table 2) while further four of the variables were > 80% complete. Ten variables had < 50% completeness. Six out of ten physiological variables (first and last value of heart rate, systolic blood pressure, heart rhythm, oxygen saturation and respiratory rate) had < 50% completeness. With the focused data collection method, seven variables were 100% complete, and overall 29 variables were > 80% complete. Two variables were < 50% complete. Except from the two

Table 1 Patient and mission characteristics. Table depicts number of missions with registered variables and percent of registered variables

	Finland (n = 4437)	Norway (n = 128)	p-value[1]
Type of dispatch			
1 = Medical mission	2509 (57%)	77 (60%)	0.417
2 = Trauma mission	1687 (38%)	33 (26%)	0.005
3 = Inter hospital transfer	80 (2%)	17 (13%)	< 0.001
4 = Search and rescue mission	0	1 (1%)	< 0.001
5 = Consultation	161 (4%)	0	0.028
6 = Other	0	0	
Missing	0	0	
Type of transportation			
1 = Ground ambulance	3599 (81%)	35 (27%)	< 0.001
2 = Helicopter ambulance	95 (2%)	80 (63%)	< 0.001
3 = Fixed-wing	0	0	
4 = Other	0	0	
5 = No transportation	723 (16%)	4 (3%)	< 0.001
Missing	20 (0.5%)	9 (7%)	
Age			
Median (IQR)	58 (34–73)	54 (0–89)	0.002
Co-morbidity			
1 = No (pre-event ASA-PS = 1)	1213 (27%)	51 (40%)	0.002
2 = Yes (pre-event ASA-PS = 2–6)	2560 (58%)	73 (57%)	0.881
3 = Unknown	664 (15%)	4 (3%)	< 0.001
Medical problem			
1 = Cardiac arrest	889 (20%)	17 (13%)	0.059
2 = Trauma	1313 (30%)	35 (27%)	0.582
3 = Breathing difficulties	259 (6%)	8 (6%)	0.844
4 = Chest pain	128 (3%)	20 (16%)	< 0.001
5 = Stroke	256 (6%)	12 (9%)	0.087
6 = Acute neurology excluding stroke	606 (14%)	15 (12%)	0.528
7 = Psychiatry including intoxications	413 (9%)	2 (2%)	0.003
8 = Obstetrics and childbirth	74 (2%)	2 (2%)	0.927
9 = Infection	45 (1%)	6 (5%)	0.001
10 = Other	446 (10%)	11 (9%)	0.588
On scene time (min)			
Median (IQR)	22 (13–33)	12 (6–20)	< 0.001
Time from origin call to arrival hospital (pre-hospital time interval) (min)			
Median (IQR)	83 (62–109)	72 (49–98)	0.001
Transport time (min)			
Median (IQR)	24 (14–39)	23 (15–33)	0.585
Time call received at emergency medical communication centre – arrival at scene (min)			
Median (IQR)	23 (16–34)	26 (14–44)	0.199
Patients registered with advanced procedures	3064 (69%)	23 (18%)	< 0.001
Patients given medication	2470 (56%)	74 (58%)	0.630
Patients given medication and registered with advanced procedures	2101 (47%)	16 (13%)	< 0.001

Table 1 Patient and mission characteristics. Table depicts number of missions with registered variables and percent of registered variables (Continued)

	Finland (n = 4437)	Norway (n = 128)	p-value[1]
Patients given either medication, advanced procedures or both	3433 (77%)	81 (63%)	< 0.001

1: Chi-Square for categorical data and Mann-Whitney U Test for continuous data
ASA-PS: American Society of Anaesthesiologists Physical Status classification
IQR: Inter Quartile Range

variables reporting first and last systolic blood pressure, all physiological variables were > 80% complete.

Completeness rate and patient characteristics

Completeness rates were affected by clinical problems encountered and mission characteristics. Significantly more variables were collected with a focused data collection method than with a standard data collection method, both for different medical conditions, when patients were severely ill or injured and when patient care was less than 20 min. An additional file (Additional file 2) depicts our definition of a severely ill or injured patient. More variables were collected with focused data collection, regardless of transport mode. Completeness rate variations among different clinical problems are depicted in Figs. 1 and 2 and Table 3.

When comparing different patient groups for each data collection method, we found that for both methods, significantly less variables were collected when patient care was less than 20 min than when patient care was more than 20 min. Further, to be escorted by a physician to hospital resulted in more reported variables than when patients were treated by physicians on-scene and transported without physician. For children under 10 years of age, less variables were collected than when patients were older. Transport by helicopter resulted in significantly higher completeness rates with a standard data collection method, but there was no significant difference regarding transport mode with a focused data collection method. With standard data collection, significantly more variables were collected when patients were severely ill or injured compared to not severely ill or injured patients. There was no significant difference among these patient groups with a focused data collection. Differences in completeness rates among different patient groups with the two data collection methods are summarized in Table 4.

Discussion

When efforts are optimized, p-EMS can achieve high completeness rates in collecting prospective data using a template. Motivation and focus on documentation, rather than operational context, seems to affect data completeness rates most.

Lack of documentation is often highlighted as a limitation for research in emergency medicine, especially for retrospective registry studies [5, 35, 43–45]. Putting attention to increase the quality of routinely collected data may enable such data to be an important and effective source to monitor and compare services. As such, strategies to increase data capture should be sought [30, 43, 45–48]. Training programs may increase data capture, most likely by increasing attention to documentation [43, 48]. In our study the effect of motivation was evident, where significantly more data were registered with a focused data collection method than with a standard data collection method. Feedback on how high-quality research or quality assurance will benefit from complete data registration can make physicians more aware of the importance of data registration, thereby increasing data capture.

Echoing our results, several studies have found physiological variables to be the least documented variables [44, 45, 49]. Laudermilch et al. [44] found that 28% of patient records had missing physiological data and Bergrath et al. [45] reports vital parameters necessary to document Mainz Emergency Evaluation Score (MEES) to be present at two time points in only 31.08% of patients. Gravel et al. reports from the paediatric population that high rates of vital signs data are missing [50]. With a standard and a focused data collection method, 48 and 85% of physiological variables were registered, respectively, indicating that high completeness rates are achievable. However, physiological data were not complete, even with a focused data collection method. Good clinical assessment depends on correct evaluation of vital signs; thus, documentation of physiological variables is important [48, 50] and strategies for improvement of reporting should be sought.

Physiological data change according to patient state and repeated registrations of the same variable capture trends and reveal changes in patient condition and the effect of treatment [30–32, 46, 47, 51]. The p-EMS template requests documentation of physiological variables at two time points. For all repeated parameters we found the first value to be more complete than the last value, thereby complicating intervention comparison and comparison of changes in patient state. This is comparable with the findings of Bergrath et al. [45]. Medical directors should emphasize the statutory requirement for temporal documentation of physiological parameters and that this also pertains to p-EMS [52].

Table 2 Completeness rates for reporting in p-EMS. Table depicts number of missions with registered variables and percent of registered variables for standard and focused data collection method

Data point name	Standard (n = 4437) (%)	Focused (n = 128) (%)	p-value[1]
Event operational descriptors			
Call received at emergency medical communication centre	3085 (69.5)	128 (100)	< 0.001
Unit arrival at scene	4437 (100)	128 (100)	NA
Patient leaving scene	2493 (56.2)	117 (91)	< 0.001
Patient arriving hospital	1804 (40.7)	110 (86)	< 0.001
Type of dispatch	4437 (100)	128 (100)	NA
Type of transportation	4417 (99.5)	128 (100)	1.0
Result of dispatch	4437 (100)	128 (100)	NA
Patient descriptors			
Age	4434 (99.9)	127 (99)	0.108
Comorbidity	4437 (100)	128 (100)	NA
Medical problem	4437 (100)	128 (100)	NA
Glasgow coma score first	3712 (83.7)	125 (98)	< 0.001
Glasgow coma score last	1843 (41.5)	124 (97)	< 0.001
Heart rate first	2898 (65.2)	119 (93)	< 0.001
Heart rate last	1591 (35.9)	109 (85)	< 0.001
Systolic blood pressure first	2827 (63.7)	99 (77)	0.001
Systolic blood pressure last	1561 (35.2)	90 (70)	< 0.001
Rhythm first	3363 (75.8)	118 (92)	< 0.001
Rhythm last	1533 (34.6)	117 (91)	< 0.001
SpO2 first	2761 (62.2)	110 (86)	< 0.001
SpO2 last	1600 (36.1)	106 (83)	< 0.001
Pain first	863 (19.5)	123 (96)	< 0.001
Pain last	447 (10.1)	122 (95)	< 0.001
Respiratory rate first	2040 (46)	112 (88)	< 0.001
Respiratory rate last	1043 (23.5)	105 (82)	< 0.001
Process mapping			
Diagnostic procedures	4437 (100)	53 (41)	< 0.001
Drugs to facilitate airway procedure	4437 (100)	122 (95)	< 0.001
Device for successful airway management	4437 (100)	121 (95)	< 0.001
Breathing – procedures used	4437 (100)	46 (36)	< 0.001
Circulation – procedures used	4437 (100)	126 (98)	0.001
Disability – procedures used	4437 (100)	111 (87)	< 0.001
Medication – drugs administered	4437 (100)	127 (99)	0.028
Type of medication)	4437 (100)	123 (96)	< 0.001
Outcome Measures and Quality Indicators			
Mission Outcome	4419 (99.6)	127 (99)	0.418

1: Fisher's exact test
NA: not possible to calculate as two cells have a frequency of zero

Ideally data capture in pre-hospital critical care should be simple, accurate and fast. For both cohorts, clinical data are registered on paper during the mission and are later digitally registered. This process is time-consuming, inexpedient and carries a risk for recall-bias and documentation fatigue. Automated data capture from monitors may increase completeness rates and is widely used in anaesthetic services documenting every change in the patient state [53]. Implementation of these readily available concepts to the pre-hospital environment is

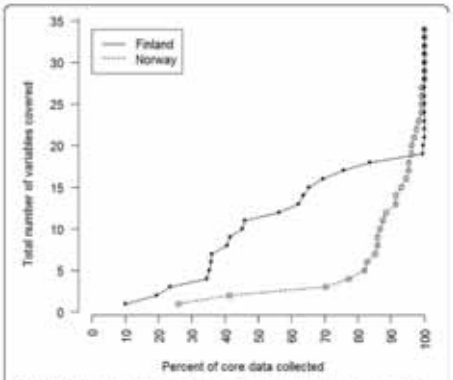

Fig. 1 Completeness rates for standard and focused data collection method. Figure depicting completeness rates for all variables with a standard and a focused data collection method. Each dot represents one variable, and the corresponding percent of core data collected for that variable. For perfect collection, the figure would be a vertical line of dots a 100%

increasing [54]. Although there are still challenges, automated data capture may reduce administrative workload, improve patient focus and transferal of patient documentation to the next level of care [54–58].

Laudermilch et al. [44] suggests that datasets are less complete for more severely injured patients and that increased workload reduce data capture. This is in contrast to our findings, where data capture was increased or remained equal for patients with a critical condition (Table 3). Corresponding with our findings, Bergrath et al. report calculability of MEES to improve with increasing medical severity [45]. Patients with minor complaints might be considered to require less attention and thereby an increased amount of missing data occurs [49, 59, 60]. However, with a focused data collection method, we found no differences in data completeness for less critical patients.

Time available for data capture may affect completeness rates. We found missions with less than 20 min of patient encounter were associated with lower completeness rates than missions lasting more than 20 min. This may reflect increased workload. For children below 10 years of age, we found lower completeness rates of vital parameters than for patients above 10 years of age. For less severely ill or injured children, measuring blood pressure can be uncomfortable and doctors may be reluctant to perform the measurements, resulting in lower completeness rates.

Categorization of data may increase data capture compared to registering exact values [59]. In Finland, where data were collected by a standard method, the template has been modified and pain was reported using a scale from 1 to 10 instead of using the original three-parted scale described in the template; no pain, moderate pain and severe pain. Jennings et al. [61] recommends the verbal numerical rating scale to measure pain in the pre-hospital setting, corresponding with the FinnHEMS template modification. In Norway, where a focused data collection method was used, pain was reported according to the original template. With the standard data collection method, we found that completeness rates for data on pain were low while with the focused data collection method, data on pain were almost complete, supporting a reduced number of categories to increase data capture. However, fewer categories reduce precision, leading to imprecise estimates, and must be weighed against the need for accuracy.

Outcome comparison often adjust for on-scene time, making low documentation completeness or imprecise registrations of this variable a limitation for research [62–64]. Eckstein et al. [65] found on-scene time being documented in 70% in a cohort of major trauma patients. In our study, on-scene time was documented in 56% an 91% of the cases with a standard and focused data collection method respectively, indicating that high completeness rates are achievable when attention is directed towards documentation. In Norway, the emergency medical communication centres automatically documented the origin time data whereas the response units registered other time variables on paper or non-portable devices [59]. Due to weather and operational conditions, paper registration was often not feasible, and variables were often registered in retrospect, increasing the risk for imprecise registrations. Portable devices available for registrations on site could further increase completeness rates and accuracy of data.

In our data Finland report significantly longer median on-scene times than in Norway (22 versus 12 min), still on-scene times are considerable shorter than reported from German (32 min) and Dutch (27.2 min) services [66]. For trauma patients, the concept of aiming for a pre-hospital time period less than one hour ("The golden hour") and of keeping on-scene times to not more than 10 min, have been directional for organization of pre-hospital care [67]. In recent years these concepts have been challenged [67–69]. Harmsen et al. conclude that emphasis should be on making sure the patient receives proper pre-hospital care rather than on getting the patient to hospital as fast as possible [70]. In our data, physicians in Finland are providing significantly more advanced procedures than in Norway. This may explain the longer on-scene times in Finland. We do not know, for our system, which advanced procedures should be performed by pre-hospital physicians to

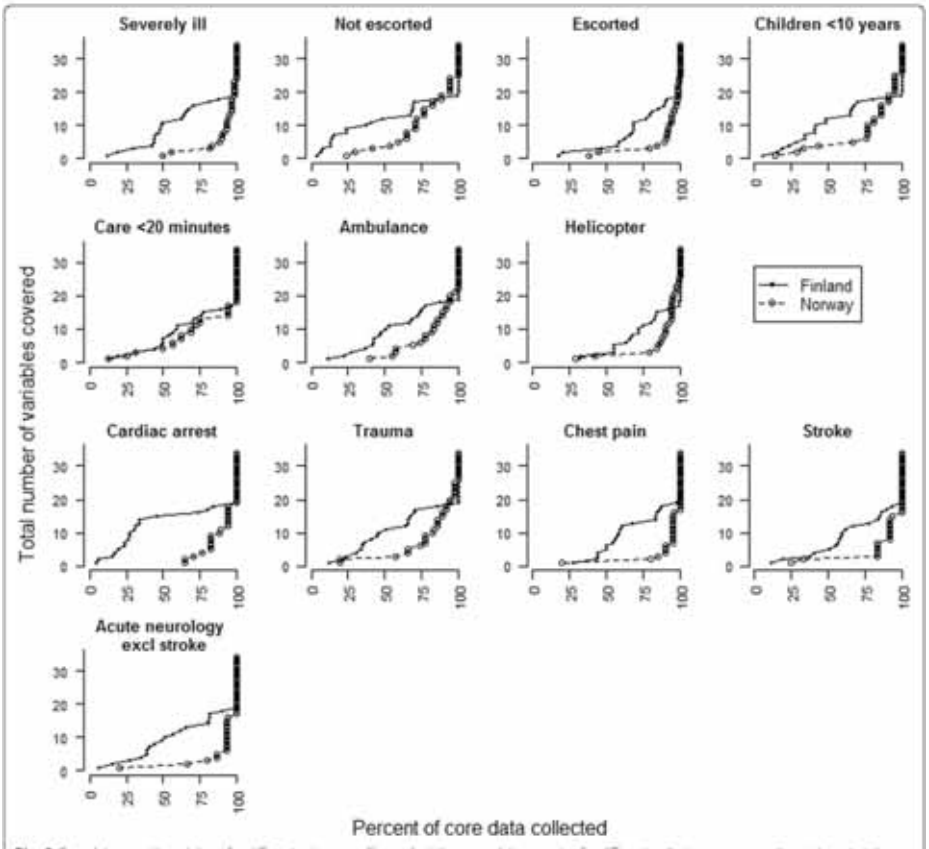

Fig. 2 Completeness rate variations for different subgroups. Figure depicting completeness rates for different patient groups, operational characteristics and medical conditions for standard and focused data collection methods. Each dot represents one variable, and the corresponding percent of core data collected for that variable. For perfect collection, the figure would be a vertical line of dots a 100%

improve patient care. However, we believe that uniform documentation may enable us, in the future, to identify procedures beneficial in p-EMS.

All process mapping data (procedures performed, and medication administered) are mandatory in Finland, possibly explaining the 100% completeness rates. In Norway, where no data points are mandatory, completeness vary between 26 and 99% for process data.

Two variables showed particularly low completeness rates in Norway: "Diagnostic procedures" and "Breathing – procedures used". For these two variables there is no option for choosing "none" or "not relevant", and when no procedure is performed these data fields will appear as missing. We suggest this to be revised in the template.

Comparing data from two countries had some practical challenges. Although both data collection methods collected data according to the same template, the data were registered in different data formats and in different language. To be able to compare the datasets a work-intensive data management job was needed to standardize categories. Thus, to allow rapid and accurate comparison we recommend data to be registered in the same data format. This is achievable and one might suggest a digital template with predefined names and categories to be implemented. This means that data, when

Table 3 Completeness rates per patient group, operational characteristics and medical conditions. Table depicts percent of data documented with standard and focused data collection method

	Standard (%)	Focused (%)	*p*-value
Cardiac arrest	66	92	< 0.001
Trauma	73	85	< 0.001
Chest pain	80	94	< 0.001
Stroke	80	91	< 0.005
Acute neurology	75	93	< 0.001
Severely ill	75	93	< 0.001
Care ≤20 min	82	88	< 0.001
Transport: Ambulance	75	87	< 0.001
Transport: Helicopter	91	85	0.002

transformed into statistical analysis software, must have the same properties, names and limitations to be able to be easily merged into the same database and analyzed. Adaptions where additional variables are included for local purposes can easily be managed within such a digital template without hampering template comparisons. We believe that simplifying the comparison processes by standardizing data entry will generate more multi-centre research.

Limitations

The present study has several limitations. We did not include a formal questionnaire to investigate reasons for missing data, although most physicians in Norway provided informal information regarding this. A questionnaire could have been useful to discover reasons for registration failure of importance to aid revision of the template. In Finland, the physicians were not informed about the study in advance, so the database reflects normal documentation rates in FinnHEMS bases. In Norway, the Hawthorne effect is an obvious and wanted effect, whereas the risk for this in Finland is lower.

The data are from 2013/2014 and this may be considered old. However, documentation method or organisation of p-EMS have not changed in either Finland or Norway since 2014, thus we believe the results still are valid and that newer data would have yielded similar results.

In Norway, 16 physicians participated, and each physician had on average 5 shifts during the data collection period. Each physician registered on average 8 cases, this is on average 1,6 cases per shift. This is a low number if each physician were to be evaluated individually. Because the aim of the study was to evaluate the documentation system, not the individual physician, we find the total number of cases registered in Norway to be acceptable.

The study was conducted in two similar p-EMS settings in two high-income countries and results may not be applicable to all other EMS settings. However, documentation for the study was paper-based, not including expensive equipment. The principles for pre-hospital emergency medical treatment are generally recognized, and international expert consensus on important data to be collected in the field should apply to both low- and high-income EMS systems. The concept of using a template by motivated personnel for data collection may therefore be applicable to other less resource-intensive settings.

Thirteen of the variables are mandatory to register in Finland and electronic patient files cannot be saved unless these variables are registered; completeness rates are therefore 100%. To compare these with Norwegian data will not give an idea of what is possible to collect in an everyday setting or if implementation challenges also apply for this type of data. Finally, the challenge with possible fabricated data to finalize registrations must be addressed.

Conclusions

We found that a focused data collection method increased data capture compared to a standard data collection method. With a focused data collection method, 88% of variables were more than 80% complete. The greatest deficiencies in completeness rates were evident for physiological parameters. Short missions were associated with lower completeness rates whereas severe illness or injury did not result in reduced data capture. We find the template for p-EMS feasible but highlight motivation and

Table 4 Comparison of completeness rates for different patient groups. Table compare different patient groups with standard and focused data collection method

	Standard (%)	*p*-value[1]	Focused (%)	*p*-value[1]
Severely ill or injured vs. not severely ill or injured	75 vs. 66	< 0.001	93 vs. 87	0.094
Care ≤20 min. vs. care > 20 min.	79 vs. 84	< 0.001	82 vs. 93	0.009
Escorted by physician vs. not escorted by physician	83 vs. 68	< 0.001	93 vs. 80	0.017
Transport ambulance vs. transport helicopter	75 vs. 85	< 0.001	87 vs. 91	0.394
Patients ≤10 years old vs. > 10 years old	70 vs. 73	0.030	82 vs. 91	0.008

1: Kolomogorov-Smirnov-test

training to maintain high rates of data capture after implementation.

Based on the findings in this study an international consensus-based revision of the template studied will be initiated.

Additional files

Additional file 1: Template for documenting and reporting in physician-staffed pre-hospital services. A full description of all variables listed in the template for documenting and reporting in physician-staffed pre-hospital services (DOCX 30 kb)

Additional file 2: Definition of severely ill or injured patient. A patient is considered severely ill or injured if one of the listed items are present. (DOCX 17 kb)

Abbreviations

ASA-PS: American Society of Anaesthesiologists Physical Status Classification; EMS: Emergency Medical Service; FinnHEMS: Finnish Helicopter Emergency Medical Service; IQR: Interquartile Range; MEES: Mainz Emergency Evaluation Score; NAAF: The Norwegian Air Ambulance Foundation; p-EMS: Physician-staffed pre-hospital Emergency Medical Services; SpO2: Saturation of peripheral Oxygen

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Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Authors' contributions

KT, AJK and HML conceived the idea. KT, AJK, ØØ and IV were involved in acquisition of data. KT analyzed the data, AJK and JR supervised the analysis. KT, MR, KGR, HML, IV, ØØ, JR and AJK were involved in discussions of interpretation of the data. KT drafted the manuscript and all authors (KT, MR, KGR, HML, IV, ØØ, JR and AJK) revised it critically during several revision rounds. All authors have approved the final version of the manuscript. All authors agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Ethics approval and consent to participate

The Norwegian Regional Committee for Medical and Health Research Ethics deemed the system revision to be a quality improvement initiative not in need of formal approval (REK 2013/397b). The Privacy Ombudsman at the individual health authorities in Norway gave permission for data collection (ID 2013/17 and 2013/9865). Due to the nature of the study and national regulations there were no need for written consent [71]. In Finland the study was observational in nature and the data analyzed were fully anonymized, therefore the Ethics Committee approval was not needed due to national regulations [72]. Each hospital district gave individual permission to data collection at each base (ID 85/2015, R16602, 34/16).

Consent for publication

Not Applicable.

Competing interests

The authors declare that they have no competing interests.

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Paper II

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RESEARCH ARTICLE Open Access

Assignment of pre-event ASA physical status classification by pre-hospital physicians: a prospective inter-rater reliability study

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Abstract

Background: Individualized treatment is a common principle in hospitals. Treatment decisions are made based on the patient's condition, including comorbidities. This principle is equally relevant out-of-hospital. Furthermore, comorbidity is an important risk-adjustment factor when evaluating pre-hospital interventions and may aid therapeutic decisions and triage. The American Society of Anesthesiologists Physical Status (ASA-PS) classification system is included in templates for reporting data in physician-staffed pre-hospital emergency medical services (p-EMS) but whether an adequate full pre-event ASA-PS can be assessed by pre-hospital physicians remains unknown. We aimed to explore whether pre-hospital physicians can score an adequate pre-event ASA-PS with the information available on-scene.

Methods: The study was an inter-rater reliability study consisting of two steps. Pre-event ASA-PS scores made by pre- and in-hospital physicians were compared. Pre-hospital physicians did not have access to patient records and scores were based on information obtainable on-scene. In-hospital physicians used the complete patient record (Step 1). To assess inter-rater reliability between pre- and in-hospital physicians when given equal amounts of information, pre-hospital physicians also assigned pre-event ASA-PS for 20 of the included patients by using the complete patient records (Step 2). Inter-rater reliability was analyzed using quadratic weighted Cohen's kappa (κ_w).

Results: For most scores (82%) inter-rater reliability between pre-and in-hospital physicians were moderate to substantial (κ_w 0,47-0,89). Inter-rater reliability was higher among the in-hospital physicians (κ_w 0,77 to 0,85). When all physicians had access to the same information, κ_w increased (κ_w 0,65 to 0,93).

Conclusions: Pre-hospital physicians can score an adequate pre-event ASA-PS on-scene for most patients. To further increase inter-rater reliability, we recommend access to the full patient journal on-scene. We recommend application of the full ASA-PS classification system for reporting of comorbidity in p-EMS.

Keywords: Critical care, Comorbidity, Emergency medical services, Pre-hospital emergency care, Physicians

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Background

Tailored treatment through adapted choice of therapy, medication and monitoring to each patient is a common principle in hospitals [1–3]. In all parts of critical care, decisions are made based on the patient's condition, including the patient's comorbidities [1, 2, 4]. Decisions of dose adjusted medication and volume loading before anesthesia are common examples of individualized adaptions in the operating room [4]. Pre-hospital critical care is a continuum, and pre-hospital management is often a part of the patient's course [5, 6]. As such, stratification on comorbidity, and individualized treatment, is equally relevant and valid for pre-hospital patients. In line with this principle, the patient's health status before the acute event should be accounted for in triage on-scene and to determine threshold for, and timing of interventions and physiological targets [7, 8].

Risk adjustments allows for better judgement about the effectiveness and quality of alternative therapies [1]. Comorbidity is an important risk adjustment factor when evaluating pre-hospital interventions [9, 10]. In general, there is an agreement that outcome after trauma is influenced by the patient's physical state before the trauma occurs [11]. Thus, to include a comorbidity measure is a prerequisite for comparisons and improves the precision of outcome prediction for trauma patients [8, 9, 12]. However, to obtain information on comorbidity from in-hospital records may be challenging for pre-hospital services due to logistics and legal issues of access and other strategies for obtaining this information should be explored.

Several methods for reporting comorbidities in pre-hospital emergency medical services (p-EMS) exists [8, 9, 13]. The American Society of Anesthesiologists Physical Scale (ASA-PS) classification system is used globally by anesthesiologists and classifies the preoperative physical health condition in patients before anesthesia and surgery. ASA-PS was originally designed to allow for statistical analyses of outcomes and to standardize terminology [14, 15], not to predict perioperative risk [15], but research has shown that the ASA-PS correlates well with overall surgical mortality [14]. Although the reliability of ASA-PS may be discussed, the scale is widely accepted as a tool to decide pre-operative health status [16]. The use of ASA-PS has expanded to the pre- and in-hospital critical care environment and pre-event ASA-PS, which is ASA-PS before the present injury or illness, [17] describes the inherent physiological state of a patient before an event. Pre-event ASA-PS is shown to be an independent predictor of mortality after trauma [8] and is included in templates for reporting of comorbidity in p-EMS and trauma [18, 19]. We therefore used pre-event ASA-PS as a comorbidity measure for the present study.

Ideally, pre-hospital services should have access to the full patient journal on-scene. Reality is however different and access to the full patient journal tends to be restricted for most pre-hospital services on-scene. P-EMS services must thus commonly base their decisions on the more limited amount of data and observations obtainable on-scene than for in-hospital physicians. Obtaining the complete medical history from seriously ill or injured patients on-scene is considered unfeasible, and reporting a dichotomized pre-event ASA-PS (pre-event ASA-PS 1 or pre-event ASA-PS > 1) is thus often recommended [20]. This simplification of the scale provides a very rough measure of comorbidity with low clinical discriminatory capabilities. Whether an adequate full pre-event ASA-PS can be assessed by pre-hospital physicians based only on the limited information generally available on-scene has not been explored and remains unknown. If scores between pre-and in-hospital physicians do not differ more than between in-hospital physicians, then the pre-hospital scores are just as "correct" as the in-hospital scores and can be used accordingly.

The aim of the present study was to explore whether it is possible for pre-hospital physicians to score an adequate pre-event ASA-PS already while on-scene.

Methods

Prospective observational inter-rater reliability study. We assessed the degree of agreement among two raters using the ASA-PS scale under different circumstances to decide whether different access to information influenced the scores. All patients admitted by p-EMS to two Norwegian hospitals during a period of three-months (Stavanger University Hospital 19 Aug – 18 Nov 2016 and St. Olav University Hospital 1 Feb – 30 Apr 2017) were included. Following the inclusion periods, in-hospital physicians scored all included patients (Step 1). Data collection for the second part of the study (Step 2) was finished 21 Mar 2018. All Norwegian p-EMS services are staffed with anesthesiologists and respond to all types of emergency conditions, search and rescue missions and inter-hospital transfers.

We used the pre-event ASA-PS to assess comorbidity. The pre-event ASA-PS does not take the present event into account and describes the physiological state of the patient before an event [8, 11, 21]. The ASA-PS provides a global, subjective index of a patient's overall health status, and pre-existing medical conditions are categorized on a scale of increasing medical severity (ASA-PS 1–5) [17].

Step 1. Inter-rater reliability study of pre- versus in-hospital scores

Pre-hospital physicians assigned a pre-event ASA-PS score on-scene based on information available out-of-

hospital only. The pre-hospital physicians did not have access to the full patient records. If the physician was unable to decide on a pre-event ASA-PS score on-scene, the score was kept unassigned and the main reason declared. After the three-month inclusion period, three in-hospital anesthesiologists at each of the two sites were given access to full patient records for all included patients at each site. Blinded from the pre-event ASA-PS score allocated by p-EMS each in-hospital physician used this information to assign pre-event ASA-PS scores for the included patients. No specific training for ASA-PS scoring was provided.

Step 2. Inter-rater reliability with equal access to data

Because p-EMS generally do not have access to the full patient journal comparing pre-hospital on-scene scores with in-hospital scores is an asymmetric comparison (as in-hospital physicians have access to more information). We thus did not expect perfect agreement between pre- and in-hospital raters. To assess agreement of pre-event ASA-PS scores when pre- and in-hospital physicians had access to equal data, 20 patients were selected by an online randomizer and re-scored by the pre-hospital physicians when given access to complete patient records. The rationale behind this was to assess whether an observed difference in scoring was due to different physicians (pre- versus in-hospital) or different data availability.

We were unable to identify any studies in which pre-event ASA-PS was scored in a real-time pre-hospital setting. Without prior empirical information on the variation of the phenomenon under study we were consequently unable to perform sample size calculations [22, 23]. Statistical rules of thumb for sample size varies in the literature and sample sizes from 10 to 50 is reported [24]. Combining existing advice, we chose to included 20 patients per physician to evaluate inter-rater reliability [24]. If no agreement between pre- and in-hospital physicians for 20 patients could be established, we considered the pre-hospital scores to be irrelevant.

Patients and physicians were anonymized prior to further statistical analyses.

Guidelines for Reporting Reliability and Agreement Studies (GRRAS) was used [25].

Statistical analyses

ASA-PS is an ordinal scale and agreement between two ASA-PS measures on the same individual was thus assessed using quadratic weighted Cohen's Kappa (κ_w); a modification of Cohen's Kappa that also accounts for the degree of disagreement between raters [26]. κ_w is a number between 0 and 1. $\kappa_w < 0.10$ indicates no inter-rater reliability, while 0.11–0.40 indicates slight, 0.41–0.60 indicates fair, 0.61–0.80 indicates moderate and 0.8–1.0 indicates substantial inter-rater reliability [27].

If two measurement methods are to be considered similar their results should be indistinguishable from one another [28]. Using κ_w values between pre- and in-hospital physicians as a measure of agreement, we performed minimax hierarchical agglomerative clustering; a method for exploring the inner agreement structure of a dataset [29]. The result from this clustering process is presented visually as dendrograms. Such dendrograms look like up-side-down trees, grouping elements that agree the most near the bottom of the graph, with decreasing agreement (i.e. inter-rater reliability) the higher on the graph. This approach allowed us to visually explore whether the agreement between pre-and in-hospital physicians were indeed indistinguishable from one another. The overall mean agreement [30] for all pre- versus in-hospital physicians was also calculated. Data were analyzed using IBM SPSS statistics version 22 and R 3.1.0.

Results

Pre-event ASA-PS was registered for a total of 312 patients. We excluded four patients admitted to non-participating hospitals and three patients without identifiable patient records. One physician scored only four patients, three with pre-event ASA-PS 3 and one that could not be scored. This did not allow for κ_w calculations, as scores were identical, and this physician and corresponding patients were thus excluded. In total 301 patients were available for further statistical analysis.

Pre-hospital physicians scored a median (range) of 21 (5–40) patients. Five patients (2%) could not be scored on-scene (four were unconscious and one was not able to communicate).

The distribution of ASA-PS scores between pre- and in-hospital physicians are presented in Table 1.

κ_w values for pre-event ASA-PS scores assigned by pre-hospital physicians on-scene, and subsequent scores based on complete patient records by in-hospital physicians are presented in Fig. 1.

Table 1 Distribution of ASA-PS scores. Table depicts corresponding ASA-PS scores for pre- versus in-hospital physicians for each patient

	ASA-PS	1	2	3	4	5	Total
Pre-hospital scores	1	198	72	11	0	0	281
	2	34	211	110	4	0	359
	3	0	24	123	43	1	191
	4	0	2	18	13	0	33
	5	0	0	0	0	0	0
	Total	232	309	262	60	1	864
		In-hospital scores					

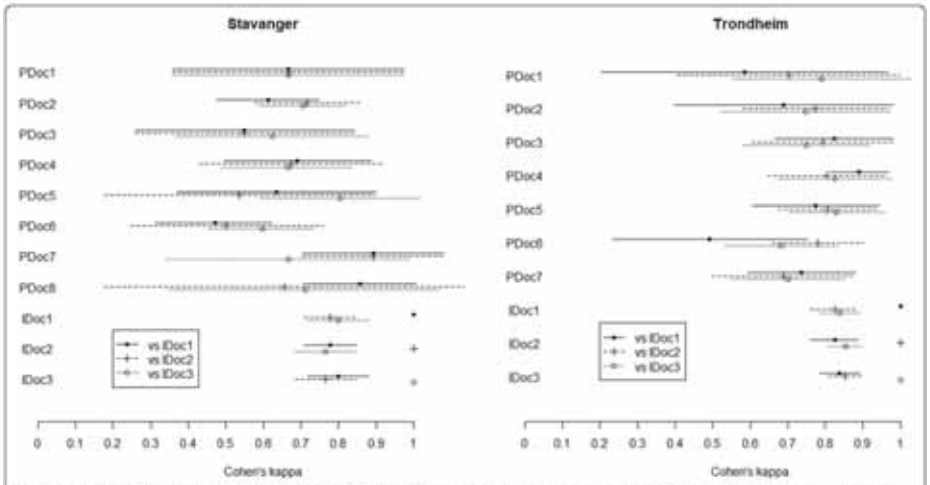

Fig. 1 κ_w values for pre-event ASA-PS scores. Estimated inter-rater reliability between each pre-hospital (PDoc) and in-hospital (IDoc) physician using quadratic weighted Cohen's kappa with 95% CI values

κ_w values ranged from 0.77 to 0.85 among the three in-hospital physicians, and from 0.47 to 0.89 when comparing the pre- to in-hospital physicians. The mean kappa values were 0,67 (PDocs Stavanger), 0,78 (IDocs Stavanger), 0,75 (PDocs Trondheim) and 0,84 (IDocs Trondheim). For most scores (82%) inter-rater reliability between pre-and in-hospital physicians were moderate to substantial ($\kappa_w > 0.61$).

The mean agreement between all pre-hospital physicians and each of the three in-hospital physicians is generally high. However, the three in-hospital physicians tend to agree more with one another than they agree with the pre-hospital physicians. This is demonstrated in Fig. 2.

When pre- and in-hospital physicians scored the same 20 patients with equal access to information, the agreement was strengthened. The difference in inter-rater reliability between the pre- and in-hospital physicians was much smaller, with κ_w values ranging from 0.65 to 0.93, indicating moderate to substantial agreement. Corresponding dendrograms for the two sites demonstrate that scores from pre- and in-hospital physicians do not cluster but remain largely indistinguishable from one another (Fig. 3).

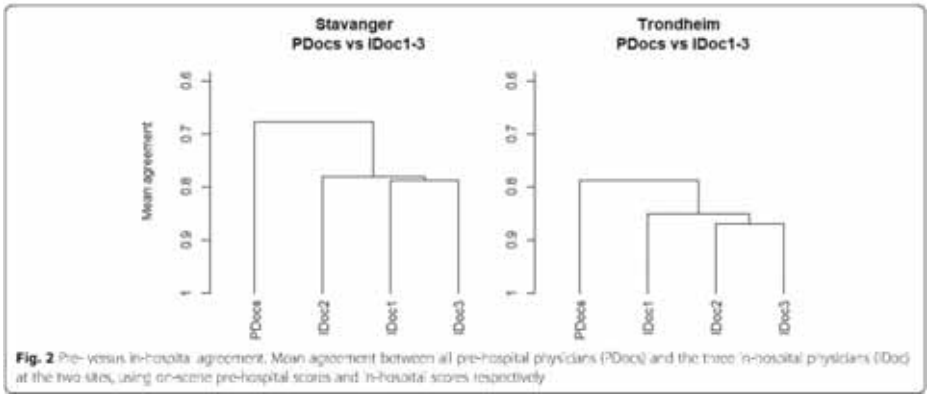

Fig. 2 Pre- versus in-hospital agreement. Mean agreement between all pre-hospital physicians (PDocs) and the three in-hospital physicians (IDoc) at the two sites, using on-scene pre-hospital scores and in-hospital scores respectively

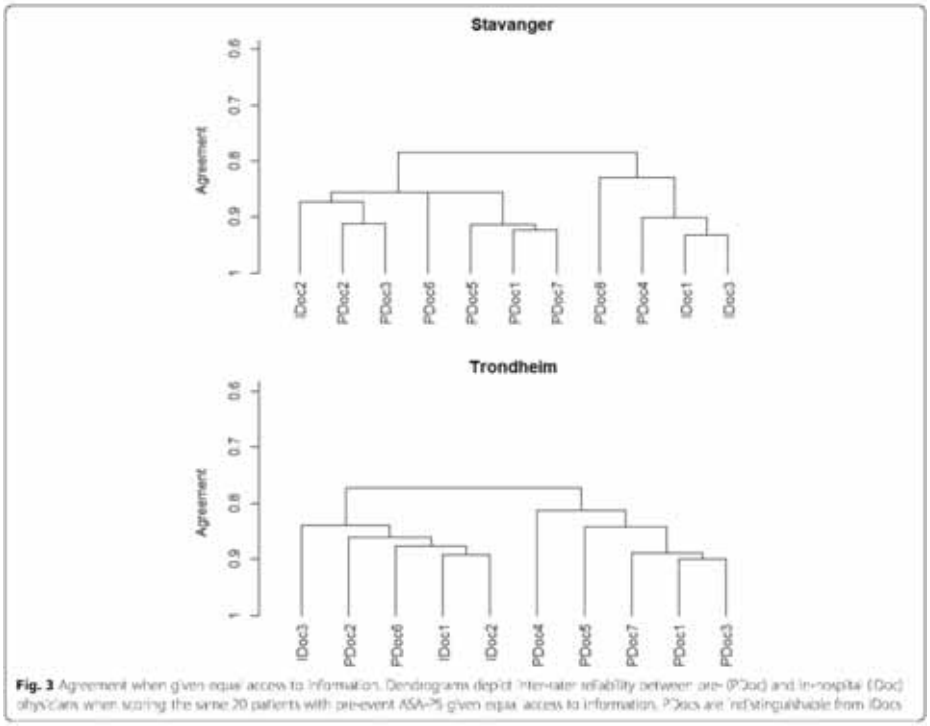

Fig. 3 Agreement when given equal access to information. Dendrograms depict inter-rater reliability between pre- (PDoc) and in-hospital (IDoc) physicians when scoring the same 20 patients with pre-event ASA-PS given equal access to information. PDocs are indistinguishable from IDocs

Discussion

The present study is a study of ASA-PS scoring in real life situations. As pre-hospital physicians did not have access to the full patient journal (Step 1), perfect agreement in ASA-PS scoring between pre-and in-hospital physicians was not to be expected. When comparing pre- and in-hospital pre-event ASA-PS scores, agreement was generally high ranging from fair to substantial. Most scores (82%) demonstrated moderate (64%) to substantial (18%) agreement, indicating that pre-hospital physicians can obtain sufficient data on-scene to score an adequate pre-event ASA-PS for most patients. Because the total number of pre-hospital scores are high, the impact of uncertainty in the scores, represented by broad 95% confidence intervals in Fig. 1, is reduced.

When pre- and in-hospital physicians scored pre-event ASA-PS on the same patients with access to complete patient records, agreement improved and ranged from moderate (52%) to substantial (48%). This indicates that ASA-PS scores from pre- and in-hospital physicians are indistinguishable from one another when they have equal data access (Fig. 3.). Accordingly, observed differences in pre-event ASA-PS scores in the first part of the study may be attributed to differences in data availability and time pressure on-scene rather than to factors related to individual physicians.

Comorbidity is an important risk-adjustment factor when evaluating pre-hospital interventions and the effect of p-EMS [9, 10]. Additionally, adjustment for comorbidity significantly increase the predictive accuracy of trauma outcome prediction models [9, 12, 31, 32]. The inherent nature of p-EMS favors a method for reporting comorbidities that is both readily available and time effective. ASA-PS is a well-known physical health condition scale, globally applied by anesthesiologists and surgeons, supporting the notion that pre-event ASA-PS may be advantageous for reporting comorbidity in p-EMS. However, studies have found substantial inter-observer variation [21, 33]. Most of these studies are hypothetical case scenarios designed by researchers [8, 16, 21]. In the present study we found that the agreement between pre- and in-hospital scores is acceptable

for most patients and argue that pre-event pre-hospital ASA-PS should be applied for documentation of comorbidity in p-EMS.

Obtaining complete medical history from seriously ill patients on-scene is considered unfeasible. Accordingly, a dichotomized pre-event ASA-PS is often reported [20]. This is a very rough measure of comorbidity with low clinical discriminatory ability and will not distinguish between mild and severe systemic disease. Our results indicate that p-EMS can assign an adequate full-scale pre-event ASA-PS score already on-scene.

Significantly less accuracy of assigning ASA-PS is reported for non-anesthesiologists compared to anesthesiologists, possibly limiting the validity of pre-hospital pre-event ASA-PS scores to anesthesiologist-staffed services [34]. Standardized education and encouraged use may decrease variability for less proficient users [35]. Knowledge of comorbidity is relevant for all emergency medical services to aid decision-making and to target the treatment. Reliability of pre-event ASA-PS scored by paramedics is unknown and should be subject for further research. Precise definitions of each ASA-PS class, along with training for use, may improve reliability and usability for all users.

Although the physicians in the present study did not have access to patient records only 2% of the patients could not be scored on-scene, all of which had impaired consciousness. These patients remain a challenge for p-EMS regarding comorbidity assessment. Access to patient records in p-EMS may increase feasibility and precision of pre-event ASA-PS scores and systems for field data access should be available. Summary care records (SCRs) are electronic records of important patient information available for authorized health care staff involved in patient care [36]. The prevalence of summary care records (SCRs) is increasing [36]. SCRs may provide timely and relevant patient information regardless of regional affiliation. Whether access to SCRs will increase reliability of pre-event ASA-PS scores on-scene remains unknown.

Limitations

The study was performed in a highly specialized anesthesiologist-staffed system and the results may not be transferable to other p-EMS. When number of assigned scores is low, conclusions may be inaccurate. Patients who died prior to hospital arrival were excluded. These patients are among the most severely sick or injured patients and may have a substantial comorbidity burden. Omitting these patients may overestimate the rate of agreement in this study.

Conclusions

For an anesthesiologist-staffed EMS covering a mixed patient population, an adequate pre-event ASA-PS can be assigned on-scene. When data access was equal, pre-event ASA-PS scores by pre- and in-hospital physicians were indistinguishable from each other. When pre-event ASA-PS was scored on-scene with restricted data access, inter-rater reliability was lower, but acceptable. We recommend application of the full pre-event ASA-PS classification system for documentation of comorbidity in p-EMS.

Abbreviations

ASA-PS: The American Society of Anesthesiologists Physical Status; p-EMS: Physician-staffed pre-hospital emergency medical services; GRRAS: Guidelines for Reporting Reliability and Agreement Studies; κ_w: Quadratic weighted Cohen's Kappa; PDoc: Pre-hospital physician; IDoc: In-hospital physician; SCRs: Summary care records

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Authors' contributions

KT, KGR and AJK conceived the idea. KT and AJK were involved in acquisition of data. KT analyzed the data. KGR, AJK, MR and JR supervised the analysis. All authors were involved in the interpretation of the data. KT drafted the manuscript and KGR, AJK, MR and JR revised it critically. All authors have read and approved the final version of the manuscript. All authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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The Norwegian Air Ambulance Foundation funded this project but played no part in study design, data collection, analysis, writing or submitting to publication.

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Ethics approval and consent to participate

The Regional Committee for Medical and Health Research Ethics in Western Norway (ID 2016/555) approved the study and ruled out that no formal consent was necessary, thus they approved exemption of consent for all patients.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Paper III

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REVIEW

acta Anaesthesiologica Scandinavica

Data quality of Glasgow Coma Scale and Systolic Blood Pressure in scientific studies involving physician-staffed emergency medical services: Systematic review

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The Norwegian Air Ambulance Foundation

Background: Emergency physicians on-scene provide highly specialized care to severely sick or injured patients. High-quality research relies on the quality of data, but no commonly accepted definition of EMS data quality exits. Glasgow Coma Score (GCS) and Systolic Blood Pressure (SBP) are core physiological variables, but little is known about the quality of these data when reported in p-EMS research. This systematic review aims to describe the quality of pre-hospital reporting of GCS and SBP data in studies where emergency physicians are present on-scene.

Methods: A systematic literature search was performed using CINAHL, Cochrane, Embase, Medline, Norart, Scopus, SweMed + and Web of Science, in accordance with the PRISMA guidelines. Reported data on accuracy of reporting, completeness and capture were extracted to describe the quality of documentation of GCS and SBP. External and internal validity assessment was performed by extracting a set of predefined variables.

Results: We included 137 articles describing data collection for GCS, SBP or both. Most studies (81%) were conducted in Europe and 59% of studies reported trauma cases. Reporting of GCS and SBP data were not uniform and may be improved to enable comparisons. Of the predefined external and internal validity data items, 26%-45% of data were possible to extract from the included papers.

Conclusions: Reporting of GCS and SBP is variable in scientific papers. We recommend standardized reporting to enable comparisons of p-EMS.

1 | INTRODUCTION

Physician-staffed emergency medical services (p-EMS) provide highly specialized pre-hospital care to severely sick or injured patients. Documentation of clinical examination and management is required by law and provides basis for further treatment, funding, clinical governance and research.[1,2] High-quality research relies on the quality of data,[3] but no commonly accepted definition of EMS data quality exits. However, one definition has been "data that are fit for use by data consumers."[4] Further, accuracy, completeness and capture are stated to be key dimensions of data quality.[5]

Accuracy of reporting is defined as the extent to which registered data are in conformity with the truth.[5] Low data accuracy may result in studies that identify problems that are not real.[2,6,7] A study from EMS reported accuracy of Glasgow Coma Score(CGS) and Systolic Blood pressure (SBP) reporting to be substandard.[8]

Completeness is defined as the extent to which all data have been collected on registered cases.[5] Missing data are a common problem in medical research and can reduce internal validity,[9,10] making completeness particularly important.[11]

Capture is defined as the extent to which all necessary patient cases that could have been registered have actually been registered.[3]

GCS and SBP are core physiological variables, but little is known about the quality of these data when reported in p-EMS research.[8]

GCS was originally designed to monitor patients with traumatic brain injury (TBI) but is widely used to assess the level of consciousness in all types of patients.[12,13] GCS is mandatory in several p-EMS reporting templates, trauma scores and in emergency departments.[14-16]

SBP is a vital sign routinely recorded in emergency patients and is commonly included in prognostic trauma models.[17] SBP can be measured continuously (Invasive Blood Pressure, (IBP)) or intermittent (Non-Invasive Blood Pressure (NIBP)) and may be used for triage purposes, as target in various treatments and for identification of change in patient condition.[17,18]

This systematic review aims to describe the quality of GCS and SBP data in studies depicting p-EMS.

2 | METHODS

2.1 | Protocol and registration

The study was registered in PROSPERO (CRD42016040031) prior to conducting the literature search.[19] The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement was consulted while drafting this review.[20]

2.2 | Eligibility criteria

Inclusion criteria.

- Original articles where any data on GCS and/or SBP captured by a p-EMS were reported
- Articles that report at least one value for GCS and/or SBP
- P-EMS present on-scene
- If a study reported data from both p-EMS and ordinary EMS, cases handled by p-EMS had to be reported separately
- Articles published between 1 January 2001 and 9 August 2019
- Articles describing both primary and secondary (transfer) missions

Exclusion criteria

- Articles in other languages than English, Swedish, Danish or Norwegian
- Book chapters
- Letters to the editor, reviews, case reports, conference abstracts, comments and editorials
- Articles where it was unclear whether service was p-EMS or not

2.3 | Information sources

An electronic database search was performed to identify papers published in the period from 1 January 2001 to 9 August 2019. The following databases were searched: CINAHL, Cochrane, Embase, Medline, Norart, Scopus, SweMed + and Web of Science.

The initial search was performed between 19 August 2016 and 5 September 2016. The search was updated to include 9 August 2019.

Editorial comment

This systematic review identifies high variability in the reporting of systolic blood pressure and Glasgow Coma Score in scientific studies involving physician staffed pre-hospital emergency medical services.

2.4 | Search strategy

The main search terms included "pre-hospital," "EMS," "physician," "GCS" and "SBP." Medical Subject Heading (MeSH) terms used for search was "Blood pressure," "Glasgow Coma Scale," "Emergency Medical Services," "Transportation Of Patients," "Ambulances," "Air Ambulances," "Physicians" and "Surgeons."

A complete search strategy is described in Appendix File 1.

2.5 | Study selection

The results were collected in Endnote X8 (2016; Clarivate Analytics, USA) before they were sent to Covidence.[21] One author (KT) scanned titles and abstracts of the identified literature. Literature that clearly did not comply with the inclusion criteria was excluded. The remaining articles were derived in full-text and each article was screened by two authors in pairs (KT and MR, KT and AJK or KT and KGR) and further for eligibility according to inclusion and exclusion criteria listed above. Excluded articles were listed with reason for exclusion. Uncertain articles were discussed among all the authors before reaching consensus.

2.6 | Data collection process

One author (KT) performed quality appraisal to depict the internal and external validity using predefined items. Uncertainties in assessments were discussed with another author (MR). Due to data heterogeneity, a meta-analysis was not performed. No ethical approval was sought because this is a literature review.

2.7 | Data items

Data analysis was performed according to the populations, interventions/exposures, comparisons, outcomes, study design (PICOS) methodology as described in the PRISMA guidelines.[20] The population was specially trained physicians working in a p-EMS. The defined exposures,

comparisons and outcomes were carried out by using the data extraction and quality appraisal variables described in methods and depicted in the results section (Figures 2 and 3) and Tables A1 and A2. Data extraction described quality of documentation (accuracy, completeness and capture), study mix, barriers and facilitators of documentation in p-EMS.

3 | RESULTS

3.1 | Study selection

The search identified 5530 records after duplicates (435) were removed and 190 full-text articles were assessed for eligibility. Of these, 132 articles were included in the study. In addition, five articles were identified by manual searches and included (Figure 1). Studies were mainly excluded because SBP or GCS were not reported or because studies did not report data from physicians-staffed units and ordinary EMS separately.

3.2 | Study characteristics

Of the included articles, 32 articles reported GCS only, 26 articles reported SBP only whereas 79 articles reported data for both GCS and SBP. Nineteen studies were registry studies and six studies were interventional studies. Nine studies included children only, 60 included adults only, 54 included both children and adults whereas 14 studies did not report age of included patients.

Physicians in the included studies were mostly anaesthesiologists, emergency physicians or a mix of both. A few were registrars from different specialties. For 48 studies the specialty of the physician was unknown.

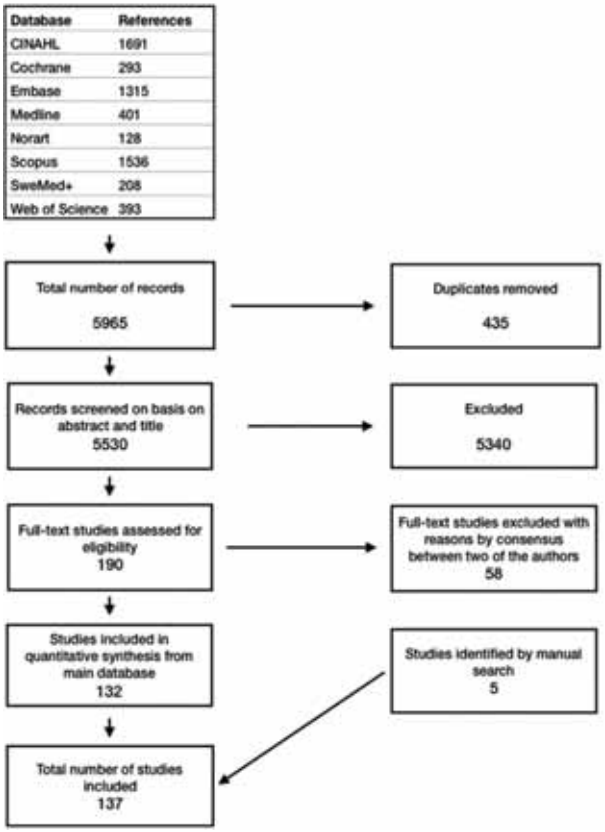

FIGURE 1 Flowchart depicting the different stages of the systematic literature review

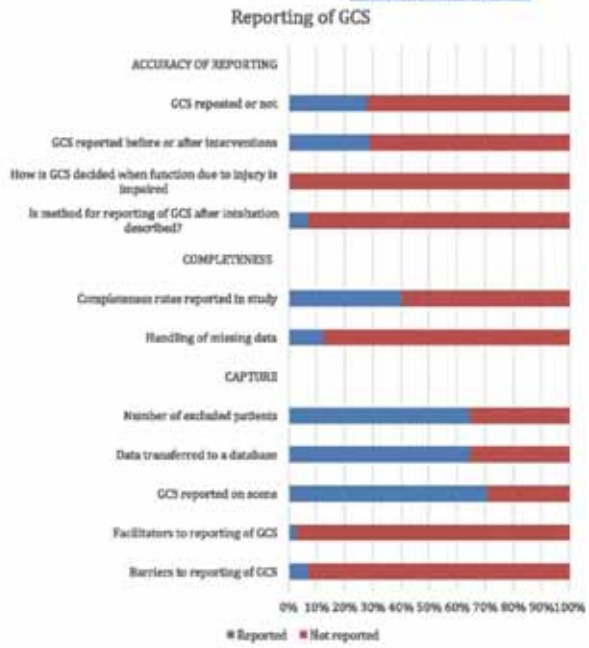

FIGURE 2 Figure depicting number of included studies who report accuracy of reporting, completeness and capture of selected GCS data [Colour figure can be viewed at wileyonlinelibrary.com]

Most studies (111) were conducted in Europe. Germany (20), United Kingdom (19), France (13), The Netherlands (12), Denmark (11) and Finland (9) conducted three fourths of the studies. Eight studies were conducted in Australia, eight in Japan, two in Brazil, two in Israel and one in USA, Russia and Taiwan respectively. Three studies did not report location.

Sixteen studies reported medical cases, 81 reported trauma cases, one reported neonatal cases and 39 reported a mix of cases.

Fifty-two studies were prospective and 83 were retrospective. For two studies we could not establish whether the studies were prospective or retrospective. Study design was clearly described for 130 studies.

An ethics committee approved 72 of the studies. For 26 studies it is described that approval was not required and 39 studies did not report information regarding approval.

3.3 | Glasgow Coma Scale (111 articles)

Reporting of GCS data are depicted in Figure 2. We found 65 studies reporting mean/median or exact values for GCS and 38 studies reporting GCS in various categories. We found 15 different ways to categorize GCS.

Three studies reported both categories and median GCS. Two studies reported both exact value and the motor component of GCS and three studies reported both Eye-Verbal-Motor (EVM) responses, and GCS exact values.

In 56 studies children were included. Of these, one study reported that paediatric GCS[22] was used.

Among studies reporting completeness rates, the lowest completeness rate was 41.5%. For 12 of the studies reporting completeness rates, GCS was a criterion for inclusion and completeness rates were therefore 100%.

Of studies reporting number of excluded patients, exclusion rates ranged from 0 to 64.4%.

Reported facilitators to GCS reporting were the presence of predefined check boxes for reporting GCS and various human factors (motivation, feedback and training of personnel).

Reported barriers to GCS reporting were related to various procedures (sedation, anaesthetic drugs, intubated patients) and difficulties of recording GCS when providing care to critically injured patients due to lack of time. Furthermore, practical challenges (difficulties of recording GCS while providing care to critically injured patients due to lack of time, inadequate documentation tools) and human factors (lack of training, inadequate motivation and inexperience in scoring) were noted as barriers.

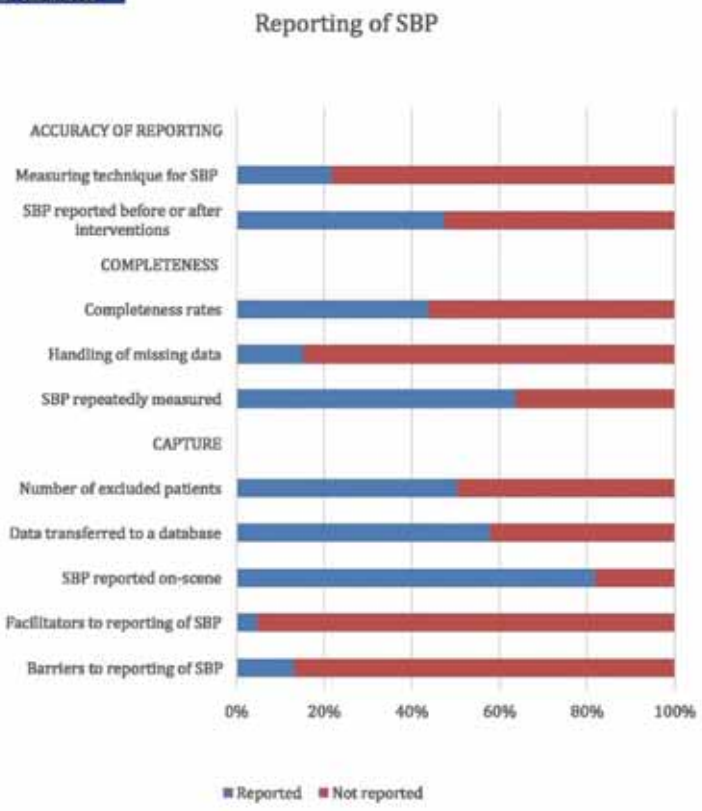

FIGURE 3 Figure depicting number of included studies who report accuracy of reporting, completeness and capture of selected SBP data [Colour figure can be viewed at wileyonlinelibrary.com]

3.4 | Systolic blood pressure (105 articles)

Reporting of SBP data are depicted in Figure 3. In 23 studies the measuring technique for SBP was reported. Of these, 20 studies reported NIBP and three studies reported IBP.

Among studies reporting completeness rates, the lowest completeness rate reported was 35.2%. Of the studies reporting number of excluded patients, exclusion rates ranged from 0% to 77.9%.

We found 61 studies reporting that data were transferred to an electronic patient management system. Of these, six studies described automatic transfer.

Facilitators to SBP reporting were reported by five studies and included technical (the presence of vibration-tolerant monitors, custom-made documentation tools, automatic devices with reliable and automated measurements) and human factors (competence, experience, feedback, motivation and personnel training).

Reported barriers to SBP reporting included practical (restricted access to patient due to clothing or entrapment, unfeasible to undress patient due to climate, lack of time, unfeasible to establish IBP in pre-hospital environment), technical (vibrations, no access to custom measurement and documentation tools) and human factors (motivation, competence, experience).

3.5 | Quality appraisal

The predefined variables for quality appraisal of the included articles are shown in Table 1. The full quality appraisal of included articles is depicted in Tables A1 and A2.

TABLE 1 Predefined variables for assessment of external and internal validity

	Glasgow coma scale	Systolic blood pressure
External validity	• Does study describe who decided/recorded GCS? • Are number of excluded missions reported? • Are completeness rates for GCS reported? • Was the feasibility of collecting GCS evaluated? • Are barriers to registration of GCS reported?	• Does study report who recorded SBP? • Are number of excluded missions reported? • Are completeness rates of SBP reported? • Was the feasibility of collecting SBP evaluated? • Are barriers to registration of SBP reported?
Internal validity	• Is the method for documenting GCS clearly defined? • Is GCS registered as exact values or categories? • Are handling of missing GCS data described? • Is there a reference to when GCS was obtained (before or after interventions)? • Are EVM responses reported? • Is there a reference to how GCS is documented if function due to injury is impaired?	• Is the method for documenting SBP clearly defined? • Is SBP registered as exact values or categories? • Are handling of missing SBP data described? • Is there a reference to when SBP was obtained (before or after interventions)? • Is there a reference to how and where SBP was obtained (EPJ/paper/other)?

Notes: EVM, eye-verbal-motor responses, EPJ, electronic patient journal.

Three articles reported all the items on the predefined data extraction list for external validity of GCS whereas no article reported all the items requested for internal validity. On average 27% of external and 31% of internal validity data were reported respectively.

Three articles reported all the items for external validity of SBP whereas two articles reported all the internal validity items. Average amount of reported data was 26% and 45% for external and internal validity data respectively. For either GCS and SBP we found no differences in the reporting rate between prospective and retrospective studies.

4 | DISCUSSION

In this systematic review, we found a variable rate of accuracy, capture and completeness for reporting of GCS and SBP in p-EMS. Quality appraisal revealed that most of the predefined variables for assessment of external and internal validity were not reported. High completeness rates are achievable in p-EMS[23] arguing for increased focus on documentation and reporting of data collected. The dynamics of patient physiology can only be captured through repeated measurements. Accurate and complete documentation and reporting are therefore important to identify effects of treatment and changes in patient state. Furthermore, comparison of studies and merging of data is difficult if reporting of data is poorly defined, hampering joint research.[24,34] Uniform documentation promotes comparisons and outcome research of high quality.[25]

4.1 | Accuracy of reporting

The accuracy of reporting GCS and SBP was low. In most studies timing or method of measurement were not reported, complicating comparisons and evaluation of results.

We found 29 studies reporting GCS as categories. Categorization of GCS originates from neurotrauma research efforts to categorize TBI patient into groups of severe (GCS 3-8), moderate (GCS 9-12) and mild (GCS 13-15) head injury.[32] Among the included studies the categories used were heterogeneous, and we found overall 15 different ways of categorizing GCS. Even for TBI studies, different categorizations were used. The category GCS 3-8 was often used, but there is a clinically significant difference between GCS 3 and GCS 8, and one might question whether categorization into such a heterogeneous group will yield valid conclusions. One study used GCS categories corresponding to the Revised Trauma Score (RTS) categorization.[26] Different categorization may reflect that the use of the scale has expanded to various patient groups, and is no longer used for TBI patients solely, thereby complicating valid comparisons in pre-hospital research.[7,34,35] Furthermore, the categories "severe" (GCS 3-8), "moderate" (GCS 9-12) and "mild" (GCS 13-15) often used in TBI research are not scientifically grounded. The categories were chosen "ad hoc" and the cut-off points are not yet validated.[32] To enable research across different countries and p-EMS systems, we recommend reporting an exact GCS whenever possible. If categories are to be used, agreement of categories and validation of these should be established.

Another obstacle to accuracy of GCS reporting is injuries or illness affecting functions like speech and motor skills. This may interact with the assessment of the GCS components and affect GCS scores.[27] We found no studies reporting how GCS was reported when injuries or illness (eg aphasia, extremity fracture, maxilla-facial trauma and paralysis due to different origins) impaired function. There is no consensus in literature on how to score, for example, aphasic or paralytic patients and strategies vary.[27] Furthermore, p-EMS commonly intubate patients, but 93% of the studies failed to describe how GCS was reported after intubation. Different approaches to GCS reporting for intubated patients are suggested, but still no consensus has been achieved.[13,28] The verbal component is particularly challenging for intubated patients and different approaches are reported; for example, to use a pseudo score of "1" for the verbal component, to substitute the verbal component with the median value of the motor and eye components or eliminating the verbal component.[29] Several studies argue that omitting the verbal sub score has similar accuracy

compared to the full GCS score.[27] However, to enable comparisons, and to increase reliability, a standardized approach is called for.[12,13] Thirty studies specify that the GCS reported is measured before sedation or intubation. Among the studies reporting how GCS was handled after intubation, two studies used the pre-intubation value and three studies used a pseudo score of "3" for all intubated patients. A pseudo score of 3 is different from a true value of 3 and using pseudo scores or conservative coding is not recommended as it does not reflect the situation.[12] It is recommended to report GCS by its three components (EVM) and assign the designation "not testable" (listed with reason) whenever a component is untestable.[13] This will allow imputation methods and provide a more reliable comparisons of patients with illness or injuries that interferes with assessment of the GCS score.

Similar to GCS, the assessment of SBP will be influenced by confounding factors. Sedation, intubation, haemorrhage control initiatives (tourniquets, pressure bandages), fluid therapy and drugs will affect SBP measurement. Several studies report the "first SBP" measured without reporting if interventions were performed prior to measurement. Whether SBP was reported before or after interventions was only reported in 45% of the studies, thereby limiting recognition of confounding factors.

IBP remains the gold standard for measuring blood pressure in hospitals but is not commonly reported in p-EMS.[30,31] We found only three of the included studies reporting IBP. For patients with acute brain injury (TBI or intracranial haemorrhage), monitoring continuous blood pressure to immediately identify changes or stabilization of blood pressure is important and linked to outcome.[32] Furthermore, IBP may immediately identify ROSC during ongoing cardiopulmonary resuscitation. For trained EMS physicians, establishing IBP pre-hospitally should be feasible and should be considered by p-EMS for selected indications.

4.2 | Completeness

Complete documentation and reporting is a quality indicator in p-EMS.[33] Missing data remain a methodologically quality concern in medical sciences[34] and high completeness rates are called for.[18]

Repeated measures and documentation of vital signs allow deeper understanding of patient's physiology and improved status may be considered a surrogate marker of quality of care.[35,36]Repeated measures and documentation of vital signs allow deeper understanding of patient's physiology and improved status may be considered a surrogate marker of quality of care.[36–39] To calculate Delta-MEES, physiological variables must be recorded at two different time points. Completeness rates are lower when two measurements are requested compared to single measurements and the last value is more often missing than the first, being a hindrance for reporting Delta-MEES and for outcome evaluation.[23,39]

Strategies for reducing missing data may reduce biased results and increase quality of research.[8] A clear strategy for documenting GCS, when function due to injury or illness is impaired, or patient is intubated, can increase completeness rates. Furthermore, customized tools for documentation should be provided. Registration on paper forms is common, but the use of automated data capture tools is increasing.[20,24] Automated data capture from monitors reduce workload and increase completeness rates for monitor data like SBP. In addition, we know that motivation and feedback may improve completeness rates.[23]

4.3 | Capture

Data capture are reported in 65% and 51% of GCS and SBP studies respectively. Thus; for a significant proportion of studies we do not know whether more cases could have been included. Furthermore, for GCS and SBP we found studies reporting up to 80% excluded cases due to difficulties in data capture. A large proportion of excluded cases may produce biased results and one might question whether the results remain valid.

Several challenges with data capture were reported. Experience in GCS scoring may influence data capture, for example, scoring of children requires competence in applying paediatric GCS. For unexperienced users, it may be difficult to score GCS when patients are severely ill or injured and attention must be focused on patient treatment.

Data capture is closely related to data completeness and strategies for increasing completeness rates, for example, customized documentation tools, motivation and feedback may also increase data capture. Monitor data may allow automated data capture, but only six studies claimed that SBP was transferred directly to a database through automated data capture on-scene.[40] Equipment enabling automated data capture from monitors and electronic patient records should be considered implemented. Also, templates may increase data capture and reporting by providing a standardized method for documentation.

For SBP, entrapment and cold climate pose particular challenges to data capture. When access is permitted, the palpation of radial or carotid pulses may be the only monitoring option. In addition, to expose the patient for NIBP measuring may inflict hypothermia and IBP measured via the radial artery may be a better choice.

4.4 | Suggestions for the future

Due to the variable reporting of GCS and SBP described in this review we suggest increasing the use of standardized reporting by use of, for example, templates with a comprehensive data dictionary with clear definitions for each variable. To increase motivation for its use, scientific journals should request details regarding reported variables, for example, timing of documentation, method used for measuring and the number of missing variables whenever appropriate. Categorization of GCS should be agreed upon. Furthermore,

automated data capture has the potential to report precise monitor data, for example, for SBP and robust systems for pre-hospital automated data capture who can integrate with hospital data should be implemented.

4.5 | Limitations

There is always a danger of selection bias when performing a systematic review, for example, erroneous exclusion or inclusion of studies. Furthermore, some relevant studies may not have been identified during our database search due to poor indexing or application of imprecise search. Furthermore, including only papers written in English or Scandinavian languages increased the risk of missing relevant studies. The quality appraisal items were designed by the authors in the absence of a universally accepted definition of data quality. Included studies were heterogeneous and information was subjectively interpreted thereby potentially introducing reporting biss.

5 | CONCLUSIONS

The quality of reporting of GCS and SBP in p-EMS is variable in scientific papers. Uniform documentation and reporting promote comparisons and high-quality outcome research. Given the variable reporting identified in this review, we recommend standardized reporting to enable better comparisons of p-EMS.

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CONFLICT OF INTEREST

We declare no conflict of interest.

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APPENDIX A

FILE 1

Federated Search performed in Embase and Medline (Ovid) 5 September 2016. (Search rerun on 8 August 2019).

Database: Embase < 1974 to 2016 September 02>, Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid

MEDLINE(R) Daily and Ovid MEDLINE(R) <1946 to Present > Search Strategy:

1. blood pressure/ (498 379)
2. (systolic pressure or blood pressure or SBP).tw. (624 425)
3. Glasgow coma scale/ (25 864)
4. (glasgow coma scale or GCS).tw. (35 746)
5. 1 or 2 or 3 or 4 (912 248)
6. patient transport/ or ambulance transportation/ or air medical transport/ or ambulance/ (37 456)
7. (ambulance* or transport* or transfer* or (emergenc* adj (car* or vehicle*)) or helicopter* or aircraft* or airplane*).tw. (2 005 063)
8. emergency health service/ (115 910)
9. ((emergenc* adj (health or medical) adj service*) or emergenc* service* or EMS or P-EMS or HEMS).tw. (41 915)
10. (pre-hospital or prehospital or out-of-hospital).tw. (44 273)
11. 6 or 7 or 8 or 9 or 10 (2 152 634)
12. physician/ or anesthesist/ or cardiologist/ or emergency physician/ or orthopedic specialist/ or surgeon/(428 571)
13. (physician* or an?esthesiologist* or an?esthesist* or an?esthetist* or surgeon* or cardiologist* or orthopedic specialist*).tw. (1 193 754)
14. 12 or 13 (1 376 457)
15. 5 and 11 and 14 (1962)
16. limit 15 to (danish or english or norwegian or swedish) and last 15 years) (1580)
17. 16 use oemezd (1271)
18. Blood Pressure/ (498 379)
19. (systolic pressure or blood pressure or SBP).tw. (624 425)
20. Glasgow Coma Scale/ (25 864)
21. (glasgow coma scale or GCS).tw. (35 746)
22. 18 or 19 or 20 or 21 (912 248)
23. "transportation of patients"/ or ambulances/ or air ambulances/ (41 792)
24. (ambulance* or transport* or transfer* or (emergenc* adj (car* or vehicle*)) or helicopter* or aircraft* or airplane*).tw. (2 005 063)
25. Emergency Medical Services/ (104 137)
26. ((emergenc* adj (health or medical) adj service*) or emergenc* service* or EMS or P-EMS or HEMS).tw. (41 915)
27. (pre-hospital or prehospital or out-of-hospital).tw. (44 273)
28. 23 or 24 or 25 or 26 or 27 (2 146 703)
29. physicians/ or surgeons/ (267 200)
30. (physician* or an?esthesiologist* or an?esthesist* or an?esthetist* or surgeon* or cardiologist* or orthopedic specialist*).tw. (1 193 754)
31. 29 or 30 (1 316 799)
32. 22 and 28 and 31 (1678)
33. limit 32 to (danish or english or norwegian or swedish) and last 15 years) (1296)
34. 33 use ppez (310)
35. 17 or 34 (1581)
36. remove duplicates from 35 (1330)
37. 36 not 17 (303) (*Medline*)

38. 36 not 34 (1027) (*Embase*)

TABLE A1 Quality appraisal Glasgow Coma Scale

	External validity				Internal validity								
	Is it described who decided/recorded GCS?	Are completeness rates for GCS described?	Are number of excluded missions reported?	Was the feasibility of collecting GCS evaluated?	Are barriers to registration of GCS reported?	Is method for documenting GCS clearly defined?	Is GCS registered as exact values or categories?	Are EVM responses reported?	Is there a reference to how GCS is documented if function due to injury is impaired?	Is there a reference to how and where GCS was obtained (EPJ/paper or other?)?	Are handling of missing data (GCS) described?	Is there a reference to when GCS was obtained (before or after interventions)?
Ahb [41]	✗	✓	✗	✗	✗	✗	✗	✗	✗	✗	✗	✗
Aussiker [42]	✗	✗	✓	✗	✗	✗	○	✗	✗	✓	✗	✗
Buch [43]	✓	✓	✓	✗	✗	✗	○	✗	✗	✓	✓	✓
Bergrath [39]	✓	✓	✗	✗	✗	✗	○	✗	✗	✓	✓	✓
Bieler [44]	✗	✗	✗	✗	✗	✗	✓	✗	✗	✓	✗	✗
Borron [45]	✗	✗	✓	✗	✗	✗	✗	✗	✗	✓	✗	✓
Brazinova [46]	✗	✗	✗	✗	✗	✗	✓	✗	✗	✓	✓	✗
Brennona [47]	✗	✗	✗	✗	✗	✗	✗	✗	✗	✗	✗	✓
Brennona [48]	✗	✗	✗	✗	✗	✗	○	✗	✗	✗	✗	✓
Cordes [49]	✓	✓	✓	✗	✗	✗	○	✗	✗	✗	✗	✗
Corfield [50]	✗	✗	✗	✗	✗	✗	✗	✗	✗	✓	✗	✗
Coniche [51]	✓	✓	✓	✗	✗	✗	○	✗	✗	✗	✗	✗
Der Harbag [52]	✗	✓	✓	✗	✗	✓	✓	✓	✗	✗	✓	✗
Dilbarbiness [53]	✗	✓	✓	✗	✗	✗	○	✗	✗	✗	✗	✗
Duhaiteau [54]	✗	✓	✓	✗	✗	✓	✓	✗	✗	✗	✗	✗
Engel [55]	✗	✓	✗	✗	✗	✗	○	✗	✗	✗	✗	✗
Follin [56]	✗	✗	✓	✗	✗	✗	✓	✗	✗	✗	✗	✗
Fortin [57]	✗	✓	✓	✗	✓	✓	✓	✗	✗	✓	✗	✓
Franken [58]	✓	✗	✓	✗	✗	✗	✓	✗	✗	✓	✗	✓
Franchina [59]	✗	✗	✓	✗	✓	✗	✓	✗	✗	✗	✗	✗
Franchinan [60]	✗	✓	✓	✗	✗	✗	✓	✗	✗	✗	✗	✗
Franchinan [61]	✗	✓	✓	✓	✓	✗	✓	✗	✗	✗	✗	✓
Fruchtnicht Christensen [62]	✗	✗	✗	✗	✗	✗	✓	✗	✗	✓	✗	✗
Fries [63]	✗	✗	✗	✗	✗	✗	✓	✗	✗	✓	✗	✗
Garrer [64]	✗	✓	✓	✗	✗	✗	○	✗	✗	✗	✗	✗
Garrer [65]	✗	✗	✗	✗	✗	✗	✓	✗	✗	✗	✗	✗

(Continues)

TABLE A1 (Continued)

	External validity				Internal validity									
	Is it described who decided/recorded GCS?	Are completeness rates for GCS described?	Are number of excluded missions reported?	Was the feasibility of collecting GCS evaluated?	Are barriers to registration of GCS reported?	Is method for documenting GCS clearly defined?	Is GCS registered as exact values or categories?	Are EVM responses reported?	Is there a reference to how GCS is documented if function due to injury is impaired?	Is there a reference to how and where GCS was obtained (EPJ/paper or other?)?	Are handling of missing data (GCS) described?	Is there a reference to when GCS was obtained (before or after intervention)?
Garnes[36]	✗	✗	✓	✗	✗	✗	✓	✗	✗	✓	✗	✗
Gartner[42]	✗	✗	✓	✗	✗	✗	○	✗	✗	✓	✗	✗
Geiger[48]	✗	✗	✓	✗	✗	✗	✗	✗	✗	✓	✗	✗
Gerritse[69]	✗	✗	✗	✗	✗	✗	✓	✗	✗	✓	✗	✗
Giannakopoulos[70]	✗	✗	✓	✗	✗	✗	✓	✗	✗	✗	✗	✓
Gienapp[71]	✗	✗	✗	✗	✗	✗	✓	✗	✗	✓	✗	✓
Grimm[72]	✓	✗	✗	✗	✗	✗	✓	✗	✗	✓	✗	✗
Hamada[73]	✗	✗	✓	✗	✗	✗	✗	✗	✗	✓	✗	✗
Helm[74]	✗	✓	✓	✗	✗	✗	✓	✗	✗	✓	✓	✗
Hesselfeldt[75]	✗	✗	✓	✗	✗	✗	✗	✗	✗	✓	✓	✗
Hofmeyr[76]	✓	✓	✓	✓	✓	✓	✓	✗	✗	✓	✗	✓
Hoiriis-Carlton[77]	✓	✓	✓	✗	✗	✗	✓	✗	✗	✓	✗	✗
Hoyer[78]	✗	✓	✓	✓	✓	✗	✓	✗	✗	✓	✗	✗
Hussmann[79]	✗	✗	✗	✗	✗	✗	✓	✗	✗	✓	✗	✗
Ishikawa[80]	✗	✗	✓	✗	✗	✗	✓	✗	✗	✗	✗	✗
Jokela[81]	✗	✗	✓	✗	✗	✗	○	✗	✗	✓	✗	✓
Joseffer[82]	✗	✗	✗	✗	✗	✗	✓	✗	✗	✓	✗	✗
Kellner[83]	✗	✓	✗	✗	✗	✗	✓	✗	✗	✓	✗	✗
Kirves[84]	✗	✓	✓	✗	✗	✗	✓	✗	✗	✗	✗	✗
Klemenc-Ketis[85]	✗	✗	✗	✗	✗	✗	✗	✗	✗	✗	✗	✗
Klemen[86]	✗	✗	✗	✗	✗	✗	✓	✗	✗	✗	✗	✗
Kordo[87]	✗	✗	✓	✗	✗	✗	✓	✗	✗	✓	✗	✓
Krayevs[88]	✓	✗	✓	✗	✗	✓	○	✗	✗	✓	✗	✗
Krüger[89]	✗	✗	✗	✗	✗	✗	○	✗	✗	✗	✗	✓
Kulla[90]	✗	✗	✓	✗	✗	✗	✗	✗	✗	✓	✗	✗
Lal[91]	✗	✗	✓	✗	✗	✗	○	✗	✗	✗	✗	✗
Lee[92]	✗	✗	✗	✗	✗	✗	✗	✗	✗	✓	✗	✗

(Continues)

TABLE A1 (Continued)

	External validity				Internal validity							
	Is it described who decided/recorded GCS?	Are completeness rates for GCS described?	Are number of excluded missions reported?	Was the feasibility of collecting GCS evaluated?	Are barriers to registration of GCS reported?	Is method for documenting GCS clearly defined?	Is GCS registered as exact values or categories?	Are EVM responses reported?	Is there a reference to how GCS is documented if function due to injury is impaired?	Is there a reference to how and where GCS was obtained (EPJ/paper or other?)?	Are handling of missing data (GCS) described?	Is there a reference to when GCS was obtained (before or after interventions)?
Lecarlova[87]	✗	✓	✓	✗	✗	✓	✓	✓	✗	✓	✗	✗
Lyon[96]	✗	✗	✗	✗	✗	✗	✓	✗	✗	✓	✗	✗
Mackay[95]	✗	✗	✗	✗	✗	✗	✓	✗	✗	✓	✗	✓
Margolis[94]	✓	✗	✓	✗	✗	✗	✓	✗	✗	✓	✗	✗
Maigrat[97]	✗	✗	✓	✗	✗	✗	✓	✗	✗	✓	✗	✓
Miller[90]	✗	✓	✓	✗	✗	✗	○	✗	✗	✗	✗	✗
Miller[89]	✗	✗	✓	✗	✗	✗	✓	✓	✗	✓	✗	✗
Moore[100]	✗	✓	✓	✗	✗	✓	✓	✗	✗	✓	✓	✓
Nevelsteen[102]	✗	✗	✓	✗	✗	✗	✓	✗	✗	✓	✗	✓
Nielsen[103]	✓	✗	✗	✗	✗	✗	✓	✗	✗	✓	✓	✓
Norgaard-Bloch[105]	✗	✓	✓	✗	✓	✗	✓	✗	✗	✓	✓	✗
O'Dochartaigh[104]	✗	✓	✓	✗	✗	✗	✓	✗	✗	✓	✗	✗
Oberholzer[101]	✓	✗	✓	✗	✗	✗	✓	✗	✗	✓	✗	✗
Orton[106]	✗	✗	✗	✗	✗	✗	✓	✗	✗	✗	✗	✗
Ong[107]	✓	✓	✓	✗	✗	✗	✓	✗	✗	✓	✗	✗
Ooe[108]	✗	✗	✓	✗	✗	✗	✓	✗	✗	✗	✗	✗
Oshiro[109]	✗	✗	✗	✗	✗	✗	✓	✗	✗	✓	✗	✗
Pakkanen[110]	✗	✓	✓	✗	✗	✗	○	✗	✗	✗	✗	✗
Pakkanen[111]	✗	✗	✓	✗	✗	✗	✓	✗	✗	✓	✗	✓
Pakkanen[112]	✗	✓	✓	✗	✗	✗	✓	✗	✗	✓	✓	✓
Perkins[113]	✗	✗	✓	✗	✗	✗	○	✗	✗	✓	✗	✗
Perkins[114]	✗	✓	✓	✗	✗	✗	○	✗	✗	✓	✗	✗
Peters[115]	✗	✗	✗	✗	✗	✗	✓	✗	✗	✓	✗	✗
Peters[116]	✗	✓	✗	✗	✗	✗	✓	✗	✗	✓	✗	✗
Ragoler[117]	✗	✗	✓	✗	✗	✗	✓	✗	✗	✓	✗	✗
Ragoler[118]	✗	✗	✓	✗	✗	✓	✓	✗	✗	✓	✗	✗
Poloujadoff[119]	✗	✗	✗	✗	✗	✗	✓	✗	✗	✗	✗	✗

(Continues)

TABLE A1 (Continued)

	External validity					Internal validity								
	Is it described who decided/recorded GCS?	Are completeness rates for GCS described?	Are number of excluded missions reported?	Was the feasibility of collecting GCS evaluated?	Are barriers to registration of GCS reported?	Is method for documenting GCS clearly defined?	Is GCS registered as exact values or categories?	Are EVM responses reported?	Is there a reference to how GCS is documented if function due to injury is impaired?	Is there a reference to how and where GCS was obtained (EPJ/paper or other)?	Are handling of missing data (GCS) described?	Is there a reference to when GCS was obtained Before or after interventions?
Ka[130]	✓	✓	✗	✗	✗	✗	○	✗	✗	✗	✓	✗
Rehn[125]	✗	✓	✓	✗	✗	✗	✓	✗	✗	✓	✗	✓
Rossi[36]	✓	✗	✓	✗	✗	✓	✓	✗	✗	✓	✗	✓
Roberts[132]	✗	✗	✗	✗	✗	✗	○	✗	✗	✓	✗	✗
Rognås[127]	✓	✓	✗	✗	✗	✗	✓	✗	✗	✓	✗	✗
Rushforth[126]	✗	✓	✓	✗	✗	✗	○	✗	✗	✓	✗	✓
Sartorius[125]	✗	✗	✓	✗	✗	✗	✓	✗	✗	✗	✗	✗
Schaller[126]	✓	✓	✓	✗	✗	✗	✓	✗	✗	✓	✓	✓
Schoettker[26]	✗	✓	✗	✗	✗	✗	○	✗	✗	✗	✗	✓
Schuster[127]	✗	✗	✓	✗	✗	✗	○	✗	✗	✓	✗	✓
Selig[128]	✗	✗	✗	✗	✗	✗	✓	✗	✗	✓	✗	✗
Shavit[129]	✗	✗	✗	✗	✗	✗	✓	✗	✗	✓	✗	✗
Sollid[130]	✗	✓	✗	✗	✗	✗	✓	✗	✗	✓	✗	✗
Sorrie[131]	✗	✓	✓	✗	✗	✗	○	✗	✗	✓	✗	✗
Stiell[8]	✓	✓	✓	✓	✓	✓	✓	✗	✗	✓	✓	✗
Stmiut[133]	✓	✗	✗	✗	✗	✗	✓	✗	✗	✗	✗	✗
Surels[133]	✓	✗	✓	✗	✗	✓	✓	✗	✗	✓	✗	✓
Talecodi[134]	✗	✗	✓	✗	✗	✗	✓	✗	✗	✓	✗	✗
Taylor[135]	✓	✓	✓	✗	✗	✗	○	✗	✗	✓	✗	✓
Theara[136]	✗	✓	✓	✗	✗	✗	○	✗	✗	✓	✗	✗
Timm[137]	✗	✗	✗	✗	✗	✗	✓	✗	✗	✓	✗	✓
Tinder[138]	✗	✓	✓	✗	✗	✓	✓	✓	✗	✓	✗	✗
Tronvoll[139]	✗	✗	✓	✗	✗	✗	✓	✗	✗	✗	✗	✗
Tsai[140]	✗	✓	✗	✗	✗	✗	✓	✗	✗	✗	✗	✗
Tønnesen[23]	✓	✓	✓	✓	✓	✗	✓	✗	✗	✓	✗	✓
Van der Velden[141]	✓	✗	✓	✗	✗	✗	✓	✗	✗	✓	✗	✓

(Continued)

TABLE A1 (Continued)

	External validity				Internal validity								
	Is it described who decided/recorded GCS?	Are completeness rates for GCS described?	Are number of excluded missions reported?	Was the feasibility of collecting GCS evaluated?	Are barriers to registration of GCS reported?	Is method for documenting GCS clearly defined?	Is GCS registered as exact values or categories?	Are EVM responses reported?	Is there a reference to how GCS is documented if function due to injury is impaired?	Is there a reference to how and where GCS was obtained (EPJ/paper or other?)?	Are handling of missing data (GCS) described?	Is there a reference to when GCS was obtained (before or after interventions)?
Von Vopelius-Feldt[142]	✓	✗	✗	✗	✗	✗	○	✗	✗	✓	✗	✗
Wallen[140]	✗	✗	✓	✗	✗	✗	○	✗	✗	✗	✗	✗
Wyer[144]	✗	✗	✓	✗	✗	✗	○	✗	✗	✓	✗	✗
Yepiskyan[145]	✗	✓	✓	✗	✗	✗	○	✗	✗	✓	✓	✗
Zhang[146]	✗	✗	✓	✗	✗	✗	✓	✗	✗	✓	✗	✗

Notes: ✓ = Reported in study, ✗ = Not reported in study, ○ = GCS is registered as categories, EVM, eye-verbal-motor responses, EPJ, electronic patient journal.

TABLE A2 Quality appraisal Systolic Blood Pressure

	External validity					Internal validity				
	Does study report who recorded SBP?	Are number of excluded missions reported?	Are completeness rates of SBP reported?	Was the feasibility of collecting SBP evaluated?	Are barriers to registration of SBP reported?	Is the method for documenting SBP clearly defined?	Is SBP registered as exact values or categories?	Is there a reference to how and where SBP was obtained (EPJ/paper or other)?	Are handling of missing reporting of SBP data described?	Is there a reference to when SBP was obtained (before or after interventions etc)?
Abe [142]	✗	✗	✗	✗	✗	✗	✓	✗	✗	✗
Autenrieth[42]	✗	✓	✗	✗	✗	✗	○	✓	✗	✗
Bergrath[38]	✓	✗	✓	✗	✗	✗	✗	✓	✗	✓
Bieler[44]	✗	✗	✗	✗	✗	✗	✓	✓	✓	✗
Burton[45]	✗	✓	✗	✗	✗	✗	✓	✓	✗	✓
Brazinova[46]	✗	✗	✓	✗	✗	✗	✗	✓	✓	✗
Chan[140]	✗	✗	✗	✗	✗	✗	✓	✓	✗	✓
Chesters[49]	✗	✗	✓	✗	✗	✓	✗	✓	✗	✓
Corfield[50]	✗	✗	✗	✗	✗	✗	✗	✓	✗	✗
Cornick[51]	✓	✓	✓	✗	✗	✗	✗	✗	✗	✗
Den Hartog[52]	✗	✓	✓	✗	✗	✗	✓	✗	✓	✗
Di Bartolomeo[53]	✗	✗	✗	✗	✗	✗	✗	✗	✗	✗
Duchateau[54]	✗	✓	✓	✗	✗	✗	✓	✗	✗	✗
Engel[55]	✗	✗	✓	✗	✗	✗	✗	✓	✗	✗
Follin[56]	✗	✓	✗	✗	✗	✗	✓	✗	✗	✗
Fortin[57]	✓	✓	✓	✗	✓	✗	✓	✓	✗	✓
Francis[138]	✓	✗	✓	✗	✗	✓	✗	✓	✗	✗
Franschman[59]	✗	✓	✗	✗	✗	✗	✗	✗	✗	✓
Franschman[60]	✗	✓	✗	✗	✗	✗	✗	✓	✗	✗
Franschman[61]	✗	✓	✗	✗	✗	✗	✗	✗	✗	✗
Garner[63]	✗	✗	✗	✗	✗	✓	✓	✗	✗	✗
Garner[64]	✗	✓	✗	✗	✗	✗	✓	✓	✗	✗
Gartner[67]	✗	✓	✗	✗	✗	✗	✓	✓	✗	✗
Gavrilovic[135]	✗	✗	✗	✗	✗	✓	✓	✓	✗	✓
Geiger[68]	✗	✓	✗	✗	✗	✗	✗	✓	✗	✗
Giannakopoulos[70]	✗	✓	✗	✗	✗	✗	✗	✗	✗	✓
Gerstaz[71]	✗	✗	✗	✗	✗	✗	✓	✓	✗	✓
Grimes[72]	✓	✗	✗	✗	✗	✗	✓	✓	✗	✗
Hamada[73]	✗	✓	✗	✗	✗	✗	✗	✗	✗	✓

(Continues)

TABLE A2 (Continued)

	External validity				Internal validity					
	Does study report who recorded SBP?	Are number of excluded missions reported?	Are completeness rates of SBP reported?	Was the feasibility of collecting SBP evaluated?	Are barriers to registration of SBP reported?	Is the method for documenting SBP clearly defined?	Is SBP registered as exact values or categories?	Is there a reference to how and where SBP was obtained (EPJ/paper or other)?	Are handling of missing reporting of SBP data described?	Is there a reference to when SBP was obtained (before or after interventions etc)?
Helm [32]	✗	✓	✗	✗	✗	✓	✓	✓	✗	✓
Helm [34]	✗	✓	✓	✗	✗	✗	○	✓	✓	✗
Hensel [103]	✗	✓	✓	✗	✗	✗	✓	✓	✓	✓
Hesselfeldt [71]	✗	✗	✗	✗	✗	✗	✗	✓	✓	✗
Höyer [28]	✗	✗	✓	✓	✓	✗	✗	✓	✗	✗
Hunsaker [154]	✗	✗	✗	✗	✗	✗	✓	✓	✗	✗
Hunsaker [79]	✗	✗	✓	✗	✗	✗	✓	✓	✗	✗
Ishikawa [80]	✗	✓	✗	✗	✗	✗	✓	✗	✗	✗
Jokela [81]	✗	✓	✗	✓	✓	✗	✗	✓	✗	✓
Jouffroy [82]	✗	✗	✗	✗	✗	✗	✓	✓	✗	✗
Joshipura [155]	✓	✓	✗	✗	✗	✗	○	✓	✗	✓
Kallrath [83]	✗	✗	✓	✗	✗	✗	✓	✓	✗	✗
Kallio [156]	✗	✗	✗	✗	✗	✗	✓	✓	✗	✓
Kirves [157]	✗	✗	✓	✗	✗	✗	✓	✗	✗	✗
Kirves [84]	✗	✗	✓	✗	✗	✗	✓	✗	✗	✗
Kleiner [158]	✗	✗	✗	✗	✗	✗	✓	✗	✗	✗
Kofoed-Nielsen [108]	✗	✗	✓	✗	✗	✗	○	✗	✗	✗
Korda [87]	✗	✓	✗	✗	✗	✗	✓	✓	✗	✓
Krzyeva [88]	✓	✓	✗	✗	✗	✗	✗	✓	✗	✗
Kristensen [159]	✗	✗	✗	✓	✗	✓	✓	✓	✗	✗
Krüger [89]	✗	✗	✗	✗	✗	✗	✗	✗	✗	✗
Kulu [90]	✗	✓	✗	✗	✗	✗	✓	✓	✗	✗
Lal [91]	✗	✗	✗	✗	✗	✗	✗	✗	✗	✗
Lee [92]	✗	✗	✗	✗	✗	✗	✗	✓	✗	✗
Lenartova [93]	✗	✓	✓	✗	✗	✗	○	✓	✗	✗
Lenzner [160]	✗	✗	✗	✗	✗	✗	✓	✓	✗	✓
Leslie [161]	✗	✗	✓	✗	✗	✗	✓	✗	✗	✓
Lindvall [40]	✓	✓	✗	✗	✗	✓	✓	✓	✗	✓
Lyon [94]	✗	✓	✓	✗	✗	✓	✓	✓	✗	✓

(Continues)

TABLE A2 (Continued)

	External validity				Internal validity					
	Does study report who recorded SBP?	Are number of excluded missions reported?	Are completeness rates of SBP reported?	Was the feasibility of collecting SBP evaluated?	Are barriers to registration of SBP reported?	Is the method for documenting SBP clearly defined?	Is SBP registered as exact values or categories?	Is there a reference to how and where SBP was obtained (EPJ/paper or other)?	Are handling of missing reporting of SBP data described?	Is there a reference to when SBP was obtained (before or after interventions etc)?
Lyon [102]	✗	✗	✓	✗	✗	✓	✓	✗	✗	✓
Mackay [95]	✗	✗	✗	✗	✗	✗	✓	✓	✗	✓
Maignan [97]	✗	✗	✗	✗	✗	✗	✓	✓	✗	✓
Massanti [142]	✗	✗	✗	✗	✗	✓	✗	✗	✗	✓
Matsumoto [64]	✗	✗	✗	✗	✗	✗	✓	✗	✗	✗
McMahon [9]	✗	✓	✗	✓	✓	✓	✓	✓	✗	✓
Miller [8]	✓	✓	✓	✗	✓	✓	✓	✓	✗	✓
Miller 2017 [9]	✗	✓	✓	✗	✗	✗	✓	✓	✓	✓
Moore [100]	✗	✓	✓	✗	✗	✗	✓	✓	✓	✓
Nauraian [103]	✗	✗	✓	✗	✗	✗	✓	✓	✗	✓
Newton [105]	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓
Nieregaard Bech [130]	✗	✓	✓	✗	✓	✗	○	✓	✓	✗
O'Dochartaigh [104]	✗	✓	✓	✗	✗	✗	✓	✓	✗	✗
Olmos [106]	✗	✗	✗	✗	✗	✗	✓	✗	✗	✗
Orio [107]	✓	✓	✓	✓	✗	✗	✓	✓	✗	✗
Osole [108]	✗	✗	✗	✗	✗	✗	✓	✗	✗	✗
Pakkanen [110]	✗	✓	✓	✗	✗	✗	✗	✗	✗	✗
Pakkanen [111]	✗	✗	✗	✗	✗	✗	○	✓	✗	✓
Pakkanen [112]	✗	✓	✓	✗	✗	✗	○	✓	✗	✓
Perkins [113]	✗	✓	✓	✗	✓	✓	✓	✓	✗	✓
Perkins [114]	✗	✓	✗	✗	✓	✓	✓	✓	✗	✓
Pöntinen [115]	✓	✗	✓	✓	✓	✓	✓	✗	✗	✓
Raj [120]	✗	✗	✗	✗	✗	✗	○	✗	✗	✓
Rehn [121]	✗	✓	✓	✗	✗	✗	✓	✓	✗	✗
Reist [36]	✓	✓	✓	✗	✗	✗	○	✓	✗	✓
Rognås [123]	✓	✗	✓	✗	✓	✗	○	✓	✓	✓
Roudsari [146]	✗	✗	✓	✗	✗	✗	✗	✓	✓	✗
Ruddell [126]	✗	✓	✓	✗	✗	✗	✓	✓	✗	✓
Sartorius [125]	✗	✓	✗	✗	✗	✗	○	✗	✗	✓

(Continued)

TABLE A2 (Continued)

	External validity				Internal validity					
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Soto Fidalgo[147]	✗	✗	✗	✗	✗	✗	✓	✓	✗	✓
Schoettker[26]	✗	✓	✓	✗	✗	✗	○	✗	✗	✗
Selig[138]	✗	✗	✗	✗	✗	✗	✓	✓	✗	✗
Stahl[9]	✓	✓	✓	✓	✓	✗	✗	✓	✓	✓
Stroud[132]	✗	✗	✓	✗	✗	✓	✓	✗	✗	✓
Sunde[131]	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Takeuchi[154]	✗	✗	✗	✗	✗	✗	✓	✓	✗	✗
Talving[148]	✗	✗	✓	✗	✗	✓	○	✓	✗	✗
Tasic[137]	✗	✗	✗	✗	✗	✗	✓	✓	✗	✓
Tinker[139]	✗	✓	✗	✗	✗	✗	✓	✓	✗	✓
Tønnesen[23]	✓	✓	✓	✓	✓	✗	✓	✓	✗	✓
Van Vopelius-Feldt[141]	✓	✗	✗	✗	✗	✓	✗	✓	✗	✗
Wahlen[142]	✗	✓	✗	✗	✗	✓	✗	✗	✗	✗
Weaver[149]	✗	✓	✓	✗	✗	✓	✓	✓	✓	✗
Webb[150]	✗	✗	✗	✗	✗	✗	✓	✗	✗	✗
Wyss[144]	✗	✓	✗	✗	✗	✗	○	✓	✗	✗
Yeşiloğlu[145]	✗	✓	✓	✗	✗	✓	○	✓	✗	✗
Zhang[146]	✗	✓	✗	✗	✗	✗	✓	✓	✗	✗

Notes: ✓ = Reported in study, ✗ = Not reported in study, ○ = SBP recorded as categories, EPJ = electronic patient journal.

Paper IV

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Scandinavian Journal of Trauma, Resuscitation and Emergency Medicine

ORIGINAL RESEARCH Open Access

Template for documenting and reporting data in physician-staffed pre-hospital services: a consensus-based update

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Abstract

Background: Physician-staffed emergency medical services (p-EMS) are resource demanding, and research is needed to evaluate any potential effects of p-EMS. Templates, designed through expert agreement, are valuable and feasible, but they need to be updated on a regular basis due to developments in available equipment and treatment options. In 2011, a consensus-based template documenting and reporting data in p-EMS was published. We aimed to revise and update the template for documenting and reporting in p-EMS.

Methods: A Delphi method was applied to achieve a consensus from a panel of selected European experts. The experts were blinded to each other until a consensus was reached, and all responses were anonymized. The experts were asked to propose variables within five predefined sections. There was also an optional sixth section for variables that did not fit into the pre-defined sections. Experts were asked to review and rate all variables from 1 (totally disagree) to 5 (totally agree) based on relevance, and consensus was defined as variables rated ≥4 by more than 70% of the experts.

Results: Eleven experts participated. The experts generated 194 unique variables in the first round. After five rounds, a consensus was reached. The updated dataset was an expanded version of the original dataset and the template was expanded from 45 to 73 main variables. The experts approved the final version of the template.

Conclusions: Using a Delphi method, we have updated the template for documenting and reporting in p-EMS. We recommend implementing the dataset for standard reporting in p-EMS.

Keywords: Documentation, Data collection, Pre-hospital, Physician, Emergency medical services, Consensus, Air ambulances, Quality of health care

Background

Physician-staffed emergency medical services (p-EMS) are common in European countries, and they provide highly specialized, goal-directed therapy. Pre-hospital physicians have the potential to restore adequate flow and physiology in severely sick or injured patients, but the subject remains debated [1–6]. P-EMS are resource demanding compared with standard paramedic-staffed services [7], and more research is needed to evaluate any potential effects of p-EMS [1, 8, 9]. High-quality research relies on data quality and uniform documentation is essential to ensure reliable and valid data. Currently, p-EMS data are low quality, and the lack of systematic documentation complicates comparison, creating a barrier for high-quality outcome research [10].

In 2011, a consensus-based template for documenting and reporting data in p-EMS was published [7]. Templates for uniform documentation may facilitate international

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multi-centre studies, thereby increasing the quality of evidence [11]. Such templates, designed through expert agreement, are valuable and feasible, but they need to be updated on a regular basis due to developments in available equipment and treatment options [12–15]. The p-EMS template has been incorporated for daily use in Finland, but it has not yet been implemented in other European countries. A recent study concluded that the published template is feasible for use in p-EMS and that a large amount of data may be captured, facilitating collaborative research [16]. However, the feasibility study revealed areas for improvement of the template. To make the template even more relevant, further revisions should be made.

The aim of this study was to revise and update the template for documenting and reporting in p-EMS through expert consensus [7] using the Delphi method.

Methods

The experts

No exact criterion exists concerning selection of participants for a Delphi study.

Many European countries share similarities with regards to infrastructure, socio-political system and health care services, favouring research collaboration [17]. Representatives from European p-EMS were invited to join an expert panel using the same inclusion criteria as the original template:

1. Clinical experience by working in p-EMS to ensure personal insight into the operative and medical characteristics of advanced pre-hospital care.
2. Scientific and/or substantial leadership responsibilities in pre-hospital care to ensure competency in research methods and governance of pre-hospital emergency systems.
3. Ability to communicate in English.

The experts were identified via the European Prehospital Research Alliance (EUPHOREA) network. The EUPHOREA network consists of representatives from p-EMS throughout central Europe, UK and Scandinavia. Experts were invited via e-mail. Non-responders were reminded via e-mail. For all rounds non-responders were reminded twice per e-mail.

The Delphi method

A Delphi technique was applied to achieve a consensus from a panel of selected experts interacting via e-mail. No physical meetings were held. A research coordinator interacted with the participants, administered questionnaires and collected the responses until a consensus was reached. The experts were blinded to each other until an agreement was reached. All responses were anonymized. The Delphi process ran from Feb. 19 to Oct. 1, 2019. The final dataset was approved by all experts.

Objectives for each round of the Delphi process

The experts were asked to propose variables within each of five predefined sections:

1. **Fixed system variables**
   Variables describing how the p-EMS is organized, competence in the p-EMS team and its operational capacities (e.g., dispatch criteria, population, mission case-mix and equipment utilized by the services). These data do not change between missions and are considered fixed.
2. **Event operational descriptors**
   Variables documenting the mission context (e.g., data on logistics, type of dispatch, time variables and mission type).
3. **Patient descriptors**
   Variables documenting patient state (e.g., age, gender, comorbidity, patient physiology and medical complaint).
4. **Process mapping variables**
   Variables documenting diagnostic and therapeutic procedures (e.g., monitoring, medication, airway devices used, etc.) performed during the period of p-EMS care.
5. **Outcome and quality indicators**
   Variables describing patient outcome and quality.

There was also an optional sixth section for proposals of variables that did not fit into one of the pre-defined sections.

Round I

Each expert suggested 10 variables considered to be most important for routine documentation in p-EMS within each of the five predefined sections.

Round II

The results from the first round were structured in a worksheet (Excel for Mac, version 16.31, 2019 Microsoft). Duplicate suggestions were removed before the variables were returned to the experts. Variables from the original template were included if not suggested by the experts. Experts were asked to review and rate all variables from 1 (totally disagree) to 5 (totally agree) based on relevance.

Round III

Variables rated ≥4 by more than 70% of the experts were included in the template draft and presented to the experts [18, 19]. In addition, the experts received a number of questions pertaining to the wording of questions,

consent to delete some questions because of overlap, relevance of alternatives under a main question, and whether there should be a free-text field for addressing key lessons. Furthermore, they were instructed to provide comments and grade the variables as either compulsory or optional. Later, the experts were asked to suggest the frequency of variable reporting (for each mission, monthly or annually). Variables rated ≥4 by less than 50% of the experts were excluded. Variables rated ≥4 by more than 50% of the experts were summarized and re-rated by the experts. If more than 70% of the experts rated a variable ≥4 in this second round, the variable was included in the final template.

Round IV

After summarizing the feedback from round III, the list of variables achieving consensus, accompanying comments, and further questions were distributed to the experts. All variables were numbered. This round provided an opportunity for the experts to revise their judgements and combine similar variables.

Round V

Feedback from round IV was summarized into a final version of the template and sent to the experts to elicit any objections and/or to give final approval of the template for routine reporting in p-EMS.

The study was drafted according to the Standards for Reporting Qualitative Research (SRQR) [20].

Results

The experts

Thirty experts were invited to join the consensus process and 15 agreed to participate. Eleven experts responded in the first Delphi round, ten responded in the second round and nine responded in the last three rounds.

Round I

The experts suggested 194 unique variables in the first round (Fig. 1). All variables from the original template were among the suggested variables.

Round II

The experts rated the variables suggested in round I from 1 (totally disagree) to 5 (totally agree) based on relevance. A total of 68 main variables (24 fixed system variables, 10 event operational descriptors, 15 patient descriptors, 10 process mapping variables, 9 outcome and quality indicators and no other variables) were rated ≥4 by more than 70% of the experts and included in the preliminary template. Thirty-five main variables and 32 sub-variables were rated <4 by 50–70% of the experts. Ninety-one variables were rated ≥4 by less than 50% of the experts and were excluded.

Round III

The preliminary template was presented to the experts. Additionally, the experts rated the 35 main variables and 32 sub-variables that were initially rated ≥4 by 50–70% once more. Five more main variables and 9 sub-variables were included after this second rating. In total, 73 main variables were included (Fig. 2). The experts agreed that all fixed system variables should be reported annually while all event operational descriptors, patient descriptors, process mapping variables and outcome and quality indicators should be reported after each mission.

Round IV

The included variables were presented to the experts. After feedback from the experts the wording of variables 1.23.6 and 3.5.6. were changed from "Chest pain, excluding MI" to "Chest pain, MI not confirmed". Variable 3.8.4. "Systolic blood pressure (SBP) not recordable" and 3.10.4. "SpO2 not recordable" were added. Variables 3.13.1. and 3.13.2. were changed to record the VAS score instead of pain as none, moderate or severe and variable 4.6.17. was changed from "Resuscitative endovascular balloon occlusion of the aorta (REBOA)" to "Endovascular Resuscitation (EVR)".

Round V

The experts approved the final version of the template (Table 1, 2, 3, 4 and 5).

Discussion

Main findings

Using Delphi methodology, we have updated a template for standard documentation in p-EMS. The new dataset includes new data variables and the template was expanded from 45 to 73 main variables.

Fixed system variables

Throughout the world, there are large differences between p-EMS [21–23], and fixed system variables are important to analyse any influence of system factors and compare systems [11, 24]. The experts suggested reporting all fixed system variables annually. Furthermore, the experts chose to include two variables related to quality. The reason for including these data in this section is that they describe the quality of the system rather than the quality delivered during each mission.

Event operational descriptors

There is no consensus in the literature on how to report mission times [15, 25, 26] and the experts had several suggestions, i.e., exact times (hh:mm), time intervals (dispatch time, on-scene time, etc.) and time reported as year/month/day/hour of event. Response time (time from unit is dispatched to at patient side), on-scene time

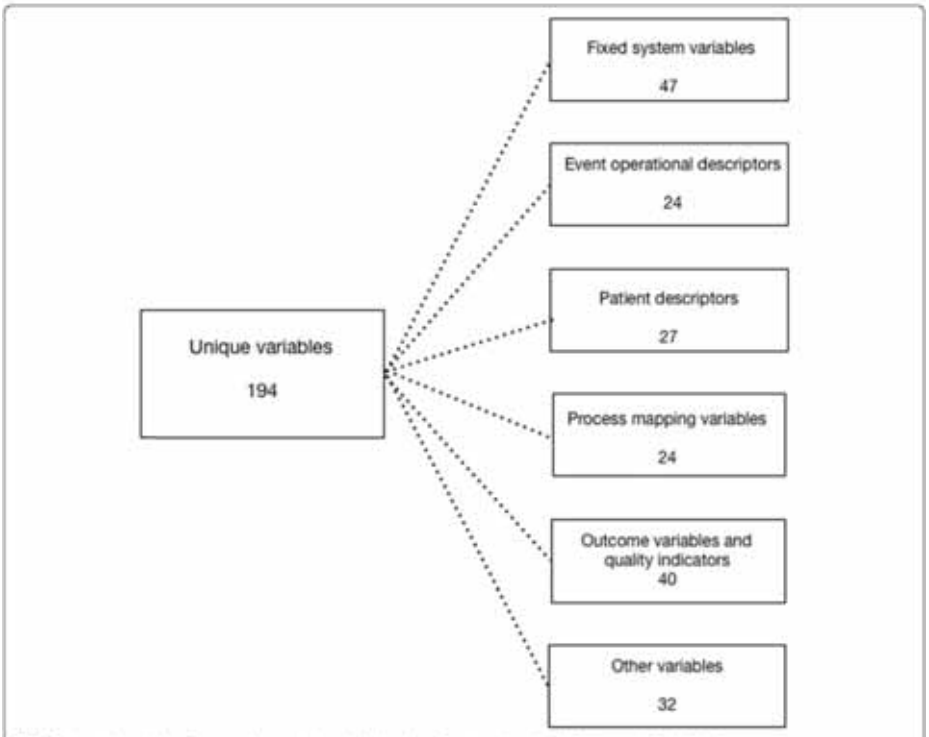

Fig. 1 Suggested variables. Number of suggested variables for the different sections in the first round of the Delphi process

and transport time (from patient leaving the scene to arrival at the hospital) and time from alarm to arrival at the hospital are all reported in various templates. We argue that by reporting exact times, all desired time intervals can easily be calculated; therefore, exact times should be documented.

The time of the event is usually not possible to accurately identify. In trauma, the time of the event will be distinct, but for other diagnoses a clearly defined start time is often missing. The time when a call is received at the emergency medical communication centre (EMCC) is a distinct time that is easy to document, substituting for the time of the event. This was also emphasized by the experts.

P-EMS differ in service profile, and documenting dispatch type is important for benchmarking. Some services are dispatched to all types of emergency missions, whereas others are dispatched to specific types, e.g., trauma. Some services have an extensive workload due to consultation responsibilities and medical direction for ordinary EMS. This may affect availability if work hours are restricted.

Patient descriptors.

Comorbidity is an important risk adjustment measure, but there is no consensus on comorbidity reporting. The original template for reporting in p-EMS used the American Society of Anesthesiologists Physical Status (ASA-PS) scale in a dichotomized form. However, using full ASA-PS scale has been found to be feasible in p-EMS [27], and it is recommended by the experts.

Reporting the present medical problem is crucial for benchmarking. P-EMS have traditionally reported symptoms, but point-of-care diagnostical options are increasingly available, allowing more precise pre-hospital diagnoses [28–30].

The experts recommended reporting physiological data at two different time points: at arrival of the p-EMS

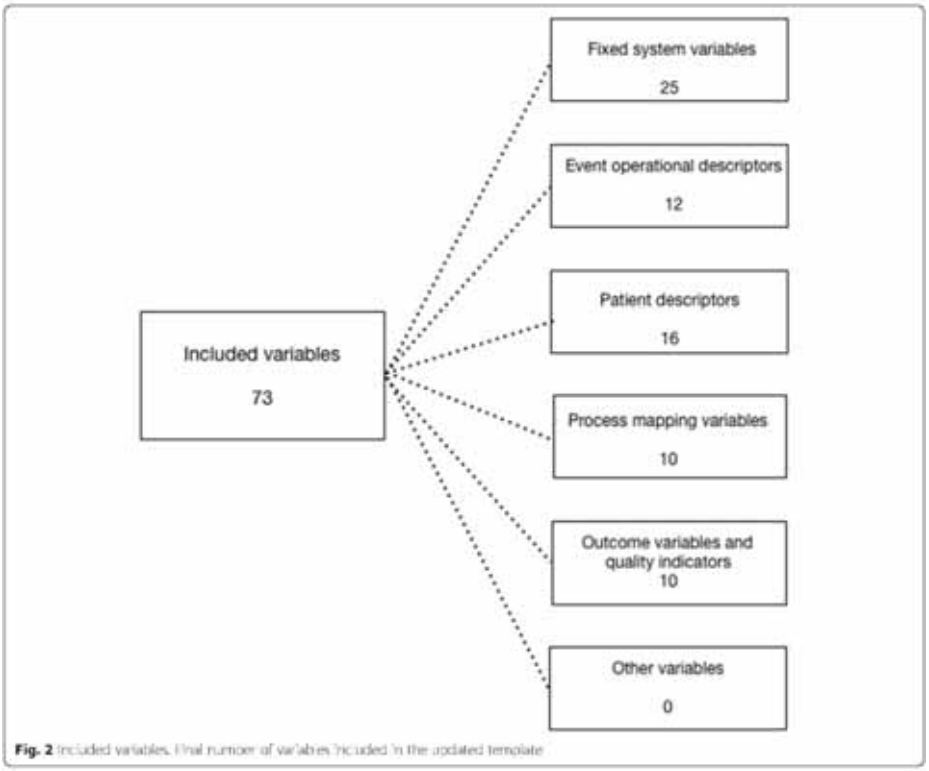

Fig. 2 Included variables. Final number of variables included in the updated template

and at hand-over or the end of patient care. This corresponds with the original template. Reporting data at two different time points allows for monitoring changes in the patient state and may serve as a surrogate measure for p-EMS performance [31]. For SBP and SpO2, the experts also suggest reporting the lowest value measured. Hypotension is an independent predictor of mortality for traumatic brain injury (TBI) patients [32], and reporting the lowest SBP value will capture hypotensive episodes. Further, automated data capture from monitors are increasingly available, enabling continuous measurement of physiological variables. Continuous reporting may capture dynamic changes in patient state, thereby increasing the precision of p-EMS research.

Pain is frequent in the p-EMS patient population, and pain relief is considered good clinical practice [33]. The original template used a three-part scale for reporting pain while the expert group of the revised template suggest reporting pain according to the Visual Analogue Scale (VAS) [34].

Process mapping variables

The resulting physiological effects of p-EMS treatment and its relation to outcome remains largely unknown in pre-hospital critical care. Such changes in physiology have earlier been difficult to capture but doing so is now more feasible due to technological developments. The experts emphasized this, and as such an expansion of the process mapping section was suggested.

Mission outcome and quality indicators

To date, there is no agreement on standard quality indicators in p-EMS but Haugland et al. recently developed a set of quality indicators for p-EMS [35]. Several of these indicators are documented in the revised template but under various sections. Additionally, the experts suggested several other context-specific quality variables related to the individual patient, but these are yet to be validated.

Table 1 Fixed system variables

Data variable number	Main data variable name	Type of data	Data variable categories or values	Data variable sub-categories or values	Type	Definition of data variable	How often should variable be reported
1. Fixed system variables							
1.1.	Specialty of physicians	Categorical	1.1.1 Anaesthesiology/		Check box	Specialty of physicians working in the service on a regular basis	Annual
			1.1.2 Emergency medicine				
			1.1.3 Intensive care				
			1.1.4 Surgery				
			1.1.5 Internal medicine				
			1.1.6 Other				
1.2.	Training level of physicians	Categorical	1.2.1 Trainee/registrar		Check box		Annual
			1.2.2 Specialist				
1.3.	Composition of team	Categorical	1.3.1 Nurse		Check box	Qualification of non-p-EMS personnel accompanying the physician during mission As defined by each national service	Annual
			1.3.2. Paramedic				
			1.3.3. EMS-technician				
			1.3.4. Other			As defined by each national service	
1.4.	Catchment population	Continuous			Number	Number of citizens in the area covered by the service on a regular basis	Annual
1.5.	Catchment area	Continuous	1.5.1. Square km		Number	Area in which the service is planned to operate on a regular basis, square km	Annual
		Categorical	1.5.2. Type	1.5.2.1. Urban	Check box	Type of area where service operate on a regular basis (as defined by each service)	
				1.5.2.2. Rural			
1.6.	Does the service conduct primary missions?	Categorical	1.6.1. Yes		Bullet list	On-scene missions	Annual
			1.6.2. No				
1.7.	Does the service conduct inter-hospital transfer missions?	Categorical	1.7.1. Yes		Bullet list	Patient transfers between different hospitals or facilities	Annual
			1.7.2. No				
1.8.	Number of consultations only (advice) per year	Continuous			Number	Physician is consulted by EMS or other professionals (give advice)	Annual
1.9.	Number of primary missions per year	Continuous			Number	Missions where physician is on-scene. Total number for the service	Annual
1.10.	Number of inter-hospital transfer missions per year	Continuous			Number	Inter-hospital or interfacility transfer. Total number	Annual

Table 1 Fixed system variables (*Continued*)

Data variable number	Main data variable name	Type of data	Data variable categories or values	Data variable sub-categories or values	Type	Definition of data variable	How often should variable be reported
						for the service	
1.11.	Number of cancelled missions per year	Continuous			Number	Any mission where p-EMS is alarmed but not able to respond or must interrupt mission	Annual
1.12.	Number of events per year per physician	Continuous			Number	The average number of missions per individual physician per year	Annual
1.13.	Number of events for p-EMS unit/100,000 inhabitants per year	Continuous			Number		Annual
1.14.	Number of EMS events/100,000 inhabitants per year	Continuous			Number	Number of events for the whole EMS system, including p-EMS	Annual
1.15.	Number of p-EMS units/100,000 inhabitants	Continuous			Number		Annual
1.16.	Number of p-EMS units/km2	Continuous			Number	Area in which the service operates on a regular basis	Annual
1.17.	Available vehicles in service	Categorical			Check box	Available vehicles on a regular basis for p-EMS	Annual
			1.17.1. Rapid response car			Regular car, no stretcher	
			1.17.2. Regular ambulance staffed with physician			Car with stretcher. Physician is attending on a regular basis	
			1.17.3. Rotor Wing				
			1.17.4. Fixed Wing				
			1.17.5. Boat staffed with physician			Physician is attending on a regular basis	
			1.17.6. Other				
1.18.	Operating hours	Categorical	1.18.1. Daytime		Bullet list	Regular working hours, e.g., 08–16, as defined by each service	Annual
			1.18.2. Daylight only			Service operates only in daylight (different opening hours during the year due to seasonal variations). Daylight as defined by each service	
			1.18.3. 24/7 (full time service)			Service operates during the day and night	
			1.18.4. Other				
1.19.	Activation criteria	Categorical	1.19.1. Criteria based		Check box	P-EMS activated in accordance with a pre-defined set of activation criteria used by EMCC	Annual
			1.19.2. Consultation with physician			Physician-staffed unit activated only after consultation with an on-call physician	

Table 1 Fixed system variables (*Continued*)

Data variable number	Main data variable name	Type of data	Data variable categories or values	Data variable sub-categories or values	Type	Definition of data variable	How often should variable be reported
			1.19.3. Individual			No predefined criteria for activation of p-EMS	
1.20.	Dispatch system	Categorical	1.20.1. Integrated EMCC		Check box	Integrated EMCC includes dispatch centres coordinating all levels of pre-hospital services	Annual
			1.20.2. Special EMCC			Special EMCC includes centres only responsible for p-EMS units	
			1.20.3. Other				
1.21.	Advanced equipment carried by service	Categorical	1.21.1. Blood products		Check box	Advanced equipment available on a regular basis to service	Annual
			1.21.2. Mechanical chest compression device				
			1.21.3. Ultrasound				
			1.21.4. Advanced drugs			Drugs not available to regular EMS in the individual system	
			1.21.5. Additional airway management equipment (e.g. videoscope)			Airway management equipment beyond the scope of regular EMS	
			1.21.6. Surgical procedures supported			Service carries equipment for predefined surgical procedures	
1.22.	Does a system for registration and reviewing of adverse events, critical incidents and educational events in the service exist?	Categorical	1.22.1. Yes		Bullet list		Annual
			1.22.2 No				
1.23.	Categorization of events/case mix	Categorical	1.23.1. Cardiac arrest medical aetiology		Check box	Mission types the service responds to	Annual
			1.23.2. Cardiac arrest traumatic aetiology				
			1.23.3. Trauma				
			1.23.4. Breathing difficulties				
			1.23.5. Myocardial infarction (MI)			Confirmed by ECG	
			1.23.6. Chest pain, MI not confirmed				
			1.23.7. Stroke				
			1.23.8. Acute neurology excluding stroke				

Table 1 Fixed system variables (*Continued*)

Data variable number	Main data variable name	Type of data	Data variable categories or values	Data variable sub-categories or values	Type	Definition of data variable	How often should variable be reported
			1.23.9. Reduced level of consciousness				
			1.23.10. Poisoning/ Intoxication				
			1.23.11. Burns				
			1.23.12. Obstetrics and children				
			1.23.13. Infection				
			1.23.14. Anaphylaxis				
			1.23.15. Surgical				
			1.23.16. Asphyxiation				
			1.23.17. Drowning				
			1.23.18. Psychiatry excluding poisoning/ intoxication				
			1.23.19. All of the above			Service responds to all types of events	
			1.23.20. Other				
1.24.	Number of intubations successful on first attempt and without desaturation (DASHI a Intubations) /100 Intubations	Continuous			Number		Annual
1.25.	Number of patients where blood glucose was measured after ROSC/100 ROSC	Continuous			Number		Annual

EMS - Emergency medical services, p-EMS - Physician-staffed emergency medical services, EMCC - Emergency medical communication centre, MI - Myocardial infarction, ECG - Electrocardiogram, DASHI a - Definitive airway, sars hypoxia/hypotension on first attempt,
ROSC - Return of spontaneous circulation

Table 2 Event operational descriptors

Data variable number	Main data variable name	Type of data	Data variable categories or values	Data variable sub-categories or values	Type	Definition of data variable	How often should variable be reported
2. Event operational descripton							
2.1.	Time points	Continuous					For each mission
			2.1.1. Call received at EMCC		hh:mm	When the alarm call is answered at the initial EMCC	
			2.1.2. Time of system activation (dispatch time)		hh:mm	When EMCC dispatch p-EMS	
			2.1.3. Unit en route/take-off time		hh:mm	When vehicle starts to move (car or rotor wing/fixed wing)	
			2.1.4. Unit arrival on scene		hh:mm	When vehicle stops at a location as close as possible to the patient	
			2.1.5. Time of first physician contact with patient		hh:mm	When pre-hospital physician arrives at patient site	
			2.1.6. Time when patient leaves scene		hh:mm	When patient is transferred from the original location or time of death if dead on scene	
			2.1.7. Time when patient arrives at hospital (or alternative site if not delivered to hospital)		hh:mm	When the patient is formally transferred to receiving medical facility personnel	
2.2.	Date of event	Continuous			dd.mm.yyyy	The date the unit was dispatched	For each mission
2.3.	Type of mission/ dispatch	Categorical			Check box		For each mission
			2.3.1. Primary medical mission			Includes all primary missions other than trauma (medical, surgical, paediatric, obstetric)	
			2.3.2. Primary trauma mission			Includes all primary trauma missions	
			2.3.3. Inter-hospital transfer mission			Inter-hospital or inter-facility mission	
			2.3.4. SAR mission				
			2.3.5. Major incident response				
			2.3.6. Contingency				
			2.3.7. Rendezvous with ambulance				
			2.3.8. Consultation				
			2.3.9. Single patient			Only one patient treated by p-EMS during the mission	
			2.3.10. Multiple patients			More than one patient treated by p-EMS during the mission	
			2.3.11. Other				

Table 2 Event operational descriptors (Continued)

Data variable number	Main data variable name	Type of data	Data variable categories or values	Data variable sub-categories or values	Type	Definition of data variable	How often should variable be reported
2.4.	Dispatch criteria	Categorical			Check box	Medical reason for dispatch	For each mission
			2.4.1. Medical				
			2.4.2. Trauma				
			2.4.3. Neurologic				
			2.4.4. Obstetric				
			2.4.5. Burn				
			2.4.6. Other				
2.5.	Activation type	Categorical			Bullet list		For each mission
			2.5.1. Primary mission				
				2.5.1.1. Initiated by dispatch centre			
				2.5.1.2. Requested dispatch from other units			
				2.5.1.3. Other			
		Categorical	2.5.2. Inter-hospital transfer mission				
				2.5.2.1. Physician-staffed unit used because of level of treatment during transport			
				2.5.2.2. Physician-staffed unit used because of speed of transport			
				2.5.2.3. Both above			
				2.5.2.4. Other			
2.6.	Mode of transportation to scene	Categorical			Bullet list	Main type of vehicle used to get p-EMS to the scene	For each mission
			2.6.1. Rapid response car			Regular car, no stretcher	
			2.6.2. Regular ambulance			Car with stretcher	
			2.6.3. Rotor Wing				
			2.6.4. Fixed Wing				
			2.6.5. Boat staffed with physician				
			2.6.6. Other				
2.7.	Mode of transportation from scene	Categorical			Bullet list	Main type of vehicle used to transport the patient to definitive care	For each mission
			2.7.1. Rapid response car				

Table 2 Event operational descriptors (Continued)

Data variable number	Main data variable name	Type of data	Data variable categories or values	Data variable sub-categories or values	Type	Definition of data variable	How often should variable be reported
			27.2. Regular ambulance staffed with physician			Physician is part of the ambulance crew on a *regular* basis	
			27.3. Regular ambulance with physician attending			Ambulance crew normally without a physician, physician is attending because of patient need	
			27.4. Patient transported in ambulance without physician				
			27.5. Rotor wing				
			27.6. Fixed wing				
			27.7. Boat staffed with physician				
			27.8. Patient not transported due to no indication				
			27.9. Patient not transported due to patient refusal				
			27.10. Patient dead and not transported				
			27.11. Other				
28.	Result of dispatch				Bullet list	Dispatch means unit alerted for mission or request/advice/supervision	For each mission
		Categorical	28.1. Patient attended			P-EMS attended the patient	
				28.1.1. Transported with physician escort			
				28.1.2. Transported without physician escort			
				28.1.3. Discharged on-scene		Patient not transported	
				28.1.4. Pronounced dead on scene			
		Categorical	28.2. Patient not attended			P-EMS did not attend the patient. The main reason why mission is aborted or refused	For each mission
				28.2.1. Weather			
				28.2.2. Technical reasons			
				28.2.3. Other mission (concurrency)			
				28.2.4. Alternative tasking			
				28.2.5. Mission refused due to duty time limitations			
				28.2.6. Fatigue			
				28.2.7. Not needed			

Table 2 Event operational descriptors (Continued)

Data variable number	Main data variable name	Type of data	Data variable categories or values	Data variable sub-categories or values	Type	Definition of data variable	How often should variable be reported
				2.8.2.8. No time benefit			
				2.8.2.9. Patient has left scene (before arrival of unit)			
				2.8.2.10. Mission taken over by another p.EMS			
2.9.	Trauma mechanism	Categorical			Bullet list	The Utstein Trauma template. The mechanism (or external factor) that caused the injury event	For each mission
			2.9.1. Not trauma				
			2.9.2. Blunt trauma				
				2.9.2.1. Traffic - motor vehicle injury		Car, pickup, truck, van, heavy transport vehicle, bus	
				2.9.2.2. Traffic - motorbike			
				2.9.2.3. Traffic - bicycle			
				2.9.2.4. Traffic - pedestrian			
				2.9.2.5. Traffic - other		Ship, airplane, railway train	
				2.9.2.6. Fall from same level		Low energy fall. From the persons height or less	
				2.9.2.7. Fall from higher level		High energy fall. From more than the persons height	
				2.9.2.8. Struck or hit by blunt object		Tree, tree branch, bar, stone, human body part, metal, other	
				2.9.2.9. Explosivm		Blast injuries	
				2.9.2.10 Other			
				2.9.2.11. Unknown			
			2.9.3. Penetrating trauma				
				2.9.3.1. Stabbed by pointed or sharp object		Knife, sword, dagger or other	
				2.9.3.2. Gun		By handgun, shotgun, rifle, or another firearm of any dimension	
				2.9.3.3. Other			
			2.9.4. Unknown			Unknown trauma mechanism	
2.10.	Specialty of the attending physician	Categorical			Check box	The pre-hospital physician attending patient on scene	For each mission
			2.10.1. Anaesthesiology				

Table 2 Event operational descriptors (Continued)

Data variable number	Main data variable name	Type of data	Data variable categories or values	Data variable sub-categories or values	Type	Definition of data variable	How often should variable be reported
			2102. Emergency medicine				
			2103. Intensive care				
			2104. Surgery				
			2105. Internal medicine				
			2106. Other				
2.11.	NACA score	Categorial			Bullet list	NACA 0–7	For each mission
			2111. NACA 0				
			2112. NACA 1				
			2113. NACA 2				
			2114. NACA 3				
			2115. NACA 4				
			2116. NACA 5				
			2117. NACA 6				
			2118. NACA 7				
			2119. NACA score unknown				
2.12.	Where patient is delivered	Categorial			Bullet list	Where physician-staffed unit delivers patient	For each mission
			2121. Major Trauma Centre/Definitive care centre			Hospital where all definitive treatment is available (to the particular patient)	
			2122. Local hospital			Hospital where all definitive treatment is not available (to the particular patient)	
			2123. Other health care facility			Facility not defined as hospital	

EMCC Emergency medical communication centre, *SAR* Search and rescue, *p-EMS* physician-staffed emergency medical services, *NACA score* National Advisory Committee for Aeronautics score

Table 3 Patient descriptors

Data variable number	Main data variable name	Type of data	Data variable categories or values	Data variable sub-categories or values	Type	Definition of data variable	How often should variable be reported
3. Patient descriptors							
3.1.	Age	Continuous			Number	Patient age at the time of event	For each mission
3.2.	Gender	Categorical	3.2.1 Female		Bullet list	Patient gender	For each mission
			3.2.2 Male				
			3.2.3 Unknown				
3.3.	Pre-event comorbidity	Ordinal			Bullet list	Pre-event ASA-PS. The comorbidity existing before event. Derangements from present disease should not be considered	For each mission
			3.3.1 ASA-PS 1			A normal healthy patient	
			3.3.2 ASA-PS 2			A patient with mild systemic disease	
			3.3.3 ASA-PS 3			A patient with severe systemic disease	
			3.3.4 ASA-PS 4			A patient with severe systemic disease that is a constant threat to life	
			3.3.5 ASA-PS 5			A moribund patient who is not expected to survive without operation	
			3.3.6 ASA-PS 6			A declared brain-dead patient whose organs are being removed for donor purposes	
			3.3.7 ASA Unknown				
3.4.	Chronic medications	Categorical	3.4.1 Yes		Bullet list	Does patient use medication on a regular basis?	For each mission
			3.4.2 No				
			3.4.3 Unknown				
3.5.	Medical problem	Categorical			Bullet list	The condition most likely to be the patient's true medical problem, main clinical symptom or diagnosis, decided by attending p-EMS	For each mission
				3.5.1 Cardiac arrest medical aetiology			
				3.5.2 Cardiac arrest traumatic aetiology			
				3.5.3 Trauma			
				3.5.4 Breathing difficulties			
				3.5.5 Myocardial infarction (MI)		Confirmed by ECG	
				3.5.6 Chest pain, MI not confirmed			
				3.5.7 Stroke			
				3.5.8 Acute neurology			

Table 3 Patient descriptors (*Continued*)

Data variable number	Main data variable name	Type of data	Data variable categories or values	Data variable sub-categories or values	Type	Definition of data variable	How often should variable be reported
			excluding stroke				
			3.5.9. Reduced level of consciousness			Aetiology unknown	
			3.5.10 Poisoning/Intoxication				
			3.5.11 Burns				
			3.5.12 Obstetrics and childbirth				
			3.5.13 Infection				
			3.5.14 Anaphylaxis				
			3.5.15 Surgical				
			3.5.16 Asphyxiation				
			3.5.17 Drowning				
			3.5.18 Psychiatry excluding poisoning/intoxication				
			3.5.19 Other				
3.6.	Glasgow Coma Scale	Ordinal	3.6.1 First		Number	First recorded pre-interventional GCS upon arrival of p-EMS	For each mission
			3.6.2 Last			GCS at end of patient care or patient handover	
			3.6.3 Not recorded				
		Categorical	3.6.4 Patient Intubated	3.6.4.1 Yes	Bullet list		
				3.6.4.2 No			
3.7.	Heart rate	Continuous			Number	Documented by ECG (1st choice), palpation or SpO2 curves (3rd choice)	
			3.7.1 First			First heart rate per minute measured by p-EMS upon arrival	
			3.7.2 Last			Heart rate per minute at end of care or patient handover	
			3.7.3 Not recorded				
3.8.	Systolic blood pressure	Continuous	3.8.1 Lowest		Number	Lowest recorded systolic blood pressure measured by p-EMS (sphygmomanometer, monitor or intra-arterial line) upon arrival	
			3.8.2 First			First recorded systolic blood pressure measured by p-EMS (sphygmomanometer, monitor or intra-arterial line) upon arrival	
			3.8.3 Last			Systolic blood pressure at end of care or patient handover	
			3.8.4 Not recordable			Not possible to record despite several attempts	
			3.8.5 Not recorded				
3.9.	Cardiac rhythm	Categorical	3.9.1 First	3.9.1.1 Sinus rhythm	Bullet	First cardiac rhythm interpreted by p-EMS (minimum 3-channel	For each mission

Table 3 Patient descriptors (*Continued*)

Data variable number	Main data variable name	Type of data	Data variable categories or values	Data variable sub-categories or values	Type	Definition of data variable	How often should variable be reported
	ECG rhythm				list	lead). At *primary survey/upon arrival*	
				3.9.1.2 SVES, VESmono			
				3.9.1.3 AF/AFL/AV-block gr II/III, VESpoly			
				3.9.1.4 VF, VT, Asystole, PEA			
				3.9.1.5 Not recorded			
			3.9.2 Last	3.9.2.1 Sinus rhythm		Cardiac rhythm at end of care or patient handover (minimum 3-channel lead)	
				3.9.2.2 SVES, VESmono			
				3.9.2.3 AF/AFL/AV-block gr II/III, VESpoly			
				3.9.2.4 VF, VT, Asystole, PEA			
				3.9.2.5 Not recorded			
3.10.	SpO2	Continuous	3.10.1 Lowest		Number	Lowest recorded oxygen saturation by p-EMS (measured with pulse oximeter or arterial blood gas (SaO2))	For each mission
			3.10.2 First			First recorded oxygen saturation by p-EMS (measured with pulse oximeter or arterial blood gas (SaO2) upon arrival)	
			3.10.3 Last			Oxygen situation at end of care or patient handover	
			3.10.4 Not recordable			Not possible to record despite several attempts	
			3.10.5 Not recorded				
3.11.	Oxygen supplementation	Categorical	3.11.1 Oxygen supplementation at first measurement of SpO2	3.11.1.1 Yes	Bullet list	First measurement by p-EMS	For each mission
				3.11.1.2 No			
			3.11.2 Oxygen supplementation at last measurement of SpO2	3.11.2.1 Yes		Last measurement by p-EMS	
				3.11.2.2 No			
3.12.	Respiratory rate	Continuous	3.12.1 First		Number	First *respiratory rate* per minute measured by p-EMS upon arrival. If mechanically ventilated, document ventilation rate	For each mission
			3.12.2 Last			Respiratory rate at end of care or patient handover	

Table 3 Patient descriptors (Continued)

Data variable number	Main data variable name	Type of data	Data variable categories or values	Data variable sub-categories or values	Type	Definition of data variable	How often should variable be reported
			3.12.3 Not recorded				
3.13.	Pain	Categorical	3.13.1 First VAS score		Number	First VAS score assessed by p-EMS upon arrival	For each mission
			3.13.2 Last VAS score			VAS score at end of care or patient handover	
			3.13.3 Not recorded				
3.14.	End-tidal CO2	Continuous	3.14.1 First		Number	First end-tidal CO2 measured by p-EMS	For each mission
			3.14.2 Last			Last end-tidal CO2 measured by p-EMS	
			3.14.3 Not recorded				
3.15.	Temperature (core)	Continuous	3.15.1 First		Number	First core temperature measured by p-EMS upon arrival	For each mission
			3.15.2 Last			Last core temperature measured by p-EMS	
			3.15.3 Not recorded				
3.16	Airway at primary survey	Categorical	3.16.1 Clear		Bullet list	As rated by attending physician	For each mission
			3.16.2 Threatened				
			3.16.3 Obstructed				
			3.16.4 Unknown				

ASA-PS American Society of Anesthesiologists physical scale, p-EMS physician staffed emergency medical services, MI Myocardial infarction, ECG Electrocardiogram, GCS Glasgow coma score, SpO2 Peripheral capillary oxygen saturation, SVES Supraventricular extrasystole, VESnoro Ventricular extrasystole, monomorphic, AF Atrial fibrillation, AFL Atrial flutter, AV-block Atrioventricular block, VESpoly Ventricular extrasystole, polymorphic, VF Ventricular fibrillation, VT Ventricular tachycardia, PEA Pulseless electrical activity, SaO2 Arterial oxygen saturation, VAS Visual analogue scale, CO2 Carbon dioxide

Table 4 Process mapping variables

Data variable number	Main data variable name	Type of data	Data variable categories or values	Data variable sub-categories or values	Type	Definition of data variable	How often should variable be reported
4. Process mapping							
4.1.	Diagnosis and monitoring procedures	Categorical	4.1.1 Blood pressure	4.1.1.1 Non-invasive	Check box	Monitoring used and procedures performed by p-EMS	For each mission
				4.1.1.2 Invasive			
				4.1.1.3. Other			
			4.1.2. SpO2				
			4.1.3. EtCO2			Capnometry or capnography used	
			4.1.4. Temperature (core)			Temperature measured during mission	
			4.1.5. ECG	4.1.5.1. Monitoring (3 or 4-lead or pads)			
				4.1.5.2. Analysis (12-lead)			
			4.1.6. Ultrasound/Doppler	4.1.6.1. FAST		By p-EMS	
				4.1.6.2. Lung for pneumothorax		By p-EMS	
			4.1.7. Point of care (POC) blood gas analysis			By p-EMS	
			4.1.8. Other POC testing			By p-EMS	
			4.1.9. POC lab test			By p-EMS	
			4.1.10. Blood glucose			By p-EMS	
			4.1.11. Other				
			4.1.12. None				
4.2.	Drugs used to facilitate airway management	Categorical	4.2.1. Sedatives		Check box	By p-EMS	For each mission
			4.2.2. NMBA				
			4.2.3. Analgesics				
			4.2.4. Local/topic anaesthetics				
			4.2.5. Other				
			4.2.6. None				
4.3.	Airway management	Categorical	4.3.1. Oxygen		Check box	Device or procedures used for successful airway management	For each mission
			4.3.2. Manual			Chin-lift, jaw thrust, recovery position	
			4.3.3. Bag Mask Ventilation				
			4.3.4. Nasopharyngeal device				
			4.3.5. Oropharyngeal device				
			4.3.6. SAD 1. generation			Laryngeal mask with no mechanism for protection	

Table 4 Process mapping variables (*Continued*)

Data variable number	Main data variable name	Type of data	Data variable categories or values	Data variable sub-categories or values	Type	Definition of data variable	How often should variable be reported
						against aspiration	
			4.3.7. SAD 2. generation			Laryngeal mask with any aspiration protection mechanism	
			4.3.8. Oral ETI				
			4.3.9. Nasal ETI				
			4.3.10. Surgical airway	4.3.10.1. Mac-blade			
				4.3.10.2. Hyper angulated blade			
			4.3.11. Other				
			4.3.12. None				
4.4.	Number of attempts to secure airway	Continuous			Number	Number of attempts needed before a definitive airway is in place by p-EMS	For each mission
4.5.	Breathing- related procedures	Categorical			Check box	Procedures performed by p-EMS	For each mission
			4.5.1. Controlled manually			Breathing assistance using physician's hands, Bag valve mask ventilation	
			4.5.2. Controlled mechanically			Use of technical respiratory support, ventilator, NIV	
			4.5.3. Needle decompression				
			4.5.4. Chest tube				
			4.5.5. Thoracostomy				
			4.5.6. Escharotomy				
		Continuous	4.5.7. FiO2			If patient is ventilated	
		Continuous	4.5.8. PEEP			If patient is ventilated	
			4.5.9. Other				
			4.5.10. None				
4.6.	Circulation- related procedures	Categorical	4.6.1. Peripheral iv. line		Check box	Procedures performed by p-EMS	For each mission
			4.6.2. Intraosseous access				
			4.6.3. Central iv. line				
			4.6.4. Arterial line				
			4.6.5. External pacing				
			4.6.6. Internal pacing				
			4.6.7. Defibrillation				
			4.6.8. Cardioversion				
			4.6.9. Volume replacement therapy		Check	Record if intention is to increase circulating volume. Do	

Table 4 Process mapping variables (*Continued*)

Data variable number	Main data variable name	Type of data	Data variable categories or values	Data variable sub-categories or values	Type	Definition of data variable	How often should variable be reported
			(n)fusional administered		box	not record if intention is to "keep-line-open"	
				4.6.9.1. Colloids			
				4.6.9.2. Crystaloids			
				4.6.9.3. Blood products			
			4.6.10. Blood products administered	4.6.10.1. Whole blood	Check box		
				4.6.10.2. PRBC			
				4.6.10.3. Liquid plasma /fresh frozen plasma			
				4.6.10.4. Lyosilas			
				4.6.10.5. Other			
		Continuous	4.6.11. Amount of fluid administered		Number	Millilters given by p-EMS	
		Categorical	4.6.12. Haemostatic dressing	4.6.12.1. Pressure bandage	Check box		
				4.6.12.2. Packing of wound			
				4.6.12.3. Tourniquet			
				4.6.12.4. Pelvic binder			
			4.6.13. Pericardiocentesis				
			4.6.14. Manual chest compressions				
			4.6.15. Mechanical chest compressors				
			4.6.16. Thoracotomy	4.6.16.1. Lateral			
				4.6.16.2. Clamshell			
			4.6.17. EVR			REBOA or other type of EVR	
			4.6.18. IABP				
			4.6.19. Other				
			4.6.20. None				
4.7.	Disability- related procedures	Categorical	4.7.1. Fracture reduction		Check box	Procedures performed by p-EMS	For each mission
			4.7.2. Fracture splinting				
			4.7.3. Spinal immobilization				
			4.7.4. Spinal protection				
			4.7.5. Therapeutic hypothermia				

Table 4 Process mapping variables (Continued)

Data variable number	Main data variable name	Type of data	Data variable categories or values	Data variable sub-categories or values	Type	Definition of data variable	How often should variable be reported
			4.7.6. Thermal protection				
			4.7.7. Amputation				
			4.7.8. Other				
4.8.	Other procedures	Categorical	4.8.1. General anaesthesia		Check box	Procedures performed by p-EMS	For each mission
			4.8.2. Sedation				
			4.8.3. Regional anaesthesia				
			4.8.4. Incubator				
			4.8.5. NO given				
			4.8.6. ECMO				
			4.8.7. Resuscitative caesarean delivery/perimortem hysterotomy				
			4.8.8. Other				
			4.8.9. None				
4.9.	Medications administered	Categorical	4.9.1. Opioids		Check box	Type of medication administered by p-EMS	For each mission
			4.9.2. Analgesics except opioids				
			4.9.3. Anaesthetics				
			4.9.4. Antiarrhythmics				
			4.9.5. Antibiotics				
			4.9.6. Antidotes				
			4.9.7. Antiemetics				
			4.9.8. Antiepileptic				
			4.9.9. Antihypertensive				
			4.9.10. Bronchodilators				
			4.9.11. Diuretic				
			4.9.12. Electrolytes				
			4.9.13. Fluids (not for keep-line cont)				
			4.9.14. NMBA				
			4.9.15. Procoagulant				
			4.9.16. Fibrinolytic				
			4.9.17. Sedatives				
			4.9.18. Steroids				

Table 4 Process mapping variables (*Continued*)

Data variable number	Main data variable name	Type of data	Data variable categories or values	Data variable sub-categories or values	Type	Definition of data variable	How often should variable be reported
			4.9.19. Thrombolytics				
			4.9.20. Vasoactive				
			4.9.21. Tranexamic acid				
			4.9.22. Other				
			4.9.23. None				
4.10.	Hospital pre-alert done	Categorical	4.10.1. Yes		Bullet list	Physician has informed receiving hospital of patient state before arriving at the emergency room	For each mission
			4.10.2. No				

SpO2 Peripheral capillary oxygen saturation, *EtCO2* End-tidal carbon dioxide, *ECG* Electrocardiogram, *FAST* Focused assessment with sonography for trauma, *p-EMS* Physician-staffed emergency medical services, *POC* Point of care, *NMBA* Neuromuscular blocking agent, *ETI* Endotracheal intubation, *SAD* Supraglottic airway device, *NIV* Non-invasive ventilation, *FiO2* Fraction of inspired oxygen, *PEEP* Positive end-expiratory pressure, *IV* Intra venous, *PRBC* Packed red blood cells, *REBOA* Resuscitative endovascular balloon occlusion of the aorta, *EVR* Endovascular resuscitation, *IABP* Intra-aortic balloon pump, *NO* Nitric oxide, *ECMO* Extracorporeal membrane oxygenation

Table 5 Mission outcome and quality indicators

Data variable number	Main data variable name	Type of data	Data variable categories or values	Data variable sub-categories or values	Type	Definition of data variable	How often should variable be reported
5. Mission outcome and quality indicators							
5.1.	Mission outcome	Categorical	5.1.1. Patient left at scene		Check box	Patient left by p-EMS at scene, if necessary, taken to GP or other	For each mission
			5.1.2. Patient taken to hospital, not escorted by p-EMS			To hospital by EMS or other	
			5.1.3. Patient taken to hospital, escorted by p-EMS				
			5.1.4. Patient declared dead on arrival at hospital				
			5.1.5. Patient declared dead at scene				
			5.1.6. Discharged alive from scene			Patient is alive when leaving scene	
			5.1.7. Transported to hospital in cardiac arrest with ongoing CPR				
			5.1.8. Patient alive at handover			Patient is alive when p-EMS hand over patient to hospital/ GP/EMS unit or other	
			5.1.9. Patient alive at discharge from hospital				
			5.1.10. Patient alive at 30-days		Bullet list	30-day outcome or outcome at discharge from hospital	For each mission
5.2.	Was the patient's "post-p-EMS" followed up and registered?	Categorical					
			5.2.1. Yes				
			5.2.2. No				
			5.2.3. Unknown				
5.3.	Intubation success	Categorical	5.3.1. Yes, on first attempt		Bullet list	Successful ETI by p-EMS	For each mission
			5.3.2. Yes, after two or more attempts				
			5.3.3. No				
5.4.	Complications to ETI	Categorical	5.4.1. Yes	5.4.1.1. SpO2 < 90% (at any time)	Check box		For each mission
				5.4.1.2. Blood pressure below 90 (at any time)			
				5.4.1.3. If TBI: Blood pressure below 120 (at any time)			
				5.4.1.4. Blood pressure above 200 (at any time)			
				5.4.1.5. Cardiac arrest or severe, clinically significant bradycardia in relation to the procedure			

Table 5 Mission outcome and quality indicators (Continued)

Data variable number	Main data variable name	Type of data	Data variable categories or values	Data variable sub-categories or values	Type	Definition of data variable	How often should variable be reported
			5.4.2. No			No complications to ETI	
5.5.	Patient with MI	Categorical	5.5.1. Transferred to PCI centre?	5.5.1.1. Yes	Bullet list	Patient meets criteria for myocardial infection	For each mission
				5.5.1.2. No			
			5.5.2. On-scene time		Number		
5.6.	Stroke patients	Categorical	5.6.1. Transferred to a stroke centre?	5.6.1.1 Yes	Bullet list	All patients considered as having stroke by p-EMS	For each mission
				5.6.1.2 No			
		Continuous	5.6.2. On-scene time		Number		
5.7.	Cardiac arrest patients	Categorical	5.7.1. Did patient achieve ROSC for more than 5 min	5.7.1.1. Yes	Bullet list	Patients with cardiac arrest	For each mission
				5.7.1.2. No			
		Categorical	5.7.2. If ROSC patient transferred to a PCI centre?	5.7.2.1. Yes	Bullet list		
				5.7.2.2. No			
5.8.	Pain	Categorical	5.8.1. Was the patient's pain VAS score reduced below 4?	5.8.1.1. Yes	Bullet list		For each mission
				5.8.1.2. No			
				5.8.1.3. Unknown			
			5.8.2. Did the prehospital treatment reduce pain or otherwise control/improve the subjective symptoms and well-being?	5.8.2.1. Yes		As defined by attending p-EMS	
				5.8.2.2. No			
				5.8.2.3. Unknown			
5.9.	Did the prehospital interventions improve or stabilise the vital functions?	Categorical	5.9.1. Yes		Bullet list	As defined by attending p-EMS	For each mission
			5.9.2. No				
			5.9.3. Unknown				
5.10.	Adverse events during mission	Categorical	5.10.1. Adverse operational events		Check box	Missing material or teamwork issues during mission	For each mission
			5.10.2. Adverse medical events			Any adverse medical events during mission	

EMS Emergency medical services, *p-EMS* physician-staffed emergency medical services, *GP* General practitioner, *CPR* Cardiopulmonary resuscitation, *ETI* Endotracheal intubation, *SpO2* Peripheral capillary oxygen saturation, *TBI* Traumatic brain injury, *PCI* Percutaneous coronary intervention, *MI* Myocardial Infarction, *ROSC* Return of spontaneous circulation, *VAS* Visual analogue scale

The experts recommend an event-specific long-term outcome measure to be included on a regular basis. The feasibility of capturing this variable as part of a standardized documentation in the p-EMS population remains to be determined.

General discussion

Several consensus-based templates for reporting in EMS and p-EMS have been created (e.g., trauma, airway handling and cardiac arrest) [14, 15, 26, 36], and studies have proven that data collection according to such templates are feasible [12, 16, 37]. However, to increase the relevance of templates, variables should be coordinated. Of 26 variables in the template on quality indicators in p-EMS [35], five are identical to variables in the current template, six can easily be calculated and three are partially similar. Thus, little extra effort is required to document according to both templates. We believe that the coordination of variables and linking of templates will add value by reducing workload and increasing data capture, thereby facilitating future p-EMS research.

P-EMS are constantly developing, with new diagnostic and therapeutic options available, e.g. pre-hospital blood products, Tranexamic acid, extracorporeal membrane oxygenation (ECMO), thoracotomy and endovascular resuscitation on-scene. To capture these important trends, templates need to be updated regularly. Additionally, the variables shown to be not feasible to document should either be changed or removed. Physiological variables are often reported to be the most often missing variables [38, 39]. In the original template we found the feasibility of collecting physiological data to be good [16], and these variables were not substantially changed in the updated template. Thus, we expect feasibility to be good for physiological variables in the updated template as well.

To be able to compare outcomes, data must be unambiguously defined [26]. A data dictionary with precise definitions will be created for the present template. Furthermore, when implementing the template, it is important to ensure that all requested data are collected. Each service is free to choose whatever supplementary variables it wants, but all core variables should be captured by default, thereby facilitating future research.

Physician-staffed services are more expensive compared to ordinary EMS services making it a limited resource. This emphasize our obligation to use the service for the right patients. Therefore, we continually should strive to identify patients where p-EMS has an additional effect.

To provide a tool for collection of high-quality data is only a first step towards the improvement of p-EMS research. The next step is implementation, which is pivotal for template success. Aiming to increase awareness of the template, we invited experts from all over Europe to participate in its development. We believe this may facilitate implementation. Furthermore, to increase the implementation rate of the template, targeted efforts, such as involvement of stakeholders and highlighting the possibilities which lies within template data research, must be initiated.

Registries (e.g. for trauma and cardiac arrest) have facilitated a large amount of research [14, 40, 41]. In p-EMS there is currently no joint register and each national service manages its own data. Furthermore, data are often registered on paper and later converted to digital format. Automated data capture from monitors and updated digitized data catchment tools could allow for complete template data to be imported directly into a common registry. This would provide a substantial opportunity for joint research. If such a registry could also link template data to outcomes and standardized coding systems for process and outcome issues, we may be able to assess e.g. for which patients p-EMS are useful, which procedures should be performed out-of-hospital and which procedures should not. However, the ethical and legal requirements of data sharing for research purposes (e.g. General Data Protection Regulation (GDPR)) must be taken into account and a substantial work to adhere to the current regulations are needed to succeed.

In the present study, we applied a Delphi method. This approach is in contrast with the Nominal Group Technique (NGT) that was used in the development of the original template. The classic Delphi method applies questionnaires with e-mails whereas the NGT involves a physical meeting with experts to reach a consensus [42]. The methods can also be combined into a modified NGT that starts with a Delphi process and ends with a physical meeting as a final step before consensus. Because this is an update of an existing template, we considered a physical meeting to be unnecessary. Furthermore, we wanted to ensure anonymity of the experts to prevent authors from favouring certain responses.

Reaching agreement is fundamental in Delphi studies, but a commonly accepted definition of consensus is absent [43]. In the present study we defined consensus as variables rated ≥4 (on a scale from 1 to 5) by >70% of experts. We consider this a transparent and systematic method for reaching a consensus.

Limitations

The recruitment of experts is prone to selection bias. For recruitment we used a set of predefined criteria and recruited experts from the EUPHOREA network consisting of representatives from p-EMS throughout central Europe, UK and Scandinavia. The low number of participants (9–11 physicians) may have introduced a selection bias. However, we managed to recruit a representative cohort of p-EMS physicians representing a broad range of European p-EMS. The physician-staffed services

represented in the expert group are amongst the most active services in Europe and we believe this ensures generalizability of the results and that the effect of potential selection bias is minimized. By keeping proposals anonymous, we have avoided the effect of favouring proposals from certain experts.

Conclusions

Using a Delphi method, we have updated and revised the template for reporting in p-EMS. We recommend implementing the dataset for standard reporting in p-EMS.

Abbreviations

AF: Atrial fibrillation; AFL: Atrial flutter; ASA-PS: The American Society of Anesthesiologists Physical Status; AV-block: Atrioventricular block; CO2: Carbon dioxide; CPR: Cardiopulmonary resuscitation; DASH'a: Definitive airway sans hypoxia/hypotension on first attempt; ECG: Electrocardiogram; ECMO: Extracorporeal membrane oxygenation; EMCC: Emergency medical communication centre; EMS: Emergency medical services; EtCO2: End-tidal carbon dioxide; ETI: Endotracheal intubation; EUPHOREA: The European Prehospital Research Alliance; EVR: Endovascular resuscitation; FAST: Focused assessment with sonography for trauma; FIO2: Fraction of inspired oxygen; GCS: Glasgow coma score; GP: General practitioner; Iv.: Intra venous; IABP: Intra-aortic balloon pump; MI: Myocardial Infarction; NAAF: Norwegian Air Ambulance Foundation; NACA score: National Advisory Committee for Aeronautics score; NGT: Nominal group technique; NIV: Non-invasive ventilation; NMBA: Neuromuscular blocking agent; NO: Nitric oxide; PCI: Percutaneous coronary intervention; PEA: Pulseless electrical activity; PEEP: Positive end-expiratory pressure; P-EMS: Physician-staffed emergency medical services; POC: Point of care; PRBC: Packed red blood cells; REBOA: Resuscitative endovascular balloon occlusion of the aorta; ROSC: Return of spontaneous circulation; SAD: Supraglottic airway device; SaO2: Arterial oxygen saturation; SAR: Search and rescue; SBP: Systolic blood pressure; SpO2: Peripheral capillary oxygen saturation; SRQR: the Standards for Reporting Qualitative Research; SVES: Supraventricular extrasystole; TBI: Traumatic brain injury; VAS: Visual analogue scale; VESmono: Ventricular extrasystole, monomorphic; VESpoly: Ventricular extrasystole, polymorphic; VF: Ventricular fibrillation; VT: Ventricular tachycardia

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Authors' contributions

All authors (KT, AJK, KGR and MR) conceived the idea and participated in designing the study. KT analysed the data, AJK, KGR and MR supervised the analysis. All the collaborators participated in the Delphi process and all collaborators and all authors approved the final version of the template. All authors contributed to writing the manuscript and all authors have approved the final version of the manuscript.

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Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Ethics approval and consent to participate

The Regional Ethics Committee (REK 2017/2498) considered the study protocol and concluded that no ethical approval was required. The Privacy Ombudsman (NSD 58762) considered the project not to include personal information, thereby exempting the duty of notification according to the European Union (EU) General Data Protection Regulation (GDPR).

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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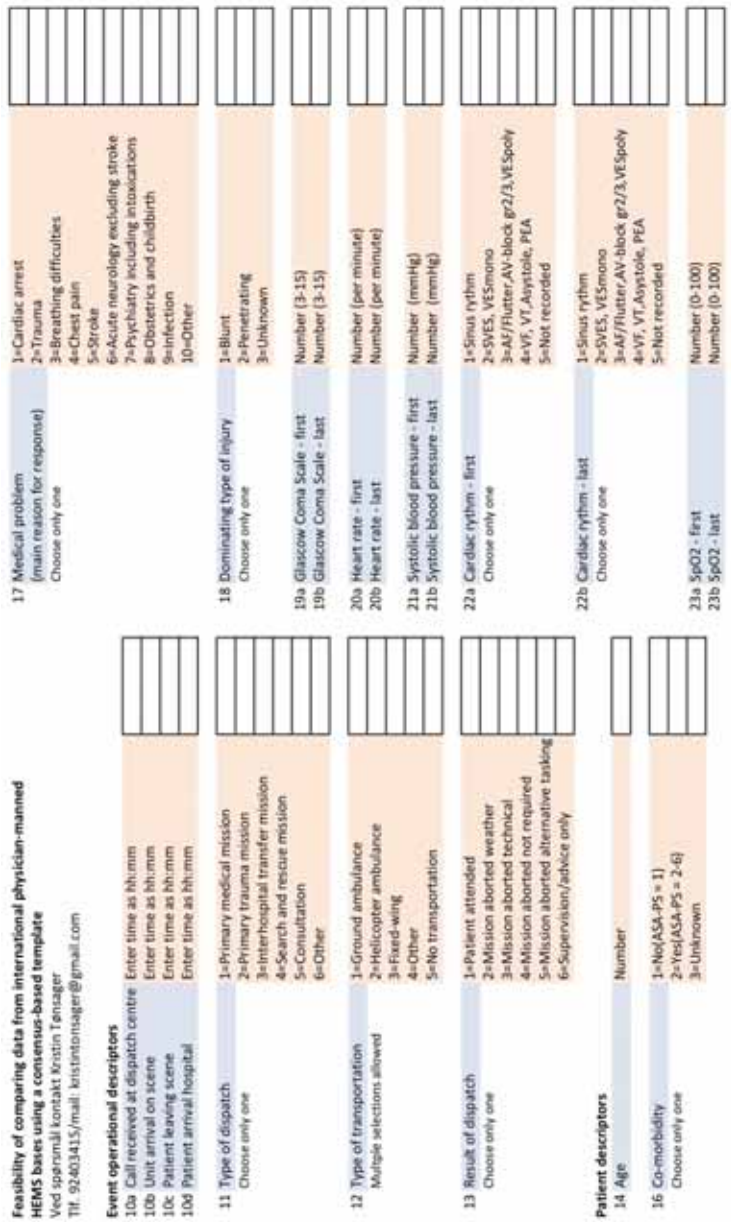
Publisher's Note

Appendices

Appendix 1 – Documentation Form, Study I



Feasibility of comparing data from international physician-manned HEMS bases using a consensus-based template
Ved spørsmål kontakt Kristin Tønsager
Tlf. 92403415/mail: kristintonsager@gmail.com

Event operational descriptors

10a Call received at dispatch centre — Enter time as hh:mm
10b Unit arrival on scene — Enter time as hh:mm
10c Patient leaving scene — Enter time as hh:mm
10d Patient arrival hospital — Enter time as hh:mm

11 Type of dispatch — Choose only one
1=Primary medical mission
2=Primary trauma mission
3=Interhospital transfer mission
4=Search and rescue mission
5=Consultation
6=Other

12 Type of transportation — Multiple selections allowed
1=Ground ambulance
2=Helicopter ambulance
3=Fixed-wing
4=Other
5=No transportation

13 Result of dispatch — Choose only one
1=Patient attended
2=Mission aborted weather
3=Mission aborted technical
4=Mission aborted not required
5=Mission aborted alternative tasking
6=Supervision/advice only

Patient descriptors

14 Age — Number

16 Co-morbidity — Choose only one
1=No(ASA-PS = 1)
2=Yes(ASA-PS = 2-6)
3=Unknown

17 Medical problem (main reason for response) — Choose only one
1=Cardiac arrest
2=Trauma
3=Breathing difficulties
4=Chest pain
5=Stroke
6=Acute neurology excluding stroke
7=Psychiatry including intoxications
8=Obstetrics and childbirth
9=Infection
10=Other

18 Dominating type of injury — Choose only one
1=Blunt
2=Penetrating
3=Unknown

19a Glascow Coma Scale - first — Number (3-15)
19b Glascow Coma Scale - last — Number (3-15)

20a Heart rate - first — Number (per minute)
20b Heart rate - last — Number (per minute)

21a Systolic blood pressure - first — Number (mmHg)
21b Systolic blood pressure - last — Number (mmHg)

22a Cardiac rythm - first — Choose only one
1=Sinus rythm
2=SVES, VESmono
3=AF/Flutter,AV-block gr2/3,VESpoly
4=VF, VT,Asystole, PEA
5=Not recorded

22b Cardiac rythm - last — Choose only one
1=Sinus rythm
2=SVES, VESmono
3=AF/Flutter,AV-block gr2/3,VESpoly
4=VF, VT,Asystole, PEA
5=Not recorded

23a SpO2 - first — Number (0-100)
23b SpO2 - last — Number (0-100)

24a Pain - first
Choose only one
1=None
2=Moderate
3=Severe

24b Pain - last
Choose only one
1=None
2=Moderate
3=Severe

25a Respiratory rate - first
25b Respiratory rate - last
Number (per minute)
Number (per minute)

Process mapping

26 Diagnostic procedures
Multiple selections allowed
1=US/Doppler
2=ECG (12-lead)
3=Invasive monitoring
4=Other point-of-care tests
5=Point-of-care lab tests
6=Other

27a Drugs to facilitate airway procedure
Multiple selections allowed
1=Sedatives
2=Neuromuscular blocking agents
3=Analgesics/opioids
4=Local/topic anaesthetics
5=None

27b Device used in successful airway management
Choose only one
1=Bag Mask Ventilation
2=SAD
3=Oral TI
4=Nasal TI
5=Surgical airway
6=None
7=Unknown

27c Breathing - procedures used
Multiple selections allowed
1=Assisted manually
2=Assisted mechanically
3=Controlled manually
4=Controlled mechanically
5=Chest tube/decormpression
6=Thoracostomi
7=Other
8=Unknown

27d Circulation -procedures used
1=Peripheral IV-line
2=Central IV-line
3=IO-Access
4=Defibrillation
5=Cardioversion
6=Pacing
7=Hemostatic, basic
8=Hemostatic, advanced
9=Other
10=None

27e Disability - procedures used
1=Reduction of fractures
2=Spinal immobilisation
3=Therapeutic hypotermia
4=Other
5=None

28 Medication, drugs administered
Choose only one
1=Yes
2=None

29 Type of medication
Multiple selections allowed
1=Analgesics/Opioids
2=Sedatives
3=Neuromuscular blocking agents
4=Vasoactive
5=Fibrinolytic
6=Antibiotics
7=Other
8=None

Outcome measures or Quality Indicators

31 Mission outcome
Choose only one
1=Left at home
2=To hospital, not escorted by physician
3=To hospital, escorted by physician
4=Decleared dead om arrival hospital
5=Decleared dead at scene

Appendix 2 – Documentation Form, Study II

1. Patient ID: _____

2. AMIS number: _____

3. Date of mission (DD.MM.YYYY): _____

4. Physician (initials): _____

5. Pre-event ASA-PS score: _____

6. Was information on pre-event ASA-PS score easy to obtain in the pre-hospital setting?
   - □ Yes
   - □ No

7. Source of information:
   - □ Patient
   - □ Next of kin
   - □ Physician
   - □ Paramedic
   - □ Nurse
   - □ Other: _____
   - □ Information was not obtainable

8. Reason that information on pre-event ASA-PS score was not obtainable:
   - □ Unconscious patient
   - □ Patient was not able to communicate
   - □ No next of kin/physician/nurse/paramedic available
   - □ Next of kin/physician/nurse/paramedic do not know
   - □ Patient did not want to inform
   - □ Other: _____

Appendix 3 – REK approval, Study II

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK vest	Øyvind Straume	55978496	09.05.2016	2016/556/REK vest
			Deres dato:	**Deres referanse:**
			30.03.2016	

Vår referanse må oppgis ved alle henvendelser

Kristin Tønsager
Anestesiavdelingen

2016/556 Kan luftambulanseleger skåre pre-event ASA-PS prehospitalt?

Forskningsansvarlig: Helse Stavanger HF
Prosjektleder: Kristin Tønsager

Vi viser til søknad om forhåndsgodkjenning av ovennevnte forskningsprosjekt. Søknaden ble behandlet av Regional komité for medisinsk og helsefaglig forskningsetikk (REK vest) i møtet 21.04.2016. Vurderingen er gjort med hjemmel i helseforskningsloven (hfl.) § 10, jf. forskningsetikkloven § 4.

Prosjektomtale
Forskningen skal avdekke om luftambulanseleger kan skåre korrekt pre-event ASA-PS eller ikke på pasienter de behandler prehositalt. Pre-event ASA-PS er en skala som sier noe om graden av komorbiditet, det vil si alvorlighetsgraden av hva pasienten feiler fra før. Studien er designet som en prospektiv observasjonsstudie hvor en luftambulanselege og 3 sykehusleger skårer pre-event ASA-PS på de samme pasientene. Luftambulanselegens skår sammenlignes med skåren til de tre sykehuslegene og sykehuslegene sammenlignes seg i mellom. Luftambulanselegen bruker all tilgjengelig informasjon før pasienten leveres til sykehuset, mens legene på sykehuset kan bruke hele pasientens journal. Ca 400 påsienter skal inkluderes og søker ber om fritak fra samtykkekravet.

Vurdering

Forsvarlighet
REK vest vurderer dette som en forsvarlig studie, men liten ulempe for deltakerne.

Studie på mindreårige
REK vest minner om kravene i helseforskningsloven ved studier på barn, jf helseforskningsloven § 18:
"Forskning som inkluderer mindreårige og personer uten samtykkekompetanse etter pasient- og brukerrettighetsloven § 4-3 kan bare finne sted dersom:
a. eventuell risiko eller ulempe for personen er ubetydelig
b. personen selv ikke motsetter seg det, og
c. det er grunn til å anta at resultatene av forskningen kan være til nytte for den aktuelle personen eller for andre personer med samme aldersspesifikke lidelse,
sykdom, skade eller tilstand.

For mindreårige kreves det at tilsvarende forskning ikke kan gjennomføres på personer som ikke er mindreårige."

Komiteen peker på at studien vil ha minimal påvirkning for pasientene. Prosjektet innebærer at noen få

Besøksadresse:
Armauer Hansens Hus (AHH), Tverrfløy Nord, 2 etasje. Rom 281. Haukelandsveien 28

Telefon: 55975000
E-post: rek-vest@uib.no
Web: http://helseforskning.etikkom.no/

helsepersonell vil foreta vurdering av pre event ASA-PS, og dermed får tilgang til journal. Komiteen vurderer ulempen ved deltakelse til å være ubetydelig, og finner at kravene er oppfylt i studien.

Unntak fra samtykkekravet jfr. helseforskningsloven § 35
Prosjektgruppen ønsker å gjennomføre prosjektet uten å innhente samtykke fra deltakerne. Hovedregelen for medisinsk og helsefaglig forskning er samtykke fra deltakerne. For at helseopplysninger innsamlet i helse- og omsorgtjenesten skal kunne benyttes i forskning uten samtykke, må kravene i helseforskningsloven § 35 være oppfylt. Dette kan bare skje dersom:

- slik forskning er av vesentlig interesse for samfunnet
- hensynet til deltakernes velferd og integritet er ivaretatt
- det er vanskelig å innhente samtykke

Komiteen vurderer dette som et viktig prosjekt å gjennomføre, og anser kravene som oppfylt. Komiteen vektlegger viktigheten av komplette og valide data, og at krenkelsen av deltakernes integritet er minimal.

Informasjonsplikt og rett til reservasjon
Ved innhenting av informasjon fra tredjepart, er hovedregelen at personen det gjelder skal informeres om bruken, jf. personopplysningsloven § 20 første ledd. Informasjon kan unnlates dersom det er umulig eller uforholdsmessig vanskelig, jf § 20 andre ledd bokstav b. Fritak fra kravet om informasjon etter §20 første ledd må vurderes etter § 20 andre ledd, bokstav b). REK vest gir fritak for plikten til informasjon og viser til begrunnelsen for unntak for samtykkekravet over.

Prosjektslutt og håndtering av data
Prosjektslutt er satt til 31.03.2020, og data ønskes lagret i fem år etter prosjektslutt for etterkontroll. REK vest har ingen innvendinger til dette. I følge søknaden så vil data lagres i låst skap (Stavanger) og i journal (Trondheim). REK vest setter som vilkår at data lagres i tråd med de respektive institusjonene sine rutiner for håndtering av forskningsdata.

Vilkår

- Prosjektdata skal lagres i tråd med de respektive institusjoner sine rutiner for håndtering av forskningsdata.

Vedtak
REK vest godkjenner prosjektet på betingelse av at ovennevnte vilkår tas til følge.

Sluttmelding og søknad om prosjektendring
Prosjektleder skal sende sluttmelding til REK vest på eget skjema senest 30.09.2020, jf. hfl. § 12. Prosjektleder skal sende søknad om prosjektendring til REK vest dersom det skal gjøres vesentlige endringer i forhold til de opplysninger som er gitt i søknaden, jf. hfl. § 11.

Klageadgang
Du kan klage på komiteens vedtak, jf. forvaltningsloven § 28 flg. Klagen sendes til REK vest. Klagefristen er tre uker fra du mottar dette brevet. Dersom vedtaket opprettholdes av REK vest, sendes klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag for endelig vurdering.

Med vennlig hilsen

Ansgar Berg
Prof. Dr.med
Komitéleder

Øyvind Straume
sekretariatsleder

Kopi til:forskning@sus.no

Appendix 4 – Additional REK approval, Study II

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK vest	Anna Stephansen	55978496	04.12.2017	2016/556/REK vest
			Deres dato:	Deres referanse:
			20.11.2017	

Vår referanse må oppgis ved alle henvendelser

Kristin Tønsager
Anestesiavdelingen

2016/556 Kan luftambulanseleger skåre pre-event ASA-PS prehospitalt?

Forskningsansvarlig: Helse Stavanger HF, Helse Stavanger HF - Stavanger universitetssjukehus
Prosjektleder: Kristin Tønsager

Vi viser til søknad om prosjektendring datert 20.11.2017 for ovennevnte forskningsprosjekt. Søknaden er behandlet av nestleder for REK vest på fullmakt, med hjemmel i helseforskningsloven § 11.

Vurdering
Prosjektgruppen ønsker å la luftambulanselegene skåre ASA-PS på 20 av de inkluderte pasientene. Det skal trekkes ut 20 tilfeldige pasienter av de inkluderte i henholdsvis Trondheim og Stavanger og deretter skal de luftambulanselegene skåre ASA-PS på disse, på samme måte som de in-hospitale legene allerede har gjort på alle de inkluderte pasientene, det vil si å gå inn i journalen og bruke opplysningene der for å skåre ASA-PS. Det betyr at luftambulanselegene må gå inn i journalen på 20 av de inkluderte pasientene. Legene har taushetsplikt.

REK vest oppfatter det slik at den omsøkte endringen er innenfor formålet definert i den opprinnelige prosjektsøknaden og har ingen innvendinger mot dette.

Vedtak
REK Vest godkjenner prosjektendring i samsvar med forelagt søknad.

Klageadgang
Du kan klage på komiteens vedtak, jf. helseforskningsloven § 10 og forvaltningsloven § 28 flg. Klagen sendes til REK vest. Klagefristen er tre uker fra du mottar dette brevet. Dersom vedtaket opprettholdes av REK vest, sendes klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag for endelig vurdering.

Med vennlig hilsen

Ketil Joachim Ødegaard
dr.med.
Nestleder REK vest

Anna Stephansen
Sekretariatsleder

Kopi til: *forskning@sus.no; forskning@sus.no*

Besøksadresse:
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