Patient Safety in Helicopter Emergency Services

Time to lift off?

A mixed methods study

by

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Preface

"It's a Bird... It's a Plane... It's Superman"

The title of the 1966 Broadway musical could illustrate the anticipation of our patients when the air ambulance approaches the scene.[1] The image of a superhero may also be the impression we like to have of ourselves as a helicopter crew. However, all stories about superheroes contain a twist, the Achilles' heel of our hero, a weakness they must overcome for the story to end well.

This PhD-journey started with an intention to look into the never-ending crew discussion based on my personal experience and the 2011 consensus report from The European Research Collaboration listing appropriate staffing and training as one of the five areas of priority for prehospital research.[2] Thus, to stick to the world of superheroes, one may say that this project started with the question of which is superior of the *"Trinity"*[3] or *"The Fantastic Four"*.[4]

Although essential, staffing is only one of many factors impacting the care and safety we provide for our patients. One of the most influential patient safety publications is the US report by the Institute of Medicine, "*To Err is Human: Building a Safer Health System*", from 2000.[5] Indeed, it may be true that to err is human, but human errors are only the tip of the iceberg. If "building a safer health system", even in the air, is our intention, it is time to lift off. From twenty years as a HEMS physician and a medical director, I know mistakes happen. How do we learn from them and prevent them from happening again?

"We cannot change the human condition,
but we can change the conditions under
which humans work."

James Reason

The long and winding road of Trollstigen in Romsdalen, Norway - Photo: Shutterstock

To all superheroes, not at least

Aina, Beate, Birgitte,
Espen, Harald and Solveig

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During the decade since my journey started with a lecture held by a fresh PhD about patient safety, I have met many exciting people, first of all, my main supervisor, Prof. Stephen Sollid. You held that lecture and have been an inspiration and guide since then. My two co-supervisors, Prof. Marit Kvangarsnes and Assoc. Prof. Håkon Bjorheim Abrahamsen, have been fellow travellers on part of the journey. I am so grateful for all your valuable advice and for showing me the right direction. To Leif Inge Kjærvoll Sørskår and Henrik Langdalen, it was pleasure writing with you!

I would like to thank Prof. Hans Morten Lossius and the Norwegian Air Ambulance Foundation Research Department for accepting me and supporting me as a PhD candidate. However, this journey would also not have been possible without the goodwill of my employer, Ålesund Hospital and Møre and Romsdal Hospital Trust.

My appreciation also to Prof. Karina Aase, Prof. Siri Wiig and the rest of SHARE - Centre for Resilience in Healthcare at the University of Stavanger for their enthusiasm for patient safety research.

It has been a long and winding road, and I am glad this journey finally has reached its destination, but I am even happier that I got the chance to travel. A new and partly unknown world has been revealed to me. At times, it has undoubtedly felt like a lonely journey. However, my wife, and dearest friend, has always been by my side and a patient listener. Over these years, our family have shared the finest moments but also illness and grief. Together, we got through it all. I am forever grateful for your love and support, Dorthe!

Kristen

Ålesund, February 2024

Summary

Background

The raised focus on patient safety in healthcare over the last decades has not gained similar attention in helicopter emergency medicine services (HEMS). Research seems to indicate a low number of adverse events in HEMS. However, there is reason to believe that underreporting can explain this and, together with a lack of key definitions and the methodological challenges of researching prehospital operations per se, contribute to the paucity of studies about the extent and nature of patient safety incidents in HEMS.

Methods

This thesis is based on quantitative and qualitative studies in a mixed methods approach to explore how the conditions of HEMS operations may affect patient safety, emphasising organisational factors, non-technical skills training and the incident reporting culture. In the first of the three studies, we surveyed medical directors of international HEMS on their perceived patient and flight safety in different medical staffing models. This study also collected information about the various educations, competencies and combinations of such in use in HEMS internationally. The second survey explored the frequency of training and assessment of non-technical skills in Norwegian HEMS. Lastly, in-depth interviews with Norwegian HEMS physicians regarding incident reporting culture and risk areas gave another valuable perspective on the research theme.

Results

The findings were summarised in the subsequent main themes: The helicopter, the medical crew, transition of care, procedures and checklists, non-technical skills and incident reporting. Recommended actions were categorised after effectiveness using the Action Hierarchy Tool from the

Institute of Healthcare Improvement and the "Risk and Incident Analysis – Handbook for the Health Service" by the Norwegian Board of Supervision. System-based changes regarding helicopter size and design of interior, medical competence and staffing and standardisation of medical equipment and protocols with local hospitals are evaluated as the most effective actions, while actions for better use of incident reporting and checklists and initiatives to team training within the crew and with the receiving emergency departments as moderately effective. The least effective measures are based merely on personal compliance, such as double control of medication and coping with fatigue.

Conclusion

An essential premise for improved patient safety in HEMS is a national and coordinated system for reporting incidents and near misses. This system should facilitate learning between different bases while maintaining anonymity. In addition, other system-based actions should be prioritised to improve patient safety in HEMS. Such actions include helicopter and staffing choices according to mission profiles, standardising medical equipment, medication protocols and the handover process with the local hospitals, and mandatory non-technical skills training and assessment using behavioural marker tools. Further research should explore the rationale behind medical personnel's perception of incidents and reporting culture in more depth and the effect of different staffing models on patient safety.

Sammendrag

Bakgrunn

Luftambulansetjenesten er en integrert del av helsetilbudet, men fokuset på pasientsikkerhet har ikke vært like sterkt som i helsevesenet forøvrig de siste tiårene. Studier indikerer at det er få uønskede hendelser i luftambulansetjenesten, men dette kan skyldes en høyere terskel for å melde avvik. Mange begreper om pasientsikkerhet er uklart definert, og tradisjonell forskning innen akuttmedisin har vist seg utfordrende. Dermed har vi for lite kunnskap om hendelser som påvirker pasientsikkerheten i luftambulansetjenesten.

Metode

Denne avhandlingen er basert på kvantitative og kvalitative delstudier ved bruk av mixed-method for å utforske hvordan ulike forhold ved luftambulansevirksomhet kan påvirke pasientsikkerhet. Studien legger særlig vekt på organisatoriske faktorer, trening i og vurdering av ikke-tekniske ferdigheter samt rapporteringskulturen til medisinsk personell. I den første av de tre studiene undersøkte vi pasient- og flysikkerhet i ulike bemanningsmodeller ved å be medisinske ledere for internasjonale luftambulansetjenester om å vurdere sikkerheten i sin egen tjeneste under ulike typer oppdrag. Denne studien samlet også informasjon om de ulike utdanningene og bemanningsmodellene som er i bruk internasjonalt. Den andre undersøkelsen så på hyppigheten av trening og vurdering av ikke-tekniske ferdigheter i norsk luftambulansetjeneste. I den siste studien ble norske luftambulanseleger intervjuet om erfaringen med avviksrapportering og deres oppfatning av hvilke områder ved tjenesten som var særlig risikoutsatt.

Resultat

Funnene i studiene kan oppsummeres i følgende hovedtema: helikopteret som arbeidsplattform, den medisinske bemanningen, pasientoverlevering, prosedyrer og sjekklister, ikke-tekniske ferdigheter og avviksrapportering. Anbefalte tiltak ble kategorisert etter effektivitet ved bruk av Action Hierarchy Tool fra Institute of Healthcare Improvement og «Risiko- og hendelsesanalyse – Håndbok for helsetjenesten» fra Helsedirektoratet. Systembaserte tiltak vedrørende helikopterstørrelse og utforming av interiør og medisinsk bemanning vil ha størst effekt. Standardisering av medisinsk utstyr og felles medikamentprotokoller med lokalsykehus hører også til denne kategorien. Bedre avviksrapportering, økt bruk av sjekklister og tiltak som teamtrening innad i mannskapet eller sammen med akuttmottak ble vurdert som middels effektive. De minst effektive tiltakene er kun avhengige av enkeltpersoner slik som dobbeltkontroll av medisiner og å kunne håndtere fatigue.

Konklusjon

En viktig forutsetning for bedre pasientsikkerheten er et nasjonalt og samordnet system for rapportering av avvik og nestenuhell. Dette systemet bør legge til rette for læring på tvers av tjenesten samtidig som det ivaretar anonymiteten til de som rapporterer. I tillegg til dette er det avgjørende å prioritere andre systembaserte og organisatoriske tiltak for å øke pasientsikkerheten i luftambulansetjenesten. Disse tiltakene inkluderer å velge helikopter og bemanning som er tilpasset tjenestens oppdragsprofil. Det er også viktig å standardisere medisinsk utstyr, medikamentprotokoller og selve pasientoverleveringen mellom luftambulansen og akuttmottakene på sykehusene. Det anbefales også å innføre systematisk trening og evaluering av ikke-tekniske ferdigheter. Det er nødvendig med ytterligere forskning for å undersøke grundigere helikopterlegenes rapporteringskultur og oppfatning av hendelser. Videre forskning bør også undersøke hvordan ulike bemanningsmodeller påvirker pasientsikkerheten.

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List of papers

This thesis is based on the following original papers:

I. Rasmussen K, Røislien J, Sollid SJM.

Does Medical Staffing Influence Perceived Safety? An International Survey on Medical Crew Models in Helicopter Emergency Medical Services.

Air Med J. 2018;37(1):29-36. doi:10.1016/j.amj.2017.09.008

II. Rasmussen K, Langdalen H, Sollid SJM, Abrahamsen EB, Sørskår LIK, Bondevik GT, Abrahamsen HB.

Training and assessment of non-technical skills in Norwegian helicopter emergency services: a cross-sectional and longitudinal study.

Scand J Trauma Resusc Emerg Med. 2019;27(1):1. Published 2019 Jan 7. doi:10.1186/s13049-018-0583-1

III. Rasmussen K, Sollid SJM, Kvangarsnes M.

Sky-high safety? A Qualitative Study of Physicians' Experiences of Patient Safety in Norwegian Helicopter Emergency Services.

J Patient Saf. 2024;20(1):1-6. doi:10.1097/PTS.0000000000001172

Abbreviations

AAMS	Association of Air Medical Services, USA
ACCT	Association of Critical Care Transport, USA
AHRQ	Agency for Healthcare Research
ASA	Aeromedical Society of Australasia
ECMO	Extracorporeal membrane oxygenation
EHAC	European HEMS and Air Ambulance Committee
EMS	Emergency Medical Service
EMT	Emergency medical technician
ETI	Endotracheal intubation
EUPHOREA	European Prehospital Research Alliance
HEM-Net	Emergency Medical Network of Helicopter and Hospital, Japan
HEMS	Helicopter Emergency Medical Service
HCM	Hems Crew Member
IABP	Intra-aortic balloon pump
IOM	Institute of Medicine
ISMP	Institute for Safe Medication Practices, Canada
NHS	National Health Service
RCA	Root cause analysis
RSI	Rapid sequence intubation
WHO	World Health Organization

Table of Contents

List of figures and tables

Figures

Tables

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1 Introduction

1.1 Patient safety – a global challenge

Even though the concept of patient safety can be traced back to ancient Greece with the Hippocratic oath, stating that all treatment should be beneficial and not cause harm,[6] it first gained adequate focus during the 1990s after the publication of "Error in Medicine," by Lucian Leape, a paediatric surgeon,[7] leading to the US Institute of Medicine (IOM) report *"To Err is Human: building a safer health system"*[5] in 2000, and the UK NHS report *"An organisation with a memory"*.[8] The World Health Organization (WHO) has named unsafe care "a global public health challenge".[9] A systematic review found adverse events in every tenth admission to hospitals, and a substantial part preventable.[10] A retrospective chart review found 4.2% of the deaths in a Norwegian hospital to be probably avoidable.[11] For low- and middle-income countries, it is estimated that one in every four patients may be unnecessarily harmed.[9] As well as a heavy burden for the individual, this is also a significant challenge for the society.

1.2 A brief history of HEMS

Helicopter, as a means of medevac transportation, was first used for military purposes. During the 1960s, civilian helicopter emergency medical services (HEMS) emerged in the USA and Europe. Norway's first dedicated HEMS service was established in 1978, leading to a national and government-funded service in 1988. Today, HEMS is an integrated part of healthcare worldwide.

From merely a mode of transportation initially, the evolution to offering advanced treatment such as thoracotomy, intra-aortic balloon pump (IABP), or even extracorporeal membrane oxygenation (ECMO),[12,13] has led to the expression of HEMS as the hospital's extended arm. Despite advanced therapeutic measures being introduced, the fundamental challenges on the prehospital scene remain: the hazardous environment with

Medevac in the Korean War – Transport of casualties in pods on the outside of the crew compartment.
Photo by John Sanford – Printed with permission.

limited space, time and resources, all increasing the possibility of errors.[14] As these challenges may be even more prominent during transport, determining between using time for measures at the scene or during transport is essential, often referred to as the dilemma of "*stay and play*" or *"scoop and run"*.

1.3 Adverse events in HEMS

Critical events during air or ground transport are reported to be mainly related to airway management, circulatory instability, and sedation,[15–18] with equipment problems a leading contributor to most unexpected events.[19] What factors may lead to such events? In a study of a large Canadian air medical provider, MacDonald et al. categorised adverse events from medical crew reports for the years 2002-2005.[20] Of non-aviation-related events, *communication problems*, both within the crew and with co-working partners such as sending and receiving hospital, were the leading cause of patient care problems, followed by events with *medical equipment, patient management,* and *clinical performance*. In a systematic review from 2011, Bigham et al. categorised the 88 included publications regarding patient safety threats unique to the EMS environment into the following themes: *medication errors, clinical judgment, communication, vehicle safety, interfacility transport,* and *intubation*.[21] Two recent studies from fixed-wing air ambulances have emphasized *preparedness*, *good teamwork, communication, experience, training,* and *checklists* as essential.[22,23]

1.4 The frequency of patient safety events in HEMS

The knowledge of the frequency of adverse events in HEMS is still sparse. Some parallels can be drawn from research on ground emergency services and intra-hospital transports. However, study designs and lack of definitions make drawing firm conclusions difficult.[24] In his article, Seymour defined a *major event* as death, cardiac or respiratory arrest, pneumothorax or seizure.[16] The definition of *critical events* by Singh et al. included death, major resuscitative procedures, hemodynamic deterioration, inadvertent extubation and respiratory arrest.[17] This lack of consensus in key definitions and the heterogeneity of the patient population illustrate the challenges in prehospital research and safety improvement.

Alabdali et al. found a prevalence of adverse events from 5 to 18% in seven studies in a systematic review of inter-hospital transports by paramedics published in 2017.[25] In a meta-analysis by Jeyaraju et al. from 2021, medical adverse events occurred in 11% of inter-hospital transports.[26] Both studies included air and ground transports. For intra-hospital transports, Parmentier-Decrucq et al. found adverse events affecting the patient in 26% in an observational study.[15]

Two studies in Alabdali's review included only helicopter transports. Seymour et al. (2008) found that in-flight major events are rare in inter-hospital transports with helicopters.[16] However, 22% of the patients experienced minor physiologic events with a higher risk of requiring vasopressor treatment and longer transport duration. In the study by Singh et al. from 2009, critical events occurred in 5.1% of urgent air-medical transports.[17]

MacDonald et al. found a low incidence of adverse events reported by flight paramedics in the before-mentioned Canadian study.[20] However, underreporting of adverse events by paramedics, despite an obligation to report, was a limitation of the study, and also for other healthcare personnel, error identification, disclosure and reporting of medical errors varies.[27,28] In a systematic review, Davis et al. found the worst accuracy of self-assessment among the least experienced and the most confident physicians.[29] The sensitivity of reporting systems itself in identifying key sources of errors is another issue.[30] This raises the question of incident-reporting systems as a reliable source of the frequency of errors in healthcare.[31]

1.5 Monitoring and measuring safety events

To address the nature and frequency of both critical and minor patient safety events, a system detecting adverse events and monitoring patient safety in HEMS is needed. In a systematic review, O'Connor et al. found 67 methods in use for measuring and monitoring patient safety in prehospital care, most dominantly surveys, patient record reviews, incident reporting systems, interviews and checklists.[32] Thomas and Petersen have proposed a general framework for measuring errors and adverse events in healthcare, suggesting that incident reporting and malpractice claims

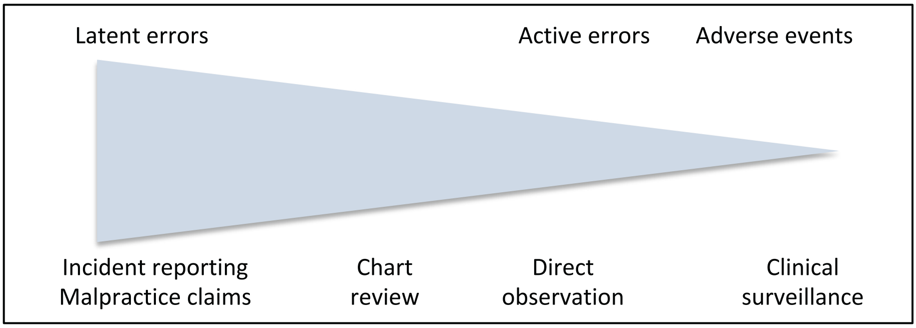

Figure 1: Framework for measuring errors and adverse events in healthcare. From Thomas and Petersen: Measuring errors and adverse events in health care. Used with permission.

may address latent errors and direct observation and clinical surveillance be suitable to identify active errors, while chart review somewhere in between.[33]

Direct observation and clinical surveillance may be the best way to detect adverse events. However, due to high costs, these methods are seldom used in the prehospital setting. Reviewing patient records may be more feasible depending on the number of reviewers and inter-rater consistency. Incident reporting is a relatively low-cost method; however, it only reveals a limited number of events.[34] By comparing medical record re views to incident reporting systems, studies from hospitals show that only one in every twenty harmful incidents was reported.[35,36]

1.6 Patient safety research

Battles and Lilford recommended using multiple approaches and combining different research methods to identify patient safety risks in healthcare, as no single method is perfect.[37] The Agency for Healthcare Research and Quality (AHRQ) has outlined three paths for patient safety research:[38] (1) *'Fundamental research on errors'*, e.g. root cause analysis (RCA) and the role of human factors, (2) *'Evaluation of reporting systems'*, by identifying critical components of successful incident reporting, and (3) *'Applied research on patient safety'*, such as design and processes. Hofoss and Deilkås outlined three main paths in patient safety research in a *"Roadmap for patient safety research"*: (1) *particular cases of adverse events,* (2) *the design of healthcare*, and (3) *the culture of care-giving institutions*.[39] Hagiwara et al. call for research on the frequency and nature of adverse events in prehospital care, along with safety culture and incident reporting.[40]

In this thesis and the studies it is based on, we have focused on areas of risk and, in particular, the contributing organisational factors, human factors, and the safety culture, understood as how the personnel assess what constitutes a patient safety incident and their use of incident reporting systems.

1.7 Structure of the thesis

In this chapter, a status is given for patient safety in HEMS. The next chapter provides the terminology and framework used in patient safety literature and this thesis. After the following two chapters, Aims and Methods, the results of the three studies are presented in Chapter 5, followed by the discussion of the results in Chapter 6, and a summary with interpretation in Chapter 7. After Conclusion in Chapter 8, implications for future research are provided in the final chapter.

2 Patient safety – a framework

2.1 Definitions

In its "*Conceptual framework for the international classification for patient safety*", WHO gives the following definition:[41]

> *"Patient safety is the reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum. An acceptable minimum refers to the collective notions of given current knowledge, resources available and the context in which care was delivered weighed against the risk of non-treatment or other treatment."*

By this understanding, the context in which the care is given would influence what is considered an acceptable safety level, i.e., what is acceptable in the prehospital field could be different from what is acceptable in a hospital setting. Another implication would be that what is considered acceptable must be time-sensitive; what was regarded adequate yesterday may not be so tomorrow.

WHO also defines a *patient safety incident* as an *"event or circumstance that could have resulted, or did result, in unnecessary harm to a patient".* In the literature, such incidents are often named *adverse events, errors* or *near misses*. The Agency for Healthcare Research and Quality (AHRQ) uses the following definitions for these terms:[42]

- *Adverse events:* patient harm as a result of medical care that could be preventable or less harmful if care had been different
- *Error:* any act exposing patients to hazard either by doing something wrong or failing to do the right thing
- *Near miss:* an unsafe situation not causing harm

According to this definition, an organisation's patient safety initiatives must include incidents that could have caused harm but which, however, "went well".

2.2 The individual versus the system approach

The traditional and common understanding is that errors are fundamentally due to human mistakes and, thus, individuals are responsible for errors, either based on lack of knowledge or skills. This *individual approach* emphasises human behaviour as the cause of adverse events. After analysing the aviation and nuclear industry, James Reason, a British psychologist, published his book *Human Error* in 1990.[43] Reason's work led to the development of the *system approach*, pointing at the contribution of a poorly designed system to most human errors. He argued that accidents seldom were caused by isolated errors by individuals but rather by failure in one or more of four domains: organisation, supervision, preconditions and specific acts.[44] Similar to Reason, Leape proposed that success depends more on procedures, systems and routines and less on individual human actions.[7]

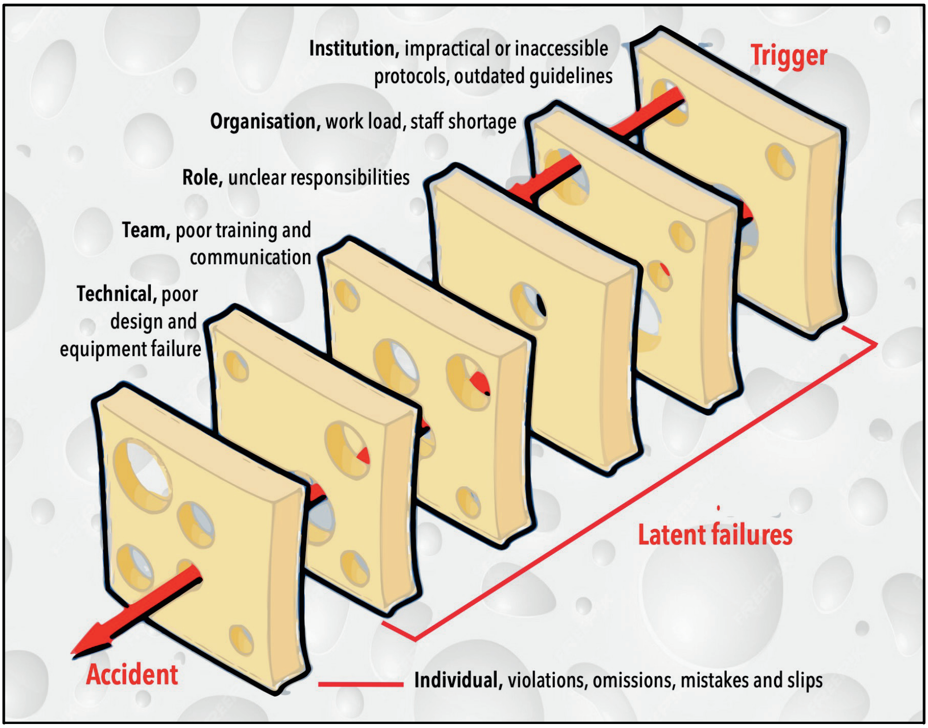

Figure 2: Swiss Cheese Model. Adapted from Core Concepts in Patient Safety - Royal College of Nursing, UK (Archived material). Used with permission.

The *Swiss Cheese Model* is probably the most widely known contribution to safety theory after Reason. The model was developed in several steps over a decade, and although criticised for simplification, it remains relevant to illustrate how a sequence of flaws in a system may contribute to an error.[45] The different layers in the model represent barriers against accidents. Unlike the ideal world where the barriers are impenetrable, in reality, all protective layers have defects, and the holes in each layer represent the defects in each barrier. The holes in these barriers are dynamic; they open and close and vary in size and time. When holes in all layers align, an *"accident trajectory"* is created, leading to a potential failure.

2.3 Active and latent failures

Reason also introduced the terms active failures and latent conditions. Active failures are unsafe acts by persons in direct contact with the system or patient, whereas latent conditions describe the weaknesses in the system that may lie dormant before combining with an active failure into an accident.[46] Organisational factors, both from the management itself or external decision-makers, may impact local workplace factors that, in turn, lead to unsafe acts. Reason uses the term *'latent condition pathway'* about this chain of causality.

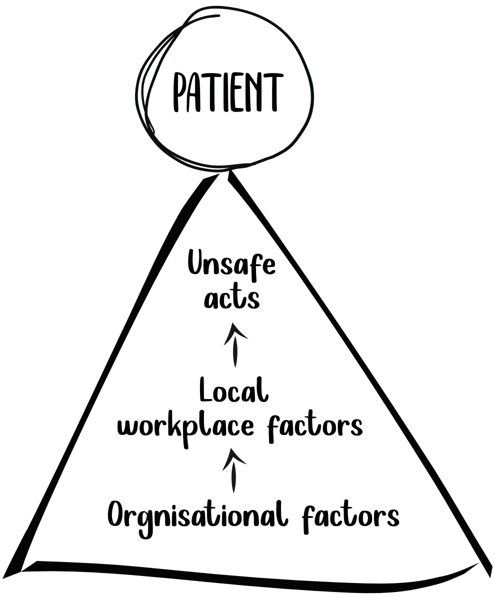

Figure 3: The latent condition pathway

According to Reason, the latent condition pathway has the shape of a pyramid where the many organisational factors form a wide basis, and the unsafe acts occur at *the sharp end* where an individual, as the last barrier, makes a mistake. This may be understood literally in some situations, such as when a surgeon holding the scalpel performs a procedure on a patient in contrast to personnel at *the blunt end* not in direct contact with the patient.

2.4 From reactive to proactive risk management

In the individual approach, error prevention focuses on penalising the individual, primarily at “the sharp end”. By such *reactive* measures, one hopes to achieve a deterrent effect on themselves and others. In contrast, the system-centred approach seeks to reveal and eliminate the latent factors leading to the error and, by this, *proactively* prevent the same accident. Without a focus on the latent conditions, or, to quote Reason, *“the resident pathogens within the system”*, risk management will remain reactive, and the same errors will reoccur regardless of the persons involved.[44]

The system-centred approach does not disregard the influence of human behaviour on adverse events or exempt individuals from responsibility. Nevertheless, even in such cases, it will always be necessary to review which factors in the organisation, conditions at the workplace and others may have played a role. The *“Risk and Incident Analysis – Handbook for the Health Service”* (2017) by the Norwegian Board of Health Supervision reflects this shift of emphasis from an individual to a system-centred approach.[47]

2.5 Factors influencing patient safety

Since the mid-1980s, Charles Vincent, another influential British psychologist, has focused on improving healthcare safety. He postulated that adverse events usually originate in various systemic features: the task, the team, the work environment, and the organisation. Together with Taylor-Adams and Stanhope, he developed a framework for analysing risk and safety in clinical medicine to facilitate a broader approach to the factors influencing clinical practice.[48]

Table 1: Factors influencing clinical practice. Adapted from Vincent et al. 1998. Used with permission.

Factors that influence clinical practice

Institutional context

- Economic and regulatory context

Organisational and management factors

- Financial resources and constraints
- Organisational structure
- Policy standards and goals
- Safety culture and priorities

Work environment

- Staffing levels and skill mix
- Workload and shift patterns
- Design, availability, and maintenance of equipment
- Administrative and managerial support

Team factors

- Verbal communication
- Team structure

Individual (staff) factors

- Knowledge and skills
- Motivation
- Physical and mental health

Task factors

- Task design and clarity of structure
- Availability and use of protocols
- Availability and accuracy of test results

Patient characteristics

- Condition (complexity and seriousness)
- Language and communication
- Personality and social factors

A team consists of two or more individuals with specific competencies and specialised roles, working coordinated together to achieve a shared goal.[49] In a literature review,[50] Manser listed relevant aspects of teamwork:

Table 2: Aspects of teamwork in healthcare. From Manser: Teamwork and patient safety in dynamic domains of healthcare: a review of the literature. Used with permission.

Aspects of teamwork relevant to the quality and safety of patient care in dynamic domains of healthcare	
Quality of collaboration	• Mutual respect • Trust
Shared mental models	• Strength of shared goals • Shared perception of a situation • Shared understanding of team structure, team task, team roles, etc.
Coordination	• Adaptive coordination (e.g. dynamic task allocation when new members join the team; shift between explicit and implicit forms of coordination; increased information exchange and planning in critical situations)
Communication	• Openness of communication • Quality of communication (e.g. shared frames of reference) • Specific communication practices (e.g. team briefing)
Leadership	• Leadership style (value contributions from staff, encourage participation in decision-making, etc.) • Adaptive leadership behaviour (e.g. increased explicit leadership behaviour in critical situations)

Manser concluded that raising awareness of psychological factors, communication, and team training could improve clinical performance and, thus, patient safety. MacDonald et al. found communication problems to contribute to one-third of all identified adverse events in air medical transports.[14] This involved issues within the crew but also with other stakeholders, such as the sending or the receiving facility.

Künzle et al. characterised effective leadership with unambiguous behaviour adapted to the situation and shared within the team.[51] Rosenman et al. have the proposed following competencies for a leader of an emergency medicine team:[52]

Table 3: Team leadership behaviours for emergency medicine. From Rosenman et al.: Assessing Team Leadership in Emergency Medicine: The Milestones and Beyond. Used with permission

Leadership of an interdisciplinary team				
Level 1	Level 2	Level 3	Level 4	Level 5
Asks for help when appropriate Treats team members with respect	Assigns roles to team members Formulates and communicates a plan Communicates clearly	Sets and communicates priorities for patient care Monitors team progression towards goals Maintains big picture Effectively manages individual patient resources	Formulates and communicates a contingency plan Assists/coaches other providers Balances authority and team member input Copes with pressure and distractions	Effectively debriefs team Effectively manages system resources Motivates team members Manages conflict effectively

2.6 Hard and soft defences

According to Reason, the barriers in a complex technological system are a mixture of 'hard' and 'soft' defences. The hard defences are technical, automated safety features, physical barriers and protective equipment, whereas the soft defences can be legislation, procedures, training, certification, what Reason refers to as the 'combination of paper and people'.[53] Accordingly, correcting measures are called strong and weak actions.

Kellogg et al. have demonstrated an example of the efficiency of different forms of defence in preventing incidents from reoccurring in an organisation.[54] After reviewing root-cause analyses over an 8-year period at a major US medical centre, they found the proposed solutions were weaker actions, most common training, process change, and policy reinforcement. These actions did not affect the occurrence of, for instance, retained foreign body events at this centre during the period. In an editorial comment on this study, this is explained by the lack of authority in healthcare to implement often expensive but effective system-based changes and not primarily aim at changing human behaviour.[55] The editors use the analogy of James Reason of swatting at mosquitos instead of draining the swamp to describe this failed approach.[44]

To classify the strength of proposed action in a root-cause analysis (RCA), an action hierarchy tool can be helpful.[56,57] Actions are ranked as weaker, intermediate and stronger, or as in the example below by the Institute for

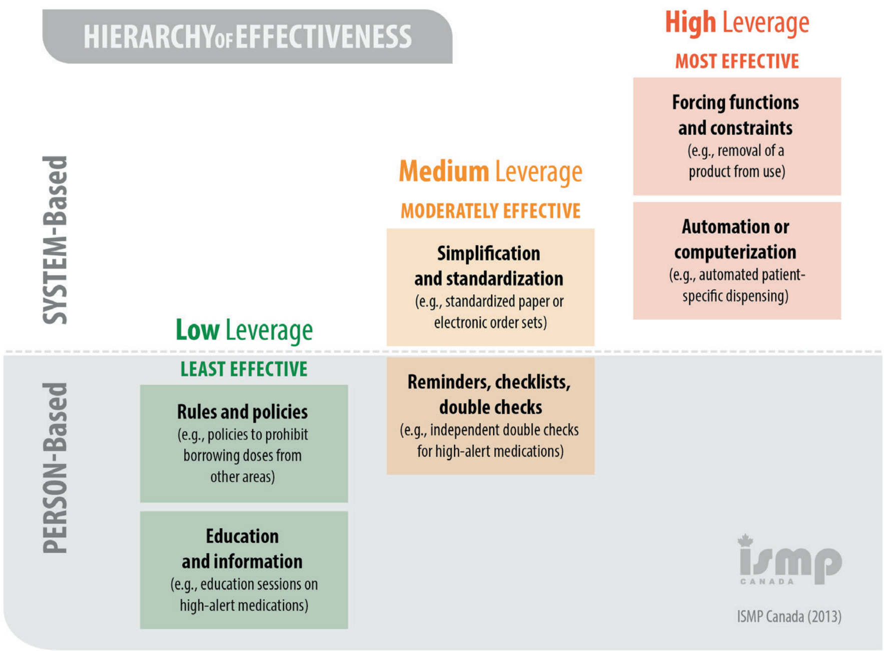

Figure 4: Designing effective recommendations. Institute for Safe Medication Practices Canada. Ontario Critical Incident Learning, 2013. Reprinted with permission.

Safe Medication Practices Canada, as *least, moderately* and *most effective*.[58] System-based actions introducing physical and automated barriers will be characterised as most effective, while actions based entirely on changes in human behaviour as least effective. Between these extremes, actions combining human and technological changes will mostly be placed in an intermediate section with moderate effectiveness. The categories are not rigidly defined, leaving the analysis team some leeway.

2.7 Safety culture

The *safety culture* is by most authors defined as the part of an organisation's overall culture and a set of shared fundamental values and attitudes defining how safety issues are dealt with. Assessing the safety culture could, thus, give information about the organisational factors leading to adverse events.[59] Safety climate is most often understood as the workers' individual attitudes and experiences towards safety at a given time,[60] and a good patient safety climate is also shown to strongly correlate with good staff safety.[61]

There is no unambiguous definition of which factors are included in *patient safety culture.* However, the AHRQ has defined the following dimensions within patient safety culture: *leadership, teamwork within and across units, communication, staffing,* and *reporting systems with non-punitive feedback*.[63]

To assess the safety culture within a healthcare organisation, tools such as the Safety Attitudes Questionnaire[62] and the Hospital Survey on Patient Safety Culture[63] have been developed, the latter also validated for prehospital use.[64]

2.8 The framework in the thesis

The terminology and framework presented in this chapter have guided this thesis, particularly in the categorisation, analysis, and interpretation regarding the understanding of organisational factors, latent risks, hard and soft defences, and the effectiveness of measures.

3 Aims

3.1 Main aims of the thesis

This thesis aims to explore how the unique characteristics and conditions of HEMS operations affect patient safety by identifying the impact of organisational factors, how training in and assessment of human factors can guide quality, and the safety culture among providers of medical care in HEMS. Based on the findings, the thesis intends to answer the question: What initiatives should be prioritised to enhance patient safety in HEMS?

3.2 Aims of the individual studies

3.2.1 Study I

This study aimed to describe the diversity of medical crew compositions currently used in international HEMS, and how patient and flight safety was perceived in these crew models. In addition, the study explored the medical directors' preferred crew compositions.

3.2.2 Study II

The study objectives were to explore the present frequency of simulation-based training and assessment of each of the seven generic non-technical skills for physicians, HEMS crew members and pilots in Norwegian HEMS and the changes in frequency over time.

3.2.3 Study III

This study aimed to explore the physicians' experience with incident reporting and their perceived areas of risk in HEMS.

3.2.4 Relationship between the studies

Following the aims of this thesis, the main themes of organisational factors, training and assessment and safety culture were covered in the three studies as follows: Organisational factors in the understanding of the choice of helicopter and staffing were surveyed in Study 1 and a theme in Study 3. Additional system-related measures, such as procedures and checklists, were other topics in Study 3. Non-technical skills training and assessment was the sole subject of Study 2; however, it was also an essential part of Study 3. Safety culture, which in this context is understood as the medical personnel's perception of errors and their reporting culture, was another topic of the last study. An overview of the relationships between the studies concerning the aims of the thesis is shown in Figure 5.

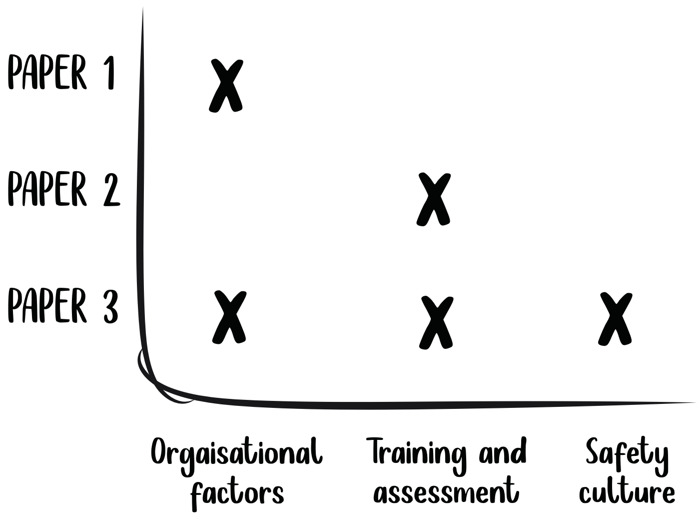

Figure 5: Relationship between the studies and the aims of the thesis.

4 Methods

4.1 Overall methodological considerations

Traditional medical research methods are challenging in the prehospital setting;[65] their use in patient safety research is also questioned.[66] Randomisation, lack of standardisation, patients who cannot consent and mortality as an insensitive endpoint are barriers to prehospital research.[65] To overcome the methodological limitation in this field, quantitative research can be complemented by qualitative methods.[67] Qualitative research aims to give a deeper understanding of a phenomenon, the 'what', 'how' or 'why' rather than 'how many' or 'how much'.[68] Over the last decades, qualitative methods have gained increasing acceptance in medical research. In a literature review, Paltved and Musaeus listed three advantages of using a qualitative approach to enhance patient safety in emergency medicine: It could illuminate the physicians' thinking and acting processes, capture organisational and team processes, and lead to clinical and organisational development.[69]

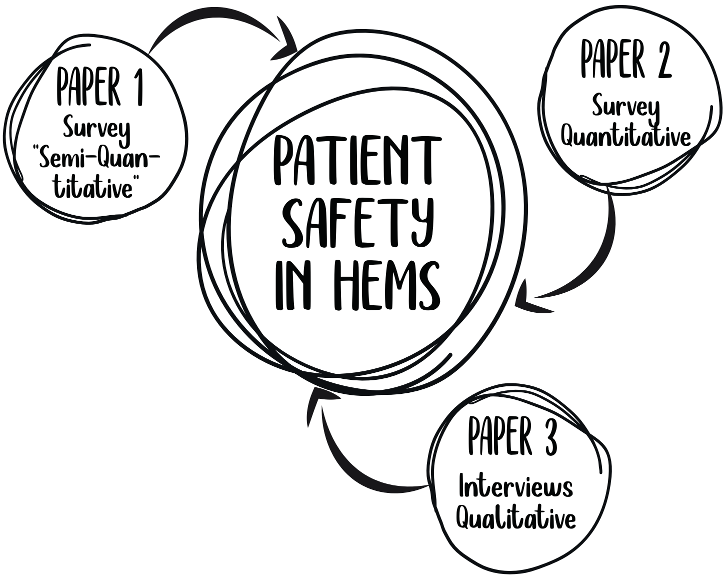

Figure 6: The different study methodologies

All three studies in this thesis were performed with different research methods. The first study was based on a survey, and even though statistically analysed, the conclusions are interpreted with "qualitative eyes" due to measuring *perceptions of safety* in a relatively limited number of responders. In this thesis, we thus, describe this as a '*semi-quantitative*' study. Aven uses this term for risk analysis where quantification of probability alone is questioned, and where other factors are included in the assessment.[70] A semi-quantitative risk assessment includes, thus, both quantitative and qualitative elements.

The second study was also based on a survey but purely quantitative, whereas the third and last was a qualitative study based on interview data (Table 4). The thesis is, thus, designed with a mixed-method approach with an analysis based on the three quantitative and qualitative studies.

4.2 Mixed methods research

4.2.1 Philosophical foundation

Tashakkori and Creswell defined mixed methods research as *"research in which the investigator collects and analyses data, integrates the findings and draws inferences using both qualitative and quantitative approaches"*.[71] Combining quantitative and qualitative methods dates back to Jick in 1979, and social science research, however, has also been found particularly useful in the study of the complex phenomena of health care.[72] Quantitative research methods are rooted in a positivist philosophy, meaning that reality can be described objectively through measurement and quantification. On the other hand, the qualitative researcher, as a constructivist, assumes that reality is based on social constructions and that there is no single truth, as knowledge is generated through interaction and interpretation.[73] Mixed methods research combines qualitative and quantitative research methods based on a pragmatic philosophy, meaning a combination of methods that best answers the research questions, and by combining methods with different weaknesses, the researcher can reduce the weaknesses of the individual method.[74]

4.2.2 Rationale for mixed methods research

In 1989, Greene et al. identified five rationales of mixed methods research:[75] (1) *triangulation*, for confirmation of results; (2) *complementarity,* to enhance or clarify; (3) *development*, to use one method to shape another; (4) *initiation*, to raise new research questions, and (5) *expansion*, for expanding the range of inquiry. The rationale for using mixed methods approach in this thesis is *complementarity*; results from one study with one method are used to elaborate results from another. To use non-technical skills as an example: In Study 2, we surveyed the training frequency in NTS for Norwegian HEMS physicians as baseline information. In Study 3, communication, leadership, teamwork, and situational awareness were essential for the informants to provide safe patient care. Both sources of information are valuable in assessing NTS training in HEMS.

4.2.3 Typology and analytic strategies

The weighting of the qualitative and quantitative elements in mixed methods research varies from equal weight to dominance of one.[74] Equal status is often symbolised in mixed methods research as 'QUAL+QUAN', qualitative dominant studies as 'QUAL+quan', and predominantly quantitative as 'QUAN+qual'. In this thesis, most emphasis is placed on the qualitative findings and interpretation; hence, a *QUAL+quan* study.

Östlund et al. explored the different analytic approaches used in mixed methods research in health care.[72] In the *concurrent* approach, data are integrated during the analytic phase after being converted to either qualitative or quantitative form. In the *parallel* analysis, the datasets are collected and analysed independently and integration is not performed until the interpretation stage. In *sequential* analysis, data are analysed separately in a sequential order but not with the intent of integration, i.e. when a qualitative study with the intention of developing variables for a subsequent quantitative study. In this thesis, analysis is closest to the *concurrent* approach. Quantitative data from the two surveys are transformed into narratives and then integrated with qualitative data from the interview study in the analysis.

Caracelli and Greene (1993) propose four different strategies for mixed methods data analysis:[76] (1) *data transformation*, (2) *typology development*, (3) *extreme case analysis*, and (4) *data consolidation/merging*. In data consolidation, both data types are used to create new variables with the intent of initiation. In data transformation, integration can be achieved by transforming qualitative data numerically or quantitative data into narratives. In this thesis, we used predefined themes based on patient safety literature and earlier research and did not intend to create new variables, so *data transformation* was used as an integration strategy in this thesis.

4.3 Thematic analysis

Braun and Clarke endorse thematic analysis as a flexible and pragmatic method for identifying, analysing, organising and reporting themes in a data set.[77] They have presented a six-stage method for thematic analysis but underline that this is not a sequential process but involves moving back and forth between phases. The process starts with *familiarisation with the data*, continues with *generating codes*, *searching for themes*, *reviewing themes*, *defining and naming themes* and ends with *producing the report*.

In an *inductive* approach, themes are generated from the text without any pre-existing coding frame. For this thesis, the *deductive* approach was used based on the framework described in Chapter 2, the results of the individual studies, and the aims of this study.

Themes may be identified either at a semantic or latent level. *Semantic* themes are identified on the surface, whereas the underlying meaning is searched for in the *latent* approach.[77] The themes in this thesis resulting from the overall data will be at a *semantic* level. From this follows an *essentialist/realist* approach to thematic analysis as the text presented is analysed in a straightforward way.

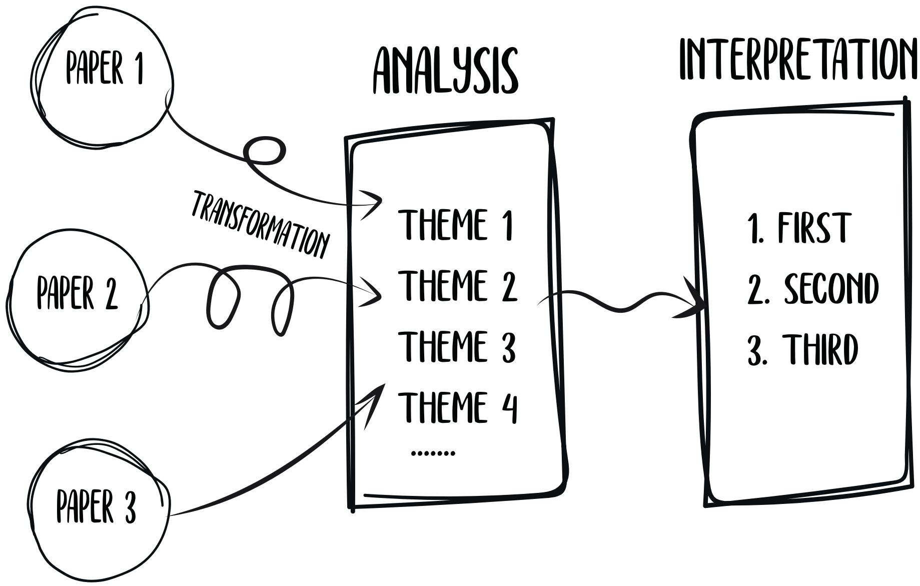

Figure 7: Analytic process of the thesis. Quantitative results from the first two papers are transformed and merged with results from the last paper and sorted into predefined themes in the analysis (Chapter 6). The implications of the analysis results are interpreted in Chapter 7 using RCA tools.

4.4 Summary of thesis methodology

This thesis is designed as a mixed method with qualitative dominance. The rationale is complementarity. Familiarisation of the data has been achieved in the work with the individual studies and during the writing of this thesis's introduction and theory chapters. Data from the individual studies are integrated in the analytic phase. For the analysis, we applied a deductive and semantic thematic analysis with predefined themes based on earlier research and patient safety literature together with our individual papers. To interpret the results from the thematic analysis, commonly used tools for root cause analysis, described in more detail in Chapter 2.7, were applied as guidance.

4.5 Methodology of the individual studies

The methodology of the individual studies is presented in Table 4 regarding design, data sources, participants, approvals and analysis and discussed more in detail in the following sections.

Table 4: Overview of study methodology

	Study I	Study II	Study III
Design	Cross-sectional, 'semi-quantitative'	Cross-sectional and longitudinal, quantitative	Qualitative
Data source	Questionnaire	Questionnaire	Individual interviews
Participants	Medical directors, international	Norwegian HEMS pilots, HCMs and physicians	Norwegian HEMS physicians
Data prot. approval	2014/38659	2016/45723	2019/531035
Ethical approval	2014/760	2015/2249	2019/33093
Analysis	Fisher's exact test Excel 2011/SPSS 22.0	Fisher's exact test R 3.1.3	Qualitative description/inductive qualitative content analysis

4.5.1 Study I – An international, cross-sectional study

Participants

We invited medical directors in Europe, North America, Australia, New Zealand, and Japan to participate in this study. This group was chosen, as we aimed for responses from participants with a system responsibility representing a cross-section of crew models in use. Participants were identified through various organisations such as the European HEMS and Air Ambulance Committee (EHAC), the European Prehospital Research Alliance (EUPHOREA), the Association of Critical Care Transport (ACCT), the Association of Air Medical Services (AAMS), the Aeromedical Society of Australasia (ASA) and the Emergency Medical Network of Helicopter and Hospital of Japan (HEM-Net). Each medical director was responsible for one to more than 10 HEMS bases. We could not collect all e-mail addresses for confidentiality reasons, making calculating a response rate difficult.

Data collection and material

An electronic questionnaire was developed and tested on a number of HEMS professionals and revised according to their feedback. Internal consistency was tested with Cronbach's alpha for the two patient safety items and six flight safety items, respectively. The survey was distributed as a web-based questionnaire (SurveyXact™) and open from June to October 2014.

After initial questions about background data of their service, we asked the participants for their *perception of risk* in the absence of an objective measure of risk.[78–80] The medical directors were asked to evaluate patient and flight safety in their service during various mission types on a 7-point symmetric Likert scale.[81]

Table 5: Likert-scale used in Study I

Likert scale Study I	
1	Totally unacceptable
2	Unacceptable
3	Slightly unacceptable
4	Neutral
5	Slightly acceptable
6	Acceptable
7	Perfectly acceptable

Approvals

- Data Protection Official for Research, Norwegian Social Science Data Services (NSD), Bergen, Norway (date of approval: April 23, 2014, ref. no. 38659)
- Exempt from ethical approval by the Regional Ethical Committee of Western Norway (REK Vest), Bergen, Norway (date of approval: April 20, 2014, ref. no. 2014/760)

Statistical analysis

We considered the difference between positive ratings ("acceptable" or "perfectly acceptable") and negative ratings ("slightly acceptable" or less) to be of particular clinical relevance, and, thus, responses were dichotomised in two groups. We defined "slightly acceptable" as a negative rating in this setting, as we assumed that the medical directors' ambition level of safety was higher than this.

The dichotomous data were presented as counts and valid percents and the ordinal data as medians and quartiles and visualised with box plots for the different mission types for (1) single and dual medical crew and (2) with or without physicians as part of the crew. Due to the small sample with categorical and non-normally distributed data, we used Fisher's exact test. All statistical analyses were performed using Microsoft Excel 2011 for Mac (Microsoft Corporation, Redmond, WA) and SPSS Statistics for Mac (Version 22.0; IBM, Armonk, NY).

4.5.2 Study II – A quantitative, cross-sectional and longitudinal study

Participants

All pilots, HEMS crew members (HCM) and physicians working in the civilian Norwegian HEMS were invited. Due to their limited number, the additional flight nurses serving at one of the bases were not included for confidentiality reasons. Personnel from fixed-wing ambulances or the military search-and-rescue helicopters (SAR) were excluded.

Data collection and material

A web-based survey (SurveyXact™) was distributed via e-mail. The survey was open from October through December 2016. The study was part of a safety climate questionnaire with eight additional questions regarding non-technical skills (NTS). In addition to a cross-sectional design, this study was also a comparison with the previous results of Abrahamsen et al.[82], which guided the study's design. Our study focused on the two question categories of the extent of simulation-based training and assessment on a four-point ordinal scale (0, 1–2, 3–5, >5 times per year) for each of the seven generic NTS categories proposed by Flin et al.[83] The questionnaire also contained seven background variables.

Approvals

- The Norwegian Centre for Research Data approved the study (Ref. no. 2016/45723)
- Exempt from ethical approval by the Regional Committee for Medical and Health Research Western Norway (Ref. no. 2015/2249).

Statistical analysis

To compare the frequency of training/assessment with the previous study, a ratio of the percentages of each ordinal group was calculated and presented as bar charts, with a ratio >1 indicating a positive development. For statistical testing of the development for each professional group and each generic NTS, the results were dichotomised into "no training/assessment" and "some training/assessment" and analysed with Fisher's exact test using the freeware R 3.1.3.

4.5.3 Study III – A qualitative, individual in-depth semi-structured interview study

Participants

We intended to recruit 6 to 12 HEMS physicians with at least five years of experience for an in-depth interview study. Physicians with any formal leadership role at the base were intentionally not invited. The study was conducted with individual interviews and not as a focus group interview to allow the informants to speak more freely about self-experienced incidents.

We planned to recruit 1-2 informants per HEMS base to ensure that physicians with the same professional background but from different bases and, thus, different experiences regarding incident reporting systems, helicopter types, and crew configuration were represented. This group of informants would then serve as a purposeful sample.[84,85] Recruitment continued until little new information emerged from the interviews. Eight informants were eventually included in the study.

Data collection and material

The interviews were based on a semi-structured interview guide and took place during regular working hours at the informants' workplace from February to July 2020. Interviews were performed with a recorder or via video (Microsoft Skype or Microsoft Teams, Microsoft Corp., Redmond, WA, USA). The recorded video files were converted to audio files, and all audio files were transcribed verbatim.

The interview opened with questions about the informants' experience with incident reporting systems and continued with questions about incidents or near misses they had experienced or expected could occur in the different phases of a mission. At the end of the interview, the informants were asked to summarise essential factors for patient safety in HEMS.

Ethical considerations

All informants received written information first through the person of contact and then by e-mail before the interviews. This information contained information about the purpose of the study and the possibility of withdrawing at any point. To ensure the informants' anonymity towards their own leader and avoid the risk of retaliation, we asked the medical directors of all Norwegian HEMS bases to appoint a person of contact who was then requested to recruit one or two informants from their base.

We chose individual interviews instead of focus group interview to let the informants speak more freely about their own experiences. The interviewer had the same professional background as the informants, and even individual interviews by a peer may lead to professional vulnerability for the informants.[86]

Approvals

- Norwegian Data Protection Official (NSD ref. 531035, Sep 05, 2019)
- Exempt from ethical approval by the Regional Ethical Committee (REK Vest, ref. 33093, Aug 20, 2019).

Analysis

With findings not far from the literal description and a low level of interpretation, we decided to apply a qualitative descriptive approach to the study.[85,87,88] Qualitative description is an inductive process to describe a phenomenon and develop an understanding, where the researcher has an active role through interviews and interpretation but takes the participants' perspectives.[89]

For data analysis, an inductive qualitative content analysis was used.[90,91] Text was divided into meaning units, condensed and coded before the codes repeatedly were sorted by similarities and differences in subcategories, and eventually into two main categories according to the research objectives.[92]

5 Results

5.1 Summary of Study I

The scientific evidence to support one crew composition over another is ambiguous. This study intended to add knowledge to this field from a novel perspective by using *perception of safety* in different crew models in various mission settings.

5.1.1 Staffing models

According to the medical directors responding to this study, the most common staffing models in Europe, North America, Australia and Japan were physician and Hems Crew Member (HCM) (38%), physician and nurse (20%) and nurse and EMT/paramedic (17%). Physicians were single medical care providers in 26 services and had assistants in 22, whereas nurses were single providers in two services and had assistants in 13 services. Paramedic-led services were rare. Overall, 45% of services had a single medical provider, and 55% had a dual medical crew.

5.1.2 Education and competence

One of the key findings was the wide range of education and training represented. Two-thirds of the physician-led services used board-certified doctors only, and one-third also in-training physicians. Anaesthesiology and emergency medicine were most commonly represented, and 60% of the services used physicians from multiple specialities. Most services with nurses require additional training, most commonly as a Certified Flight Nurse, Emergency Nurse or Critical Care Nurse. Paramedics were certified in advanced airway skills in 59% of the services.

5.1.3 Patient and flight safety

Services with a single medical crew in the cabin generally scored lower for *patient safety* during night missions than daytime missions and significantly lower for both night and daytime missions compared to systems with an assistant in the cabin. No difference was found between crews with and without physicians (Table 6, Fig. 7).

Single crews also assigned significantly lower scores for *flight safety* to all flight operations compared to dual crews except for transports without patients on board (Table 6, Fig. 8).

Table 6: Number of observations (n), medians and quartiles for all subgroups and percentage of observations with perceived safety 'acceptable' or better. P-values (p) from the Fisher's Exact test comparing perceived safety in the dichotomised groups (Likert scale 1-5 vs. 6-7) for single and dual medical crew.

	Single medical crew			**Dual medical crew**			
	n	Median (Q1, Q3)	% 6-7	*n*	Median (Q1, Q3)	% 6-7	*p*-value
Patient safety							
Daylight missions	28	6.0 (4.5, 7.0)	71	33	7.0 (6.0, 7.0)	97	0.009
Night missions	22	6.0 (4.0, 6.0)	55	25	7.0 (6.0, 7.0)	96	0.001
Flight safety							
Flight without patient	28	7.0 (6.0, 7.0)	79	32	7.0 (6.0, 7.0)	94	0.130
During patient transport	28	6.0 (4.5, 7.0)	68	32	7.0 (6.0, 7.0)	97	0.004
Daylight missions	28	7.0 (5.5, 7.0)	75	32	7.0 (6.0, 7.0)	97	0.020
Night missions	22	6.0 (5.0, 7.0)	64	23	7.0 (6.0, 7.0)	96	0.010
Primary missions	28	6.5 (5.0, 7.0)	71	29	7.0 (6.0, 7.0)	97	0.012
Inter-hospital transfers	21	6.0 (4.0, 7.0)	71	30	7.0 (6.0, 7.0)	97	0.015

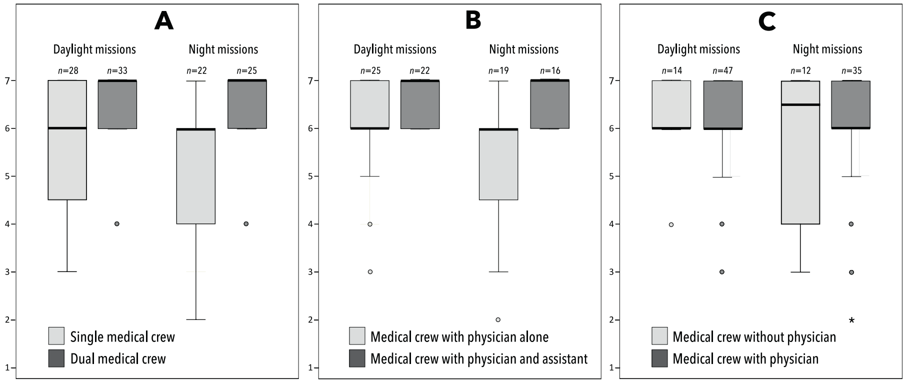

Figure 8: Respondents' perceived patient safety in Helicopter Emergency Medical Service (HEMS) daylight and night missions for single and dual medical crews (A), crews with physician alone and physician with a medical assistant (B) and crews without and with physician (C), rated from 'Totally unacceptable' (1) to 'Perfectly acceptable' (7).

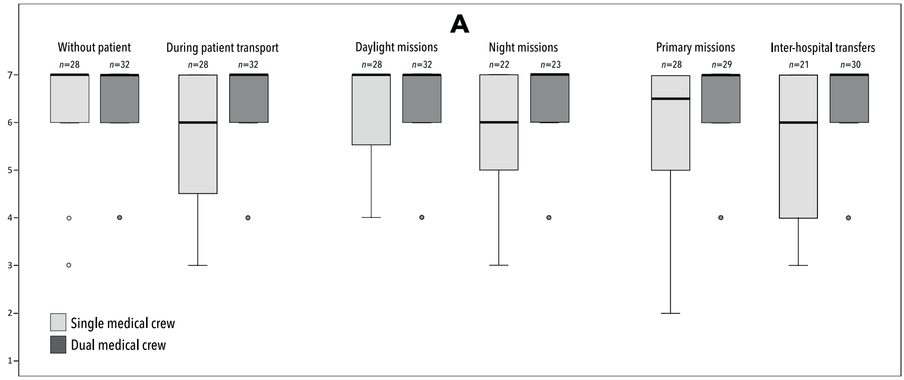

Figure 9: Respondents' perceived flight safety in Helicopter Emergency Medical Service (HEMS) missions for single and dual medical crews, rated from 'Totally unacceptable' (1) to 'Perfectly acceptable' (7).

5.1.4 Reasons for choice of crew concept

The most common reasons for choosing the current medical crew concept were tradition and scientific evidence, followed by aircraft configuration, company politics, and economy. Reasons for choosing a single crew were most commonly tradition and aircraft configuration. Scientific evidence was a more frequent reason for choosing a dual medical crew than a single medical crew, but surprisingly, also for having a crew without a physician. Economy was typically given as a reason for choosing a single crew model but not for omitting the physician.

5.1.5 Optimal crew configuration

When asked what the medical directors considered to be the optimal medical crew configuration if allowed to choose freely, nine of 25 systems with a physician as the single medical crewmember would have preferred to add an assistant to the crew, and 6 of the 15 systems without a physician in their crew would have preferred to have one.

5.1.6 Conclusion

HEMS crews with a dual medical crew scored highest in perceived patient safety among medical directors. Various staffing models are used with a wide range of education and competencies. The rationale behind different medical crew concepts was mainly founded on tradition and scientific evidence and not economy. Future studies must confirm whether these perceived patient safety challenges are quantifiable and relevant to all HEMS missions.

5.2 Summary of Study II

Non-technical skills (NTS) such as teamwork, leadership, and communication may affect the quality of care in emergency medicine, but systematic training in and assessment of NTS in HEMS has gained little attention and research in HEMS is still sparse.

This study was a follow-up of a previous survey of the level of training and assessment of NTS among Norwegian HEMS Crew Members (HCM), pilots, and physicians, and as such, both a cross-sectional and longitudinal study. For both studies, seven generic categories of NTS were used: decision-making, leadership, communication, situation awareness, teamwork, managing stress and coping with fatigue.

We included 109 responses in the study, yielding a response rate of 55.1%. Approximately half of the respondents were physicians. Three-fourths of the respondents had more than five years of HEMS experience.

Overall, the frequency of simulation-based training and assessment of NTS had increased significantly in Norwegian HEMS from 2011 to 2015. Although the physicians reported an increased training frequency in most NTS categories, they still train significantly less than flight operative personnel. Despite similar findings in the previous study of limited fatigue training, no significant increase for the category *coping with fatigue* was found for any professional group. The frequency of assessment was generally lower than the training frequency for all groups. Based on this study, systematic assessment of NTS, including *fatigue management*, should be a future focus area in HEMS.

5.3 Summary of Study III

Eight physicians from four HEMS bases with a median of 11 years of HEMS background were included as informants in an interview study regarding their perceived areas of compromised patient safety and experiences with incident reporting. Two main categories emerged from the interviews: *"Learning from mistakes"* and "*Managing the risk"*.

5.3.1 Learning from mistakes

For the physicians, the threshold for defining a prehospital incident as an error seemed higher than for their in-hospital work. They justified this lack of consistency by HEMS missions' unpredictable and demanding nature, which are less suitable for standardised procedures. Written reports were mainly due to technical failure or medication errors, but overall, the physicians preferred informal reporting to a colleague rather than to a superior. Formal reporting systems were perceived as cumbersome and seldom provided feedback. Although none had experienced it, fear of consequences was still an objection to reporting for the physicians.

5.3.2 Managing the risk

The team leader role was considered essential for the HEMS physicians. The demanding conditions at the scene could challenge decision-making and lead to over- and under-triage. The size and interior of the helicopter could limit access to the patient. Rear loading and unloading increased the likelihood of dislocating cannulas and tubes. The lack of an assistant during flight made intervening more complex and increased the possibility of medication errors. If intervention en route to the hospital could be expected, transport by ground was often chosen, even if transport duration was prolonged. Checklists were perceived as helpful if restricted to complicated or seldom-performed procedures.

The physicians highlighted the potential for incidents during the handover process. They emphasised standardising equipment and medication protocols between HEMS and retrieving and receiving hospitals to enhance patient safety during the transition of care. The lack of mutual understanding of prehospital working conditions was perceived as a hindrance to the transfer of information.

5.3.3 Conclusion

The HEMS physicians in this study preferred informal incident reporting to colleagues due to ease of use, better feedback, and less fear of personal consequences. The limited incident reporting was explained by the scarcity of procedures and the inherent unpredictability of HEMS missions. The team leader role and the handover process were underlined as challenging. Other areas of concern were helicopter cabin size, rear loading, and the lack of an assistant.

6 Discussion

WHO has described *patient safety* as "a framework of organised activities that creates *cultures, processes, procedures, behaviours, technologies and environments* in healthcare that consistently and sustainably lower risks, reduce the occurrence of avoidable harm, make errors less likely and reduce the impact of harm when it does occur."[9] Based on this definition and the findings in our three studies, the factors that influence patient safety in HEMS include the competence and composition of the crew, the use of procedures and checklists, the reporting culture, non-technical skills such as teamwork, leadership and communication in addition to the helicopter as a work platform and flight safety per se.

6.1 The helicopter as a workplace

In Study 1, cabin size was the most frequent limitation by the helicopters, as reported by the medical directors, with Airbus EC135 and Leonardo AW109 dominating. This result was not included in the original paper but published as a meeting abstract.[93]

In Study 3, all informants highlighted the importance of the configuration and size of the helicopter. Limited access to the patient and equipment made intervening difficult should the patient deteriorate. Loading and unloading of the patient through the helicopter's rear increased the possibility of accidental extubation or cannula dislocating compared to side loading and unloading.

Optimising working conditions when caring for a patient in a critical condition is essential, and intubation is regarded as a crucial intervention. An early study found intubation in Eurocopter AS365N2 Dauphin to be more time-consuming than in Eurocopter BK117 due to the cabin configuration.[94] McHenry et al. found rapid sequence intubation (RSI) feasible in the Leonardo AW169 in a simulated setting on-ground.[95] A single-centre retrospective Japanese study showed the same success rate for on-ground as for in-flight intubation in Airbus EC135.[96]

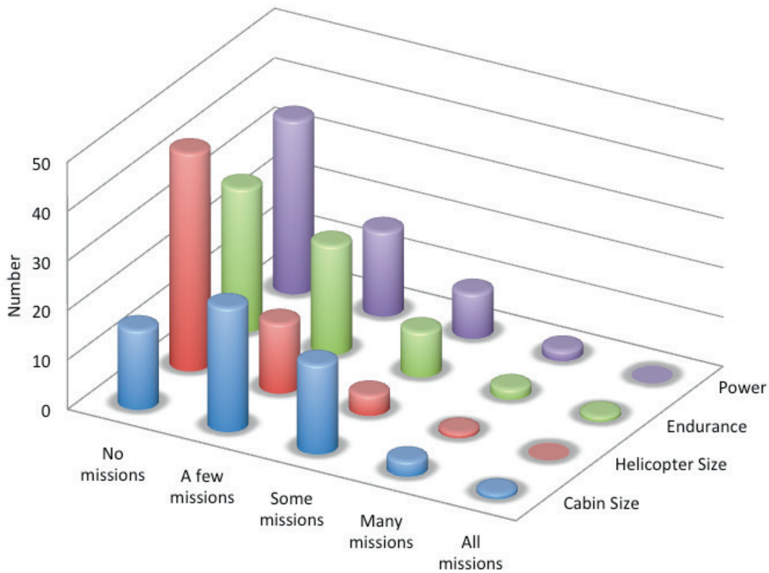

Figure 10: Factors possibly affecting medical care and perceived degree of influence. Results from Study 1 - Published as meeting abstract.[93]

To summarise, smaller helicopters, more than larger ones, challenge the possibility of intervention. However, a prerequisite for all helicopters is an ergonomic interior design that facilitates patient access and treatment. Thus, the opinion of the medical crew must be given significant weight when introducing new helicopters and interiors. In such a process, a standardised protocol could be beneficial when comparing, for instance, intubation feasibility in different helicopter types.

6.2 Medical staffing

According to the WHO definition, the acceptable minimum of patient safety depends on the context and available resources.[41] The medical staffing must, therefore, be adapted to the mission profile and the healthcare needs in the area it serves, which raises two topics of discussion: What competence is required, and is there a need for more than one medical provider for patient transport?

6.2.1 Education and competence

Numerous educations, certifications and combinations were reported regarding medical personnel in Study 1. Anaesthesiology, emergency medicine, intensive care medicine, surgery, and internal medicine were represented among the group of physicians. Both board-certified specialists and in-training physicians were serving, and many services employed physicians from multiple specialities.

The majority of nurses were certified as flight, emergency, or critical care nurses. HEMS crew members (HCM) were either trained as nurses, emergency medical technicians (EMT) or paramedics, and some nurses, for instance, were also certified paramedics. For some services, the number of medical care providers also depended on flight operative conditions.

Services without physicians were mostly dual crews with a nurse and a paramedic, two nurses or two paramedics. Earlier studies have found these models to be broadly equivalent.[97] However, as our study shows, comparing staffing models when each occupational group's education and training varies to such a degree has presumably limited scientific significance. Thus, research on medical staffing may have compared "apples and oranges",[98] and future research needs to define education unambiguously to compare staffing models.

6.2.2 Is there a doctor on board?

Physicians as part of the crew are common in Europe, Japan and Australia but rare in North America, as our first study confirmed. The medical directors of physician-manned services did not evaluate patient safety higher than others. Nevertheless, 6 of the 15 services without a physician in the crew would have preferred one if allowed to choose freely, and only one would have omitted the physician. As previously pointed out, the group of HEMS physicians is not uniform regarding education and competence. However, the numbers in this study were too low to compare subgroups of the physicians.

Two early studies have compared crews with and without physician for patients with blunt trauma. In 1987, Baxt and Moody randomised blunt trauma response between two treatment teams trained in the same procedures, either an emergency physician/nurse or a paramedic/nurse team, with lower mortality in the physician group.[99] A decade later, Garner et al. compared HEMS staffed with either physician/paramedic or paramedic/paramedic and found higher rates of advanced procedures and lower mortality in the physician group.[100] Other studies have failed to demonstrate the same positive effect on mortality in trauma patients[97,101] or in a mixed population of patients.[102,103]

In their article, Wirtz et al. summarised results published from 1984 to 1998, with seven studies speaking in favour of physicians as part of the HEMS crew and nine studies indicating no benefit.[97] A literature review from 2004 included 12 papers comparing physician versus paramedic HEMS teams, with 10 papers showing a survival benefit for prehospital trauma patients treated by physicians and two articles with no difference.[104]

Even though research suggests the benefit of a physician in various aspects of the treatment of critically ill or injured patients,[105] studies have often emphasised advanced airway management skills as the most important factor,[106,107] and the reason for better outcomes by physician-led services.[108] A systematic review by Bossers et al. found a twofold rise in mortality for prehospital patients intubated by providers with limited training in airway management.[109] Although studies have demonstrated acceptable success rates in prehospital intubation for nurse anaesthetists and critical care paramedics,[110,111] most seem to conclude that intubation is safer "in the context of a physician-based prehospital care system"[112] as physicians overall have a higher success rate than other EMS providers.[113]

Baxt and Moody concluded that the lower mortality in their study was due to the clinical judgement from the physicians rather than the procedural capacity.[99] Snow et al. named both judgement and skills as factors,[114] and Rhee et al. found judgement to be the most significant contribution from the physicians.[115] Timmermann et al. endorse that critically ill patients would benefit from a physician's skills in "advanced airway management or invasive procedures, well-directed fluid management and pharmacotherapy as well as diagnostic-based decisions".[116] Sollid and Rehn advocate that the focus should not be on an isolated factor but on the combination of many advanced life support skills, such as airway management, haemorrhage control, pain management and point-of-care diagnostics, together with the ability to perform complex inter-hospital transports and advanced interventions and that this is a set of skills that fits like a glove for anaesthesiologists.[117]

6.2.3 Do you need a hand?

In Study 3, the situations highlighted as challenging without an assistant were double-checking medication, patients needing intervention or becoming agitated, or when multiple tasks are required simultaneously.

Crews with two medical providers scored significantly higher on perceived patient safety in Study 1, compared to single crews on both daylight and a night mission, whereas the differences with or without a physician were negligible.

Single medical crews also scored lower on perceived flight safety for flights with patients. In the paper, we discussed if an explanation of the positive effect on flight safety might be higher vigilance and the possibility of better distributing the workload in dual crews under demanding flying conditions.

The effect of independent double control of medication is not unambiguous.[118] From the in-hospital setting, an association between healthcare provider-patient ratio and mortality is shown.[119] Still, studies on staffing level and outcome in inter-hospital transports are sparse, and published guidelines are based mainly on consensus between experts in the field.[120-125] According to these, a standard recommendation is a medical transport team of two or more to accompany a neonatal, paediatric or critically ill patient. However, the guidelines regarding the medical education of the team members are not unambiguous.

Patient deterioration is a leading contributor to adverse events,[126] but the lack of an assistant and the limited access to patients in the smallest helicopters in use make intervening in-flight demanding. The options in these situations are to do expected interventions at the scene prior to flight or use ground transportation as suggested by the HEMS physicians in Study 3. Both alternatives would most often prolong the time to definitive care, which is shown to be unfavourable for trauma patients and medical patients with stroke or myocardial infarction.[127,128]

Although patient-related factors do not explain all variation in on-scene time,[129] endotracheal intubation alone is shown to increase the on-scene time by 10 minutes,[128,130] and other interventions also contribute to prolonged on-scene time.[131] Prehospital intubation is associated with adverse events, not only in untrained professionals. In a systematic review, Fevang et al.[132] found higher mortality rates for patients intubated prehospital than in the emergency department. Thus, they questioned a broad and unspecific indication for intubation as a precaution prior to transport.

Physicians tend to perform more on-scene interventions than non-physicians.[100,133] However, more emphasis is needed on which prehospital interventions are beneficial or not,[134,135] and the system-related factors contributing to the variation in on-scene time.[129]

6.2.4 The choice of medical crew

The diversity of answers to the questions of competence and the number of medical providers among the many HEMS services worldwide is interesting. Many air ambulance services have had the same medical crew composition for 20-30 years. In Study 1, we explored the rationale behind the choice of crew by asking the medical directors for their arguments for choosing the present medical staffing.

Overall, *tradition* and *scientific evidence* were the most common reasons given for the present model, followed by *aircraft configuration*, *company politics* and *economics*. *Scientific evidence* was the most prominent argument for a crew without a physician but only the fifth most used in favour of a physician in the crew. *Tradition* was a common argument for both crews with and without a doctor, but *economy* was not a prominent explanation for crews without physicians. The most reported reasons for single crews were *tradition* and *aircraft configuration*, whereas *scientific evidence* was by far the argument mostly used for a *dual crew*.

When asked about the preferred crew model, nine of the 25 systems with the physician as the only medical provider would add an assistant, and six of the 15 services without a physician in the crew would have preferred one if allowed to choose freely. Only one service would omit the doctor. Eleven of 28 single-crew services would change to dual-crew.

6.2.5 And the answer is?

In the early military helicopter medevac, patients were transported without monitoring or accompanying medical personnel. Today, depending on staffing and competence, HEMS have the potential for advanced treatment options if needed.[13] Most services today have a mix of missions ranging from merely transportation to advanced lifesaving measures.[116] However, the level of care must be tailored to the group of patients with the highest benefit in terms of life years gained.[136,137] For inter-hospital transport, HEMS should offer the same quality of care and safety as in-hospital treatment despite the challenging transport environment.[138,139] To achieve this, both the helicopter cabin and the staffing must ensure the feasibility of in-flight treatment.[131,140-143]

In the Norwegian model, the HCM is the pilot's assistant during the flight, and the physician is the only medical provider. If needed, the HCM can be omitted as the pilot's assistant. This "hybrid" model is cost-effective but limited to daylight and good flying conditions. Using ad hoc personnel as an alternative to assist in such situations increases the risk of adverse events,[13] but should also be weighed against an impact on flight safety.

In a literature review, Masterson et al. found the quality of the present study too poor to draw conclusions and promote the need for trial-based studies between different HEMS crews with different competencies and qualifications.[144] The question of the optimal configuration of the medical helicopter crew is, thus, still under debate.[2,13,145] However, studies seem to demonstrate that physician-staffed HEMS is superior to or at least on par with a crew with a certified nurse, and patient safety in a dedicated dual crew is, based on our studies, evaluated as superior to a single crew. If a recommendation were to be given based on these studies, it would be to staff the helicopters with a physician educated in anaesthesiology or emergency medicine and a dedicated medical assistant on all missions.

6.3 Non-technical skills

Human factors contribute up to 80% of accidents in some sectors.[83] In Study 3, the HEMS physicians discussed how teamwork, leadership, communication, situation awareness, and decision-making could affect patient care. In addition to managing stress and coping with fatigue, these qualities are what Flin et al. refer to as the social and cognitive skills that complement the workers' technical skills and, thus, are known as *non-technical skills (NTS)*.[83] The level of training and assessment of Norwegian HEMS professionals' NTS was explored in Study 2.

6.3.1 Working as a team

The team leader role was considered essential for the physicians in Study 3. For the informants, encouraging input, assigning tasks, giving clear instructions and ensuring that all team members have the same understanding of the situation was considered necessary for good teamwork, leadership and communication.

Although still less than flight operative personnel, Study 2 showed a significantly increased frequency of NTS training in decision-making, leadership, situation awareness and managing stress for the Norwegian HEMS physicians from the previous study of Abrahamsen et al.[82]

Team training and simulation can enhance non-technical skills.[146] In healthcare, emergency departments and operating theatres are areas for interdisciplinary cooperation, and training is essential.[147–150] Neily et al. found a 2.5-fold reduction in surgical mortality in the facilities participating in a formalised medical team training program for operating room personnel compared to other.[151]

Simulation-based team training is a safe and effective method to enhance non-technical skills in anaesthesia and trauma teams.[152,153] "Better and Systematic Trauma Care"[154] has shown an effective way of implementing a system for enhanced cooperation in multi-professional teams in Norwegian emergency departments.[155] Although this is developed for intra-hospital purposes, the philosophy also applies to the pre-hospital scene, and Bredmose et al. have shown that in-situ simulation is feasible even for on-call crews on busy HEMS-bases.[156]

6.3.2 Coping with fatigue

A central result in Study 2 was that the training frequency for *coping with fatigue* had not increased for any of the professional groups despite the findings and recommendations from the previous study.[82] It may seem as if medical staff underestimate the impact of fatigue on performance,[157] although fatigue is shown to degrade non-technical skills by air medical clinicians.[158]

Some studies on sleep quality and sleepiness by HEMS workers have been published.[159–162] However, the measurement of fatigue is challenging.[163] In a systematic review, Barger et al. found fatigue training to improve safety and health outcomes.[164] In a recent study of HEMS physicians and paramedics, vigilance declined over the shift cycle, and Rose et al. recommended fatigue monitoring on a day-to-day basis and fatigue awareness to be a part of the daily safety brief.[165]

6.3.3 Assessment of NTS

Another key finding from Study 2 was the lower frequency of assessment of NTS compared to the training frequency. *Assessment* is the process of evaluating the skills of individuals and teams. Assessment can also be used to evaluate training programs.[83] Thus, it can be argued that training should not be considered complete without a corresponding assessment.

Based on the *Anaesthetists' Non-Technical Skills* (ANTS) framework, Myers et al. have developed the AeroNOTS, the *Aeromedical Non-Technical Skills*, as a behavioural rating tool.[166] AeroNOTS has not fully been validated but has been tested on Norwegian HEMS in a Master's thesis.[167] Further studies are needed regarding the validity and feasibility of behavioural marker tools for HEMS.

6.4 Procedures and checklists

The Norwegian HEMS physicians in Study 3 found checklists and procedures a double-edged sword. First and foremost, the unpredictable nature of HEMS missions was challenging to describe in procedural form. Secondly, procedures and checklists were perceived as helpful in some situations but too time-consuming in others. For the physicians, a prerequisite for using checklists was that they needed to be short and only for procedures seldom performed.

The World Health Organization initiated the campaign "Safe Surgery Saves Lives" in 2009 in order to reduce avoidable complications after surgery.[168] An important issue for this campaign is the implementation of a *Surgical Safety Checklist*. Part of the positive effect of checklists is thought to be better communication between the team members.[169,170] Even though checklists are mandatory in aviation, their use in patient care in HEMS is still discussed.[139,171,172] The future may be electronic cognitive aids, which have been found to enhance adherence to standard of care in simulated scenarios.[173]

6.5 Transition of care

The handover process is an arena of collaboration with others to which the informants in Study 3 gave specific attention. The physicians pointed at communication during patient handover as challenging, both at the referring and receiving hospital, with the potential of missing vital information. Mutual understanding between the transport crew and hospital crew of one another's challenges and the use of a common language and structure in the report was emphasised as essential. Another essential source of error was not having the same equipment and medication protocols as referring and receiving hospitals. Thus, the physicians regarded procedures and protocols standard with collaborating services as a great advantage.

6.6 "The problem with incident reporting"

Study 3 showed that a clear difference in reporting culture existed between the flight operator and healthcare regarding their understanding of a reportable event and their general perception of formal incident reporting. For the HEMS physicians, the three main reasons for not writing formal reports were:

The nature of HEMS missions: Reports were mostly relevant when deviating from procedures. However, on a HEMS mission, information is often limited, and the circumstances are challenging, which makes missions unpredictable and difficult to describe in a procedural form. Incidents were, thus, often not perceived as errors, even when decisions made during the mission, in retrospect, turned out to be wrong.

The incident reporting systems of the health trusts were perceived as cumbersome, with no option for sharing with and learning from other bases. The physicians seldom experienced that their reports resulted in feedback or improvement initiatives.

Fear of retaliation: Even though no one reported to have experienced it, the fear of retaliation still seemed to be an obstacle to formal reporting.

The psychologist Carl Macrae summarised many of the challenges with incident reporting in improving healthcare quality in an article from which the title of this section is taken.[174] A key message was that "fundamental aspects of successful incident reporting systems are misunderstood, misapplied or entirely missed in healthcare." The IOM report strongly emphasised that errors can be prevented and highlighted learning from mistakes and raising standards as key factors.[5] The NHS report underlined the organisational culture and the reporting systems as barriers to healthcare to gain knowledge about failures and learn from them.[8]

According to Liam Donaldson, chairman of the NHS Expert Committee behind the report, a prerequisite to succeed is a reporting culture without fear of retribution.[175] Kapur et al. have compared features of aviation with implications for patient safety in a review.[176] A higher willingness to produce reports and documentation, even of near-misses, in a blame-free environment was highlighted as an example to be adopted by healthcare. The past experiences of searching for scapegoats in the healthcare system were deeply rooted in the physicians in Study 3. In order to make incident reporting a better tool for patient safety in HEMS, this perception needs to be altered.

6.7 Categorisation of the results

This thesis aimed to explore the impact of organisational factors, non-technical skills and the safety culture of medical personnel on patient safety in HEMS. Some of the findings above can easily fit into a single of these three categories, such as the choice of helicopter and medical staffing, which are organisational decisions. Others, like teamwork and fatigue management, are non-technical skills but depend on organisational measures. The use of incident reporting relies on a well-functioning reporting system from the organisation but also on the threshold for reporting, which is a safety culture issue. The interpretation of the results, to answer what initiatives to prioritise, a categorisation of the areas that have emerged from the three studies after the effectiveness of correcting actions seems, will be provided in Chapter 7.

6.8 Limitations and trustworthiness

The limitations of the individual studies will not be discussed in full here as they are in the published papers. However, some of their aspects are also relevant to the thesis. The results in this thesis are discussed in a qualitative context, and limitations will, thus, be closely linked to the principles of trustworthiness in qualitative studies.

6.8.1 Limitations

In Study 1, we used *the perception of safety*, a subjective assessment measured on a Likert scale, which should be interpreted cautiously. However, we believe medical directors would not respond unfavourably on behalf of their service. In Study 2, personnel who had undergone training might have been more likely to respond, which could result in a non-responder bias.

Malterud points to the challenge of admitting errors when being interviewed by a colleague or peer.[177] In Study 3, the physicians were encouraged to talk about incidents and errors they had experienced. We assume that this would rather have led to under-reporting than the opposite and that the conclusions in that paper are not overstated.

As we could not contact many of the intended respondents directly, we could not follow up with non-responders as desired or calculate a response rate in the international study. In Study 3, only a limited number of informants were included. However, these were recruited by purposeful sampling from services with different helicopters, staffing models and incident reporting systems. Hence, we do not regard this as a limitation.

6.8.2 Trustworthiness

The parallel to trustworthiness in quantitative research is validity and reliability.[178] Lincoln and Guba clarified trustworthiness with four criteria: Credibility, transferability, dependability, and confirmability.[179] *Credibility* is the analogy to internal validity in quantitative research and whether the findings make sense to the readers. *Transferability* equals the quantitative generalizability and external validity. A well-documented research process ensures *dependability*, and how conclusions have been reached provides *confirmability*.[178]

Credibility

Credibility can be enhanced by methodological triangulation or by data or investigator triangulation. Although different methods were used for this thesis to evaluate patient safety in HEMS, we believe this is not proper triangulation. However, the approaches and perspectives to the topic and the prolonged engagement support credibility.

Transferability

With the philosophical foundation of qualitative research and the idea that "knowledge is generated through interaction and interpretation", as discussed previously, the researcher plays a more active role in the research process than in quantitative research, both in the role of interviewer, in the analysis, and in the interpretation, hence, repeating a qualitative study with a different researcher in another context will not lead to the same outcome.[180] In Study 1 and Study 3, were performed in different settings, international medical directors vs. Norwegian HEMS physicians. However, we found supporting results in the overlapping themes in both studies, which could indicate that these patient safety challenges are general in HEMS. The sparse yet existent international literature on this area also supports this assumption.

Dependability

Stahl and King called dependability the *"trust in trustworthy"*.[180] Peer reviewing, both in the initial phase and in the publishing process, and acknowledging but also disclosing researcher influence in qualitative research contribute to dependability. My experiences as a former HEMS physician have motivated and guided the design of the individual studies and this thesis. This backpack of preconceptions and presumptions, as Malterud names it, can be a burden or an inspiration.[177] In Study 3, as an example, it helps in taking the insider's view and facilitates follow-up questions. To balance my preconceived assumptions, I have had co-authors and supervisors with different backgrounds, and for the thesis, I have used publicly acknowledged patient safety literature and methods in the analysis and interpretation.

Confirmability

Confirmability, the last aspect of trustworthiness, is often understood as objectivity.[180] By using predefined themes from patient safety literature and interpretation of the results with recognised tools in this thesis, we hope to have demonstrated how the conclusions of this thesis have been reached and get as close to objective reality as achievable.

7 Summary and recommendations

7.1 Summary of findings

Two main categories arose from the three studies: firstly, the HEMS operator's choice of helicopter, medical equipment and staffing, and secondly, how the medical crew themselves execute their tasks day-to-day. This duality corresponds to the latent risks and active failures and, thus, to the correlating system- and individual-based responsibility in Reason's work. As discussed earlier, these categories are not rigorously defined, and by many person-based failures, organisational factors contribute. A more didactic approach to preventive actions would, thus, be a tripartite division as used in root cause analysis where measures are categorised as *stronger, intermediate* and *weaker actions*.[56,57] In short, weaker actions rely on humans to perform the task correctly, while stronger actions, on the other hand, are based on architectural or physical changes. The intermediate actions in between rely on combined human and technological changes. Strong actions correlate to Reason's hard defences, and weak actions to soft defences.[53]

This summary will use the corresponding terms *least effective*, *moderately effective* and *most effective* as used ISMP.[58] When categorising effectiveness, the examples in the Action Hierarchy Tool from the Institute of Healthcare Improvement,[57] and the *"Risk and Incident Analysis – Handbook for the Health Service"* by the Norwegian Board of Health Supervision[47] are used as guidance. Based on these findings from this study are categorised according to Table 7.

7.2 Recommendations

7.2.1 The helicopter

A modern HEMS helicopter is not only a mode of transportation but also an arena for patient observation and treatment. Access to the patient and the medical equipment for the medical crew during loading and flight is crucial. In our studies, it seemed to be a common opinion between the medical directors and HEMS physicians that the smallest helicopters do not provide for this well enough. By the choice of helicopter and cabin configuration, the medical personnel's opinion should, thus, be given great weight.

7.2.2 The medical crew

It has been argued that critical care nurses or specially trained paramedics have sufficient medical competence in HEMS. However, despite the continued lack of scientific evidence, there are few arguments against using physicians in the crew, especially consultants in anaesthesiology or emergency medicine, with the proper prehospital training combined with intra-hospital work.

In addition to the competence, the number of medical providers has also been highlighted as possibly affecting patient safety in HEMS. Researchers have argued that HEMS, by inter-hospital transfer, should ensure a continuum of the level of care from referring to receiving facility for neonatal, paediatric and intensive care patients, and recent research is focusing on the feasibility of in-cabin treatment such as airway management to shorten time to definitive care. The number of medical providers should, thus, reflect the mission profile and the expected risk of critical incidents during transport.

Table 7: Hierarchy of effectiveness

Most effective	
Helicopter cabin size and ergonomics	
Access to patient and equipment	Design of the interior and placement of equipment that facilitates monitoring and treatment. Must allow access and sufficient space for critical care interventions during flight.
Helicopter loading	
Preferably side loading	Easy overview and access during loading/unloading. Low risk of dislocating tubes and cannulas.
Medical competence	
Competence based on mission profile	Preferably physician, consultant in anaesthesiology or emergency medicine, combined with in-hospital service.
Medical crew	
Configuration based on mission profile	According to applicable neonatal/paediatric/critical care standards. Allowing unchanged level of medical care during inter-hospitals transports and facilitate critical care interventions in-flight.
Standardised medical equipment	
Standardisation of equipment with hospitals/ambulances	Safer handover when HEMS and hospitals/ ambulances use the same medical equipment.
Standardised medication protocols	
Standardisation of medication protocols for syringe pumps	Safer handover when HEMS and hospitals use the same medication protocols

Table 7 cont.: Hierarchy of effectiveness

Moderately effective	
Checklists and procedures	
For selected procedures	Must be brief and for complicated and seldom performed procedures. Less effective if optional to use.
Incident reporting system	
User experience	Must be easy to use and provide feedback within reasonable time and experienced as a tool for improvement.
Anonymity	Fear of retaliation must not prevent reporting.
National	Comprehensive overview and easy sharing between bases.
Handover process	
Standardised procedure and communication	Training together with personnel from receiving facility.
Team training	
Include NTS training and assessment	If standardised and mandatory with assessment of communication and leadership.

Least effective	
Double control of medication	
Independent calculations	Requires familiarity with procedures, less likely to achieve with ad hoc personnel
Fatigue training	
Training in how to cope with fatigue	

7.2.3 Transition of care

As in our study, the handover process has been highlighted as a critical phase in the literature. Mutual understanding, standardised reporting, and joint training with cooperating units are needed to ensure the transition of information. According to the Norwegian HEMS physicians, this was virtually non-existent. Standardised equipment and medical protocols were also largely missing. As far as practically possible, medical equipment such as syringe pumps, ventilators and defibrillators should be equivalent to the local ground EMS service and hospitals, but different tendering and procurement arrangements challenge this. A simple and easier-to-implement but efficient measure is coordinating treatment protocols with local hospitals, e.g., using the same vasoactive infusions.

7.2.4 Procedures and checklists

The ambiguous view on checklists and procedures reported in our interview study may well reflect an inherent scepticism among physicians compared to other healthcare providers. Introducing such without them being perceived as useful will not have an effect. As earlier pointed out, a requirement is that checklists are brief and restricted to seldom-performed procedures. If perceived as valuable, mandatory use will probably be possible, increasing the effect.

7.2.5 Non-technical skills

The influence of non-technical skills (NTS) has presumably not received the same attention as equipment and technical skills for patient outcomes. However, decision-making, leadership, communication, situational awareness, teamwork, fatigue and stress management may affect team performance. The HEMS physicians are mostly aware of these factors, but their training in these skills, although increasing, is still not on par with the pilots', and the influence of fatigue seems underrated in all professional groups. A systematic and mandatory NTS training, including assessment, for HEMS crews seems appropriate.

7.2.6 Incident reporting

The basis for improving patient safety is knowledge of the nature and extent of adverse events. One prerequisite for achieving this is a well-functioning reporting system, which seems not to be in place in the Norwegian HEMS services. Another measure is to challenge the higher threshold for considering something as an error in the prehospital area, which was explained by the unpredictable nature of the missions. Medical personnel need to adopt the reporting culture of the pilots with its low-threshold improvement reports and non-punitive nature. Achieving this requires presumably connecting medical and operative incident reporting systems. Developing this as a national system increases the potential for mutual learning across bases.

7.3 Responsibility and effectiveness of actions

The most effective actions relate to the choice of helicopter, staffing and equipment. These are organisational and system-based decisions independent of the individual medical provider. Moderately effective actions combine technological changes with individual actions and are, thus, partially system-based and person-based. The organisation produces checklists, procedures and incident reporting systems, but their use depends on individual decisions. The least effective actions depend on the individual HEMS provider, even though the organisation, in most cases, also facilitates and sets training programme requirements.

All the recommended actions above are partially or entirely an organisational responsibility with a relatively high degree of effectiveness. The right helicopter and medical crew are the most effective actions. The handover process is an important arena for cooperation with hospitals, and both the very effective standardisation of equipment and medical protocols and the moderately effective standardisation of communication and joint training with the emergency departments should be implemented. Non-technical skill training is moderate to less effective but needed, according to our studies, particularly in communication, leadership, and coping with fatigue.

As Kellogg et al.[54] demonstrated, organisations tend to implement less expensive measures, despite their lower impact, aimed at human behaviour instead of system-based, technological changes with higher cost but also high effectiveness. HEMS is undoubtedly a high-cost medical service. Nevertheless, this can not be used to justify implementing low-cost but less effective measures for improving patient safety.

8 Conclusion

Research-based knowledge regarding prehospital patient safety is limited due to methodological limitations in prehospital research and a high threshold for incident reporting. To achieve a more comprehensive overview of risks, medical HEMS personnel must adopt the reporting culture of the flight operators, which is best achieved by a national anonymised incident reporting system, where near misses, as well as errors, are reported and shared between bases and used for improvement initiatives.

The choice of helicopter and staffing must be tailored to the mission profile. According to our studies, the cabin size and interior design may affect patient safety if safe loading and unloading are compromised and critical care interventions during a flight are not facilitated. The lack of a medical assistant may increase the risk of medication errors or result in delayed transport or refraining from taking life-saving measures during transport. Not having standardised medical equipment and, in particular, medication protocols with cooperating services and facilities increase the likelihood of error during handover. Additionally, a lack of training in non-technical skills such as communication, team leadership and coping with fatigue could affect medical care for HEMS patients.

To enhance patient safety in HEMS, organisational and system-based measures with high effectiveness should be prioritised, preferably at a national level. The choice of helicopter and staffing must correspond to the mission profile of each service. Medical equipment, protocols and the handover process itself should be standardised with the local hospitals. Mandatory training and assessment of non-technical skills with behavioural marker tools for the entire crew are recommended.

9 Future research

This study has raised several future research areas regarding helicopters, staffing, non-technical skills training, and safety culture.

The overall question of whether the physician is needed in HEMS is unresolved. Most studies compare intubation success rates of different professional groups without any agreement on what an adequate level is. Even though crucial, the intubation success rate is a simplification of the physician's influence on patient care, and future staffing-research should use a broader scope. It could, however, be questioned if further research will provide the final piece of this puzzle, given the methodological limitation in prehospital research.[65]

The growing focus on critical care interventions during flight to minimise time to definitive care makes feasibility studies with different helicopters and crew configurations more relevant. Both comparisons between single and dual crews and fixed versus ad hoc crews are research topics of interest. Are the perceived patient safety challenges related to crew in Study 1 quantifiable, and to what types of HEMS missions? Such studies are well suited for a simulated setting.

Behavioural marker tools for assessment of non-technical skills training, such as AeroNOTS, need to be fully validated for HEMS, and their effects on medical crews must be investigated. The effect of fatigue on clinical performance should be given specific scientific attention. The same principles for NTS training and assessment and research on performance should be applied to the handover process in the emergency departments.

HEMS safety culture should be studied with the prehospital version of the Hospital Survey On Patient Safety Culture.[64] Additionally, the incident reporting culture of HEMS physicians needs investigating, particularly the contextual factors behind the statement from Study 3 that incidents in prehospital care are "part of the normal and expected variation".

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Original Research

Does Medical Staffing Influence Perceived Safety? An International Survey on Medical Crew Models in Helicopter Emergency Medical Services

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A B S T R A C T

Objective: The competence, composition, and number of crewmembers have generally been considered to influence the degree of patient care and safety in helicopter emergency medical services (HEMS), but evidence to support the advantages of one crew concept over another is ambiguous; additionally, the benefit of physicians as crewmembers is still highly debated.
Methods: To compare perceived safety in different medical crew models, we surveyed international HEMS medical directors regarding the types of crew compositions their system currently used and their supportive rationales and to evaluate patient and flight safety within their services.
Results: Perceived patient and flight safety is higher when HEMS is staffed with a dual medical crew in the cabin. Tradition and scientific evidence are the most common reasons for the choice of medical crew. Most respondents would rather retain their current crew configuration, but some would prefer to add a physician or supplement the physician with an assistant in the cabin.
Conclusion: Our survey shows a wide variety of medical staffing models in HEMS and indicates that these differences are mainly related to medical competencies and the availability of an assistant in the medical cabin. The responses suggest that differences in medical staffing influence perceived flight and patient safety.

Despite new treatment modalities in prehospital critical care,[1] the medical staffing model in helicopter emergency medical services (HEMS) has remained largely unchanged in many systems over the last 40 years. Additionally, the heterogeneity in medical staffing in HEMS is large, and systems with similar mission profiles may have very different medical crew compositions.[2-6]

Patient safety is the prevention of errors and adverse effects to patients associated with health care.[7] Transporting critically ill patients involves a significant risk of adverse events.[8] Although the number of reported incidents in air medical transports is low,[9] the difference between the observed and self-rated performance of air ambulance clinicians may indicate that the problem is larger than the numbers reported.[10-12]

The competence, composition, and number of crewmembers may play a role in creating adequate redundancy in patient care to ensure patient safety, but supportive documentation regarding one crew configuration over another has thus far proven inconclusive. The benefit of including physicians in HEMS is highly debated.[13-15] Some studies have found that HEMS physicians contribute to improved survival,[16,17] whereas other studies showed no difference.[18] In trauma patients who were transported either with the combination of a flight nurse and a flight paramedic or with 2 flight nurses, the outcomes were also indistinguishable.[19] It has been suggested that it is the training and not the profession that is essential.[20,21]

The aim of this study was to describe the diversity of medical crew compositions currently used in HEMS and supportive

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rationales of these decisions. Our hypothesis is that the medical crew composition influences perceived patient and flight safety as reported by medical directors representing HEMS systems using different medical crew models.

Material and Methods

Questionnaire

Medical directors of HEMS in Europe, North America, Australia, New Zealand, and Japan were invited to participate in an HEMS Medical Crew Survey developed by 2 of the authors (K.R. and S.J.M.S.). This study region was chosen to include the entire spectrum of medical staffing models from well-established HEMS services. Before distribution, the questionnaire was tested on a number of HEMS professionals and revised according to their feedback. The Cronbach alpha for the 2 patient safety items and the 6 flight safety items was 0.943 and 0.952, respectively. The survey was distributed as a Web-based questionnaire (SurveyXact; Rambøll Management Consulting, Aarhus, Denmark).

To gather responses from a cross section of different crew models currently in use, participants were identified through the European HEMS and Air Ambulance Committee (EHAC), the European Prehospital Research Alliance (EUPHOREA), the Association of Critical Care Transport (ACCT), the Association of Air Medical Services (AAMS), the Aeromedical Society of Australasia (ASA) and the Emergency Medical Network of Helicopter and Hospital (HEM-Net). In North America, the invitations to participate in the survey were distributed through ACCT and AAMS, and in Japan through HEM-Net. In all other continents, the invitation was distributed directly. All invitations were sent via e-mail with a link creating a unique survey response. Two reminders were sent to all participants. All respondents were blinded to the researchers.

In the absence of a universally accepted definition of safety and a method of measuring the safety level, researchers in the oil industry have found "perception of risk" useful for understanding feelings of safety, attitudes to safety, risk-taking behavior, and accident involvement.[22,23] "Perception of flight safety" has been used as the primary outcome in HEMS research and was found to be significantly influenced by personal experience of a crash or serious incident.[24]

We asked the respondents to evaluate patient and flight safety during various mission types in their own service on a 7-point symmetric Likert scale, ranging from "totally unacceptable" (1), "unacceptable" (2), "slightly unacceptable" (3), and "neutral" (4) to "slightly acceptable" (5), "acceptable" (6), and "perfectly acceptable" (7).[25] Because we expected that medical directors respond favorably on their own systems as a sort of acquiescence bias or confirmation bias, negative or less positive scores were of interest because these responses probably represent a real negative attitude. This allowed us to dichotomize the responses and consider the difference between positive ratings ("acceptable" [6] or "perfectly acceptable" [7]) and less positive or negative ratings ("slightly acceptable" [5] or less) to be of particular clinical relevance.

To obtain the greatest degree of comparable data, respondents were asked to evaluate their program's flight and patient safety based on the regular crew configuration used to operate under similar and, in this survey, poor weather conditions. A definition of "poor weather" was not given because this varies according to each HEMS operator's procedures.

Approval

The study was approved by the Data Protection Official for Research, Norwegian Social Science Data Services, Bergen, Norway (date of approval: April 23, 2014, ref. no. 38659), and was exempt from ethical approval by the Regional Ethical Committee of Western Norway, Bergen, Norway (date of approval: April 20, 2014, ref. no. 2014/760).

Definitions and Classifications

"One service" in this study is defined as the number of HEMS bases for which 1 medical director is responsible. Many professional titles are based on different regional educational models and lack universally approved definitions. Thus, for the questionnaire, we provided definitions for all relevant professional groups that can be found in an HEMS crew. "Medical competence" in this survey is defined as formal education and not level of experience.

We decided to regard physicians as 1 group despite differences in specialty and competence among systems. Studies have shown that airway management proficiency is similar in systems with the 2 most predominant specialties of HEMS physicians—anesthesiologists and emergency physicians.[26-29]

Registered nurses were defined as nurses with a bachelor's degree or its equivalent and certified nurses as registered nurses with an additional certification examination. Nurse specialists, such as nurse anesthetists, intensive care nurses, and neonatal nurses, were defined as nurses with a college or a university education corresponding to a master's degree.

Emergency medical technicians (EMTs) and paramedics were defined and categorized according to their airway skills (ie, basic ["only supraglottic airway devices"], intermediate ["endotracheal intubation but not rapid sequence induction" (RSI)], and advanced ["endotracheal intubation including RSI" and "may use a mechanical ventilator"]). This categorization was chosen because airway control has the highest treatment priority in emergency medicine, is considered the single most important factor for good outcomes,[30,31] and contributes to paramedics' professional identity.[32]

In this study, crewmembers unavailable to assist the medical crew in patient treatment during flight were not included as part of the medical crew. Nurses and EMTs/paramedics with a combined role as a medical assistant and a pilot's assistant during flight and obliged to sit in the cockpit under normal flight operations were categorized as an HEMS crewmember (HCM).

Services with variable staffing were categorized according to the staffing variation with the lowest level of medical education; for example, a crew staffed intermittently by paramedics or nurses was classified as paramedic staffed. Similarly, additional medical personnel used by demand, most often a physician, perfusionist, respiratory therapist, nurse, or midwife, were not counted as part of the regular crew in our analysis.

For the safety analysis, we assigned the responses into 6 groups according to the common denominators of the crew configuration; services with a single medical provider were compared with those with a dual medical provider configuration, services without a physician were compared with services with a physician, and services with a physician working alone were compared with those with a physician working with a medical assistant.

Statistical Analysis

Dichotomous data are presented as counts and valid percents. Ordinal data are presented as medians and quartiles and visualized with box plots. Before analysis, we decided that a relevant break point was between "slightly acceptable" (5) and "acceptable" (6). Group differences of the Likert scale data dichotomized into the 2 groups Likert scale 1 to 5 and 6 to 7 were tested with the Fisher exact test using a significance level of $P \leq .05$. To our knowledge, no other studies exist with a comparable method or scale. We believe we have a good rationale behind the choice of break point and did not test others in search of significant results. All statistical analyses were performed using Microsoft Excel 2011 for Mac (Microsoft

Corporation, Redmond, WA) and SPSS Statistics for Mac (Version 22.0; IBM, Armonk, NY).

Results

The survey was open between June 1 and October 15, 2014. A total of 113 responses were commenced. Of these, 2 submissions did not represent HEMS, 21 were incomplete on all parts of the survey, and 24 were excluded because of missing data on the core elements of the survey (ie, crew composition and evaluation of the crew concept). The remaining 66 submissions were eligible for analysis (Fig. 1). Geographically, the majority of responses originated from Europe (17 from Scandinavia and 28 from the rest of Europe), with the remaining 21 from North America (17), Australia (3), and Japan (1). Each respondent represented from 1 to more than 10 HEMS bases. The participating services performed between 250 and 9,934 missions each in 2013, with a median of 1,007. The majority of services (84%) performed both primary missions (on-scene calls) and interhospital transfers; 11% performed only primary missions and 5% only transfers.

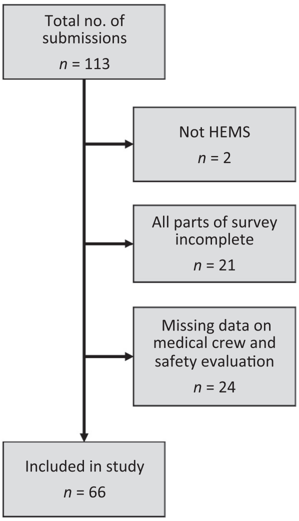

Figure 1. The inclusion flowchart.

Medical Personnel

Physicians were part of the crew in 48 services (73%), HCMs in 32 (48%), nurses in 31 (47%), EMTs/paramedics in 23 (35%), and a respiratory therapist in 2 (3%) services. Among the 48 services with physicians, 30 services (63%) used only board-certified specialists, whereas the remaining services also employed physicians-in-training. The most common specialty of the physicians was anesthesiology (85%) followed by emergency medicine (58%). Other specialties such as intensive care medicine, surgery, and internal medicine were less common. The majority of systems (60%) had physicians from multiple specialties in their crews, 27% had anesthesiologists only, 13% had emergency physicians only, and 10% had a combination of anesthesiologists and emergency physicians.

Of the 31 services with nurses, 25 (81%) required additional specialty training, most commonly as certified nurses. The most common certifications were certified flight nurse, certified emergency nurse, or certified critical care nurse (Table 1).

EMTs and paramedics were certified in advanced airway skills (RSI) in 13 (59%) of the 22 services responding to this question, intermediate skills (intubation but not RSI) in 6 services (27%), and basic airway skills (supraglottic airways only) in 3 services (14%) (Table 1). The medical training of the HCMs varied between training as a nurse in 13 services (41%) and EMTs or paramedics in 28 services (88%) (Table 1).

The respondents in this survey represented a variety of different medical staffing combinations. The 3 most common models were physician and HCM (38%), physician and nurse (20%), and nurse and EMT/paramedic (17%). Physicians were single medical care providers in 26 services and had assistants in 22 services. Nurses were single providers in 2 services and had assistants in 13 services.

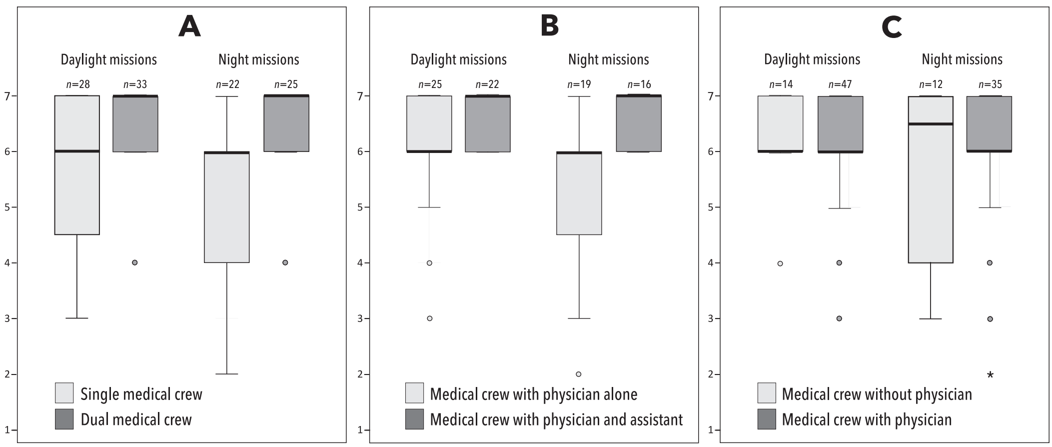

Figure 2. Respondents' perceived patient safety in HEMS daylight and night missions for (A) single and dual medical crews, (B) crews with a physician alone and a physician with a medical assistant, and (C) crews without and with a physician rated from "totally unacceptable" (1) to "perfectly acceptable" (7).

Table 1
The Distribution of Medical Training (Counts) for Nurses, Emergency Medical Technicians (EMTs)/Paramedics (PMs), and Helicopter Emergency Medical Service Crewmembers (HCMs)

Medical Training	Nurses' training (n = 31)	EMTs'/PMs' training (n = 23)	HCMs' training (n = 32)
Certified nurse	62		2
Nurse specialist	17		4
Registered nurse	6		7
EMT/PM with advanced airway skills		13	8
EMT/PM with intermediate airway skills		6	10
EMT/PM with basic airway skills		3	10

Advanced airway skills include rapid sequence intubation (RSI), intermediate airway skills include intubation but not RSI, and basic airway skills include the supraglottic airway only. The total number may exceed the number of services (n) because 1 service may have personnel with different training. One service with EMTs/PMs did not provide information on medical training.

Paramedic-led services were rare; only 2 used a paramedic alone, and 1 service operated with a paramedic and an assistant. Overall, 30 (45%) services had a single medical provider and 36 (55%) a dual medical crewmember configuration.

Evaluation of Safety

Patient Safety

Systems with a single crewmember in the cabin generally assigned lower scores for patient safety during night missions than for daytime missions and had significantly fewer respondents with perceived patient safety "acceptable or better" for both night and daytime missions when compared with systems with an assistant in the cabin. The significantly lower scores for the single crew compared with those of dual crews were also present when a physician was part of the crew; however, differences between crews with and without a physician on board were negligible (Fig. 2, Table 2).

Flight Safety

Single medical crew services generally assigned lower scores for perceived flight safety to all flight operations with a patient on board compared with dual medical crew systems, with significantly fewer respondents with a perceived flight safety of "acceptable or better" (Fig. 3A, Table 2). The same tendency was found when comparing single and dual medical crews with a physician; dual medical crews with physicians had the highest scores for flight safety (Fig. 3B, Table 2). Flight safety was given a nonsignificantly higher score in systems with a physician in the crew compared with services without a physician on board (Fig. 3C, Table 2). No differences in perceived flight safety were found for any group comparison for flights without a patient on board.

Reasons for Choice of Medical Crew Model

Sixty-two respondents provided their 3 most important reasons for choosing their current medical crew concept. Overall, the most common reasons given were tradition and scientific evidence followed by aircraft configuration, company politics, and economic reasons (Table 3). Tradition and aircraft configuration were the 2 most common reasons for choosing a single crew. Scientific evidence was a more frequent reason provided for having a crew without a physician compared with that with a physician, as well as for choosing a dual medical crew compared with a single medical crew. Economic reasons were not common in systems without physicians in their crews, but they were more often assigned as a reason for choosing a single crew model compared with a dual crew.

Table 2
The Number of Observations (n), Medians, and Quartiles for All Subgroups and the Percentage of Observations With Perceived Safety "Acceptable" or Better

	A							B							C						
	1 Medical Crewmember			2 Medical Crewmembers				Physician as Only Medical Crewmember			Physician With Medical Assistant				No Physician in the Crew			Physician in the crew			
	n	Median (Q1, Q3)	% 6-7	n	Median (Q1, Q3)	% 6-7	P Value	n	Median (Q1, Q3)	% 6-7	n	Median (Q1, Q3)	% 6-7	P Value	n	Median (Q1, Q3)	% 6-7	n	Median (Q1, Q3)	% 6-7	P Value
Patient safety																					
Daylight missions	28	6.0 (4.5, 7.0)	71	33	7.0 (6.0, 7.0)	97	.009	25	6.0 (6.0, 7.0)	76	22	7.0 (6.0, 7.0)	100	.023	14	6.0 (6.0, 7.0)	79	47	6.0 (6.0, 7.0)	87	.416
Night missions	22	6.0 (4.0, 6.0)	55	25	7.0 (6.0, 7.0)	96	.001	19	6.0 (4.5, 6.0)	63	16	7.0 (6.0, 7.0)	100	.009	12	6.5 (4.0, 6.0)	67	35	6.0 (6.0, 7.0)	80	.435
Flight safety																					
Flight without patient	28	7.0 (6.0, 7.0)	79	32	7.0 (6.0, 7.0)	94	.130	25	7.0 (6.0, 7.0)	84	22	7.0 (6.0, 7.0)	96	.352	13	6.0 (6.0, 7.0)	77	47	7.0 (6.0, 7.0)	89	.353
During patient transport	28	6.0 (4.5, 7.0)	68	32	7.0 (6.0, 7.0)	97	.004	25	6.0 (5.0, 7.0)	72	22	7.0 (6.0, 7.0)	100	.010	13	6.0 (6.0, 7.0)	77	47	7.0 (6.0, 7.0)	85	.675
Daylight missions	28	7.0 (5.5, 7.0)	75	32	7.0 (6.0, 7.0)	97	.020	25	7.0 (6.0, 7.0)	80	22	7.0 (6.0, 7.0)	100	.052	13	6.0 (6.0, 7.0)	77	47	7.0 (6.0, 7.0)	89	.353
Night missions	22	6.0 (5.0, 7.0)	64	23	7.0 (6.0, 7.0)	96	.010	19	7.0 (5.5, 7.0)	74	15	7.0 (6.0, 7.0)	100	.053	11	7.0 (4.5, 7.0)	64	34	7.0 (6.0, 7.0)	85	.190
Primary missions	28	6.5 (5.0, 7.0)	71	29	7.0 (6.0, 7.0)	97	.012	25	7.0 (6.0, 7.0)	76	20	7.0 (6.0, 7.0)	100	.027	12	6.0 (5.5, 7.0)	75	45	7.0 (6.0, 7.0)	87	.380
Interhospital transfers	21	6.0 (4.0, 7.0)	71	30	7.0 (6.0, 7.0)	97	.015	18	7.0 (6.0, 7.0)	78	21	7.0 (6.0, 7.0)	100	.037	12	6.5 (5.0, 7.0)	75	39	7.0 (6.0, 7.0)	90	.334

P values from the Fisher exact test comparing perceived safety in the dichotomized groups (Likert scale 1-5 vs. 6-7) for (A) single and dual medical crews, (B) crews with a physician alone and with an assistant, and (C) crews without and with a physician for each type of mission.

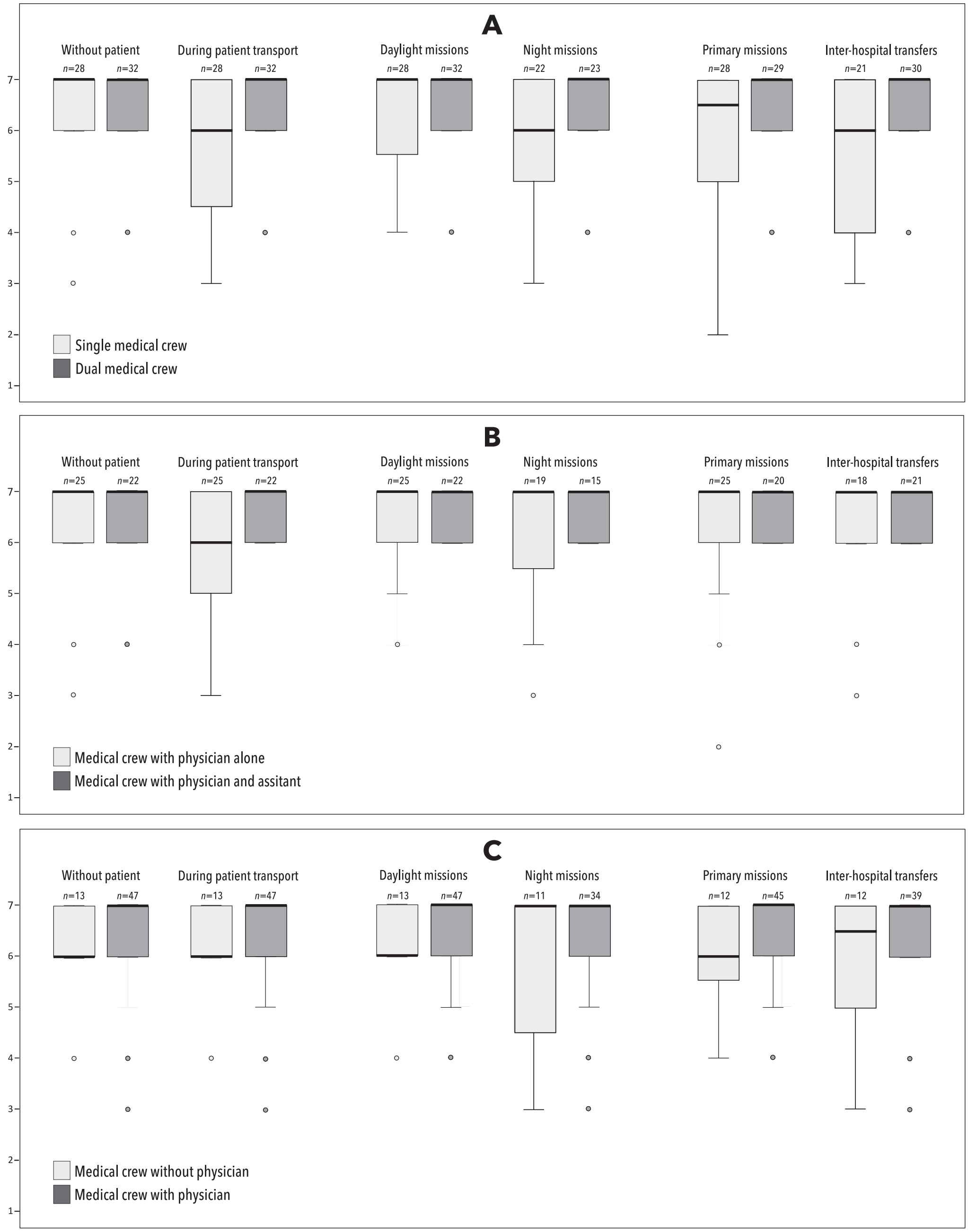

Figure 3. Respondents' perceived flight safety in HEMS missions for (A) single and dual medical crews, (B) crews with a physician alone and a physician with a medical assistant, and (C) crews without and with a physician rated from "totally unacceptable" (1) to "perfectly acceptable" (7).

Table 3
The Total Count of the Respondents (N = 62) Regarding the 3 Most Important Reasons for Their System's Medical Staffing

	Total Number of Responses	Tradition	Scientific Evidence	Aircraft Configuration	Company Politics	Economics	Recruitment of Special Personnel	Governmental Politics	Legal Issues
Overall	186	33	30	26	26	26	17	14	14
Single	84	20	6	17	13	14	5	4	5
Dual	102	13	24	9	13	12	12	10	9
DocAlone	75	17	5	16	11	13	5	3	5
DocAssist	66	8	14	7	11	7	6	9	4
Doc	141	25	19	23	22	20	11	12	9
NoDoc	45	8	11	3	4	6	6	2	5

Doc = a physician in the crew; DocAlone = a physician as the only medical crewmember; DocAssist = a physician with a medical assistant; Dual = 2 medical crewmembers; NoDoc = no physician in the crew; Single = only 1 medical crewmember.

Table 4
Contingency Table of Respondents' Actual Medical Staffing Versus Preferred Medical Staffing

		Preferred Medical Staffing						
		DocAssist	DocAlone	NurseAssist	NurseAlone	ParamAssist	ParamAlone	Total
Actual medical staffing	DocAssist	21		1				22
	DocAlone	9	16					25
	NurseAssist	3		8				11
	NurseAlone	1			1			2
	ParamAssist	1				0		1
	ParamAlone	1					0	1
	Total	36	16	9	1	0	0	62

DocAlone = a physician as the only medical crewmember; DocAssist = a physician with a medical assistant; NurseAlone = nurse as the only medical crewmember; NurseAssist = a nurse with a medical assistant; ParamAlone = paramedic as the only medical crewmember; ParamAssist = paramedic with a medical assistant.
Four respondents were excluded because they indicated no preferred medical staffing.

Preferred Medical Staffing

Sixty-two of the 66 respondents shared their opinion of what they considered to be the optimal medical crew configuration if allowed to choose freely. Of these, 46 (74%) opted to keep their current crew configuration and staffing (Table 4). Of the 47 systems with a physician in the crew, only 1 would have omitted the physician. In contrast, 6 of the 15 systems without a physician in their crew would have preferred to have one. Nine of 25 systems with a physician as the single medical crewmember would have preferred to add an assistant to the crew, and none of the systems with a physician and an assistant in the crew would omit the assistant.

Discussion

The results from this survey indicate that perceived patient and flight safety is higher when HEMS crews are staffed with a dual medical crew than with a single medical crew. A higher degree of perceived safety was also noted when a physician was part of this crew. Tradition and scientific evidence are the most common reasons for choosing a specific type of medical crew model, whereas economic reasons are less common. Most respondents would not change their crew configuration, but some would prefer to add a physician to the crew or supplement the physician with an assistant in the cabin.

Human resources and medical staffing seem to have a direct influence on patient safety.[33] Studies from other high-complexity domains of health care, such as intensive care medicine and emergency medicine in the emergency department, show that errors occur frequently because of the high complexity of care and patients' conditions.[34,35] Increased redundancy could be achieved through a higher health care provider–to–patient ratio. Our survey suggests that HEMS systems with a single medical staff in the cabin would prefer a dual medical crew to ensure improved safety.

Medical staffing models should not have a negative impact on flight safety. However, our study suggests that some HEMS systems are concerned with flight safety in certain staffing models. Dual medical crews seemed more preferable; this might be explained by the higher vigilance and ability to distribute the workload in a dual medical crew. Without patients on board, a single medical crewmember can contribute to the flight operations, but during patient transport, the focus must be on the patient.

Scientific evidence was high on the list of reasons provided for choosing a specific medical crew model. This is interesting, considering the lack of unambiguous scientific evidence in support of one crew configuration over another. The debate regarding whether to involve physicians in HEMS is still unresolved,[14-16] although several studies support staffing HEMS with physicians.[17,36-38] In Europe, this is a well-established concept, with the debate primarily regarding which specialty and training the physician should have.[39-41]

Limitations

We asked the respondents for their perception of flight and patient safety. Even though perception of risk has been found useful for safety research in the oil industry[22,23] and in HEMS for the evaluation of flight safety,[24] it is still a subjective assessment with all the limitations that this involves and must be interpreted accordingly. We did not provide a specific definition of the 2 safety concepts because we think they are commonly associated with the same interpretation in the HEMS community. A more specific definition and limitation of the safety concepts could also have limited some of the responses in which the safety concepts were interpreted in a broader context.

Alternatively, we could have asked for specific numbers of adverse events or errors reported in the different services, but we feared the quality of these reports would have been poor and difficult to compare because there are differences in definitions of what adverse events, near misses, and errors are. They may also only reflect different reporting cultures and not the true level of safety.

Because of confidentiality restrictions in some organizations, we did not gain access to the total number of HEMS systems eligible for participation. Although this precludes us from evaluating the response rate and the representativeness of this sample of all HEMS, we believe that we achieved a sample of the most common medical crew models currently used in HEMS. The survey was blinded, so we cannot confirm that the respondents were actually medical directors. The perception of flight and patient safety may depend on whether the respondent participated in active service or not and may be prone to responder bias as a result of the respondents' economic or emotional conflict of interest with the HEMS operator. Therefore, the reported attitude toward safety issues may be overconfident.

Future Studies

The findings of our survey confirm the diversity in medical crew staffing in HEMS and the inconsistency of scientific arguments for choosing one medical crew model over another. Our findings indicate that different crew configurations may have different effects on flight and patient safety. Therefore, future studies should attempt to isolate the effect of different medical crew models on patient safety and flight safety in an experimental scenario.

Conclusion

In our survey, HEMS crews with a dual medical crew and crews with physicians and an assistant in the medical cabin scored highest in perceived patient safety among medical directors. The differences in medical HEMS crew concepts are mainly related to medical competence in the crew and the availability of an assistant in the medical cabin. According to the medical directors in HEMS, the rationale behind different medical crew concepts is mostly founded on tradition and scientific evidence and not economy. Future studies must confirm if the perceived patient safety challenges related to medical crew composition are quantifiable and relevant to all types of HEMS missions.

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Preliminary data from the survey were published as abstracts at the London Trauma Conference 2014 (UK)[42,43] and the Air Medical Transport Conference 2015 (Long Beach, CA).[44]

Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.amj.2017.09.008.

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ORIGINAL RESEARCH Open Access

Training and assessment of non-technical skills in Norwegian helicopter emergency services: a cross-sectional and longitudinal study

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Abstract

Background: Deficient non-technical skills (NTS) among providers of critical care in helicopter emergency medical services (HEMS) is a threat to patient and operational safety. Skills can be improved through simulation-based training and assessment. A previous study indicated that physicians underwent less frequent training compared to pilots and HEMS crew members (HCM) and that all professional groups in Norwegian HEMS received limited training in how to cope with fatigue. Since then, training initiatives and a fatigue risk management project has been initiated. Our study aimed to explore if the frequency of simulation-based training and assessment of NTS in Norwegian HEMS has changed since 2011 following these measures.

Methods: A cross-sectional web-based survey from October through December 2016, of physicians, HCM and pilots from all civilian Norwegian HEMS-bases reporting the overall extent of simulation-based training and assessment of NTS.

Results: Of 214 invited, 109 responses were eligible for analysis. The frequency of simulation-based training and assessment of NTS has increased significantly for all professional groups in Norwegian HEMS, most prominently for the physicians. For all groups, the frequency of assessment is generally lower than the frequency of training.

Conclusions: Physicians in Norwegian HEMS seem to have adjusted to the NTS training culture of the other crew member groups. This might be a consequence of improved NTS training programs. The use of behavioural marker systems systematically in HEMS should be emphasized.

Keywords: Air ambulances, Helicopter, Communication, Leadership, Non-technical skills, Simulation-based training

Introduction

Pre-hospital critical care and transport of critically ill or injured patients involve a significant risk of adverse events [1]. Studies investigating the factors contributing to critical incidents and adverse events in highly dynamic domains of healthcare, such as emergency medicine, have shown that teamwork plays an important role [2]. Team leadership is a critical skill for emergency medicine physicians directly affecting team performance and the quality of patient care [3, 4]. Poor communication has been found to be a significant factor in adverse events in air ambulance transports [5, 6], but overall, research on the causes of human errors in helicopter emergency medical services (HEMS) is still sparse [7].

Systematic training and assessment of non-technical skills (NTS) in HEMS have received little attention in the past [8, 9]. NTS can be defined as the cognitive and interpersonal skills needed to deliver safe care [10]. Seven generic categories of NTS have been suggested: situation awareness, decision-making, communication,

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teamwork, leadership, managing stress and coping with fatigue [11].

To document the level of simulation-based training and assessment of non-technical skills in 2011 among crew members of the Norwegian HEMS, Abrahamsen and co-workers performed a cross-sectional survey [8]. The main findings from this study was a lack of simulation-based training and assessment for all professional groups in Norwegian HEMS, that physicians underwent significantly less frequent training and assessment compared to pilots and HEMS Crew Members (HCM), and that all groups received limited training in how to cope with fatigue even though they were on call for extended hours. Since then, the Norwegian Air Ambulance Foundation has implemented a crew training camp concept for the Norwegian HEMS [12], initiated a research project of in situ simulation training during on-call hours with the implementation of weekly simulation training at several HEMS bases in Norway [13], and conducted a fatigue risk management project in Norwegian HEMS.

Our study aimed to explore if the frequency of simulation-based training and assessment of non-technical skills in Norwegian HEMS has changed following the training initiatives mentioned above. Our hypothesis is that the frequency of simulation-based training and assessment of NTS has increased in all the three professional groups.

Methods

Setting

Since the previous survey, one additional HEMS base has been established in Norway. The 12 HEMS bases all have helicopters staffed with a pilot, a HEMS crew member (HCM) and a physician running 24/7 services. One HEMS base is staffed with an additional flight nurse, but because the number of nurses is low, full anonymity could not be guaranteed and this professional group was not included in the previous study. This also applies to the current survey. All Norwegian HEMS physicians are certified or soon-to-be certified anaesthesiologists and employed by the local health enterprise. HCMs and pilots are employed by one of the two flight operators, Norsk Luftambulanse AS and Lufttransport RW AS.

Questionnaire

Eight question categories regarding education and training in NTS were attached to a patient safety climate questionnaire (Additional file 1). Except for a minor adaptation in wording to also fit ground ambulance organization, the questionnaire was identical to the previous survey [8]. Similarly, our study focused on the two question categories reporting the overall extent of simulation-based training (question category I6) and assessment (question category I7) in the previous year on a four-point ordinal scale (0, 1–2, 3–5, > 5 times per year) for each of the seven generic NTS categories. The questionnaire also contained seven background variables relating to the respondents' work characteristics; work area, geographic location, field of competence, patient contact, work hours, experience in the prehospital area and seniority in position.

Data collection

All physicians, HCMs and pilots working in the civilian Norwegian HEMS were invited to participate in an anonymous, cross-sectional web-based survey (SurveyXact™, Rambøll Management Consulting, Oslo, Norway). A link to the survey was distributed via e-mail and five reminders were sent non-responders. The survey was open from October through December 2016.

Statistical analysis

All answers related to simulation-based training and assessment were dichotomized into "some training/assessment" and "no training/assessment". To visualize the development in training and assessment, ratios of the percentages from 2015 divided by the corresponding percentages from 2011, were calculated and are presented in bar charts across an ordinal scale. A ratio greater than 1, indicates a positive development in the frequency of training and assessment. To support the visuals, a series of two-sided Fisher's exact test of the dichotomized items were performed. A p-value less than 0.05 should imply a rejection of the null hypothesis, which was no association between the two groups of interest and level of training and assessment. The freeware R 3.1.3 was used for all calculations and visualization producing the results presented in this paper.

Ethical considerations

The study was approved by the Norwegian Centre for Research Data (Ref. no. 2016/45723) and was exempted from ethical approval by the Regional Committee for Medical and Health Research Western Norway (Ref. no. 2015/2249). The participants received information regarding the purpose of the study and that the questionnaires were to be treated in confidence, and their written consent to participate in the study was given at the start of the survey.

Results

In total, 214 physicians, HCMs and pilots in the Norwegian civilian HEMS were invited to participate in the survey. We received 118 responses, yielding a response rate of 55.1%. Nine responses were excluded due to either missing core data, or because respondents stated search and rescue services (SAR) or fixed wing air ambulance as their main job, giving 109 responses eligible for analysis. Of these, 49% (53) were from physicians, 28% (31) from HCM and 23% (25) from pilots. In 2011, the corresponding distribution among the professional groups was 53, 27 and 20%, respectively (Table 1, Fig. 1).

Overall training and assessment of NTS in Norwegian HEMS

When evaluating the results for all personnel in Norwegian HEMS as a whole, the frequency of both simulation-based training and assessment for all NTS categories have increased from 2011 to 2015. By statistical testing, we found that all changes were significant except for simulation-based training in "coping with fatigue" (Table 2).

Training and assessment for each professional group

Physicians were the professional group with most categories with significant increase in training and assessment from 2011 to 2015. The frequency of simulation-based training of decision-making, leadership, communication, situation awareness and managing stress has increased significantly, and physicians have been assessed significantly more frequently for all NTS

Table 1 Demographic and professional characteristics of the study populations in 2011 and 2015

	2011 ($n = 155$) %	2015 ($n = 109$) %
Professional group		
Physician	53	49
Pilot	20	23
HCM	27	28
Regional health trust		
North	14	18
Mid-Norway	22	21
West	26	21
South-East	36	39
Other	3	< 1
Prehospital experience		
Less than 1 year	5	4
1 to 5 years	19	20
6 to 10 years	27	24
11 to 15 years	16	17
16 to 20 years	15	25
21 years or more	19	10

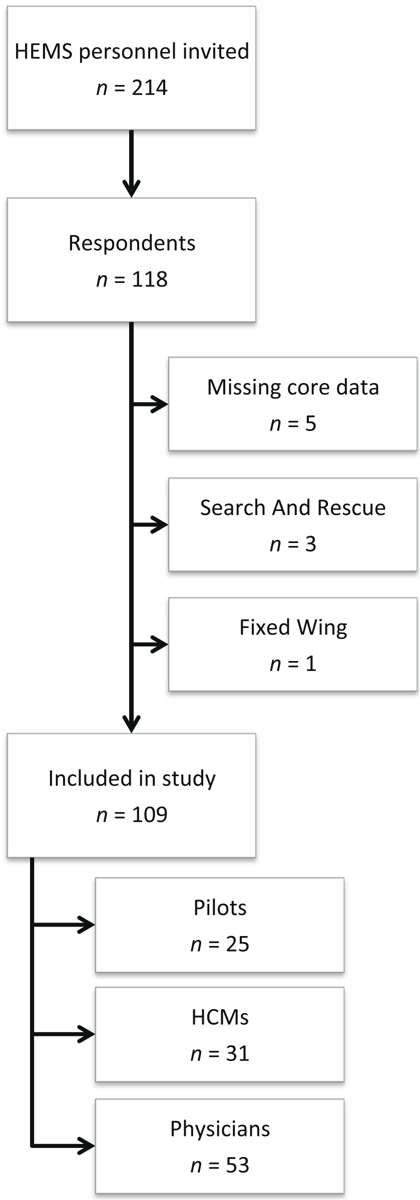

Fig. 1 Inclusion flow chart

Table 2 Norwegian HEMS personnel with simulation-based training in and assessment of non-technical skills

Question category	NTS category	2015 (*n* = 109)	2011 (*n* = 155)	*P*-value	
Simulation-based training of NTS	1. Decision-making	90/109 (82.6%)	87/149 (58.4%)	< 0.001	*
	2. Leadership	29/109 (73.4%)	84/150 (56.0%)	0.004	*
	3. Communication	21/109 (80.7%)	90/150 (60.0%)	< 0.001	*
	4. Situation awareness	22/109 (79.8%)	86/150 (57.3%)	< 0.001	*
	5. Teamwork	16/109 (85.3%)	99/149 (66.4%)	< 0.001	*
	6. Managing stress	32/109 (70.6%)	71/151 (47.0%)	< 0.001	*
	7. Coping with fatigue	61/109 (44.0%)	50/146 (34.2%)	0.120	
Assessment of NTS	1. Decision-making	78/109 (71.6%)	76/149 (51.0%)	0.001	*
	2. Leadership	74/109 (67.9%)	71/149 (47.7%)	0.001	*
	3. Communication	76/109 (69.7%)	69/148 (46.6%)	< 0.001	*
	4. Situation awareness	74/109 (67.9%)	69/148 (46.6%)	< 0.001	*
	5. Teamwork	81/109 (74.3%)	79/149 (53.0%)	< 0.001	*
	6. Managing stress	66/109 (60.6%)	64/149 (43.0%)	0.006	*
	7. Coping with fatigue	46/109 (42.2%)	44/146 (30.1%)	0.048	*

Number and proportion (%) of Norwegian HEMS personnel having undergone simulation-based training (question category I6) and assessment (question category I7) of seven (1–7) generic non-technical skills (NTS) in 2011 and 2015. **P*-values less than 0.05 from the two-sided Fisher exact test comparing the proportions in 2011 and 2015

except managing stress and coping with fatigue (Table 3, Fig. 2).

In 2011, pilots reported to be assessed more frequently than physicians, while no significant difference was found regarding simulation-based training [8]. The bar plots indicate a further increase in the frequency of training and assessments for the pilots, but these changes were not significant with the exception of training and assessment of "situation awareness" and "managing stress" (Table 4, Fig. 2).

HCMs appeared to be the professional group with the highest frequency of training and assessment in 2011, although not significantly different from the pilots [8]. We found a further and significant increase in the frequency of HCMs of simulation-based training in decision-making, communication, teamwork and managing stress. No

Table 3 Physicians with simulation-based training in and assessment of non-technical skills

Question category	NTS category	2015 (*n* = 53)	2011 (*n* = 82)	*P*-value	
Simulation-based training of NTS	1. Decision-making	39/53 (73.6%)	37/76 (48.7%)	0.006	*
	2. Leadership	35/53 (66.0%)	37/78 (47.4%)	0.049	*
	3. Communication	38/53 (71.7%)	40/77 (51.9%)	0.029	*
	4. Situation awareness	37/53 (69.8%)	37/77 (48.1%)	0.019	*
	5. Teamwork	40/53 (75.5%)	44/76 (57.9%)	0.060	
	6. Managing stress	28/53 (52.8%)	24/78 (30.8%)	0.018	*
	7. Coping with fatigue	16/53 (30.2%)	18/78 (23.1%)	0.419	
Assessment of NTS	1. Decision-making	32/53 (60.4%)	29/77 (37.7%)	0.013	*
	2. Leadership	31/53 (58.5%)	27/77 (35.1%)	0.012	*
	3. Communication	31/53 (58.5%)	25/76 (32.9%)	0.007	*
	4. Situation awareness	29/53 (54.7%)	24/77 (31.2%)	0.011	*
	5. Teamwork	32/53 (60.4%)	30/77 (39.0%)	0.020	*
	6. Managing stress	20/53 (37.7%)	21/77 (27.3%)	0.250	
	7. Coping with fatigue	14/53 (26.4%)	14/77 (18.2%)	0.284	

Number and proportion (%) of physicians working in Norwegian helicopter emergency medical services (HEMS) who have undergone simulation-based training (question category I6) and assessment (question category I7) of seven (1–7) generic non-technical skills (NTS) in 2011 and 2015. **P*-values less than 0.05 from the two-sided Fisher exact test comparing the proportions in 2011 and 2015

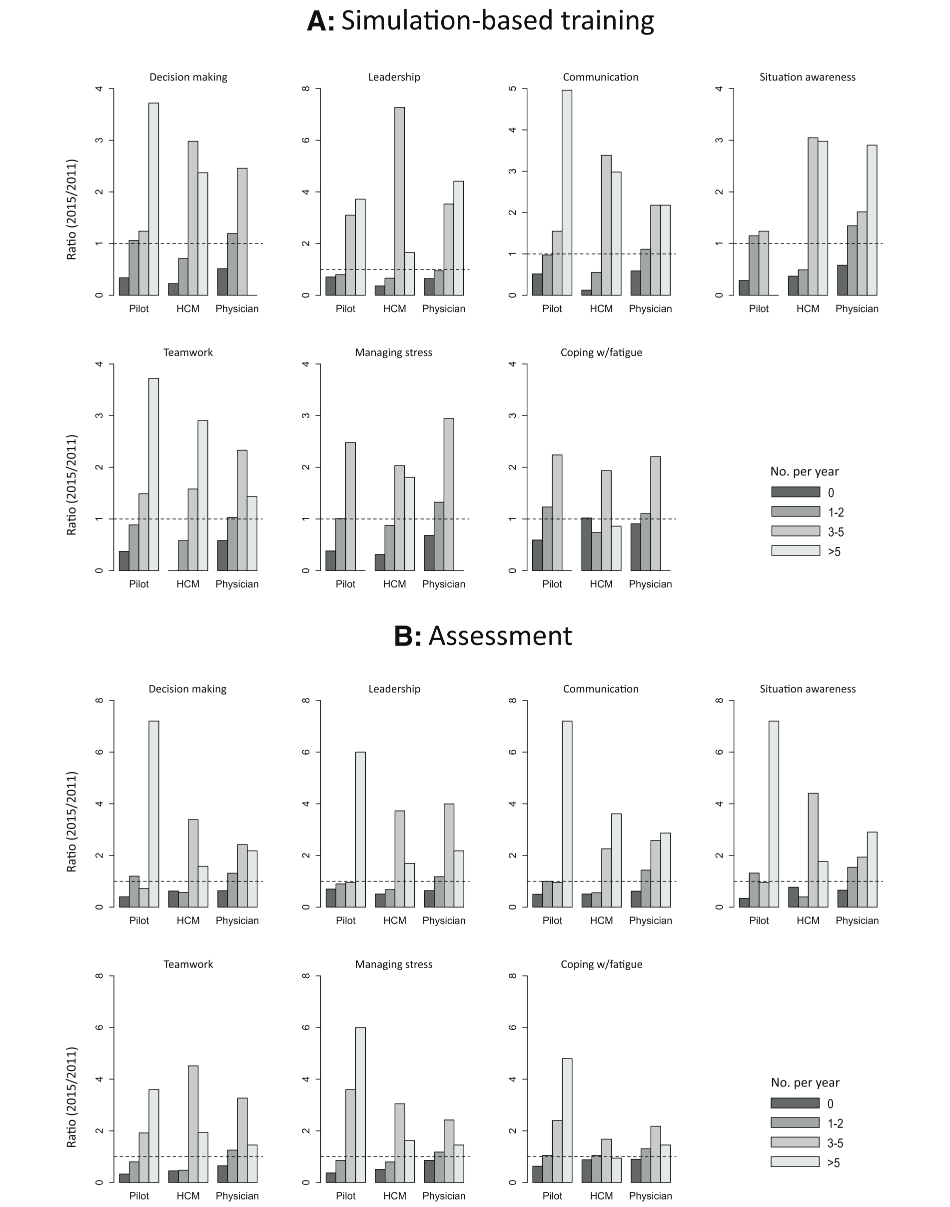

Fig. 2 (See legend on next page.)

(See figure on previous page.)
Fig. 2 The changes in (**a**) simulation-based training in and (**b**) assessment of the generic non-technical skills within each professional group from 2011 to 2015. The ratios represent the relative frequencies (%) of 2015 divided by the relative frequencies (%) of 2011 across all four ordinal categories, with a ratio = 1 (dashed line) indicating no change in relative frequency and a ratio < 1 or > 1 respectively a decrease or an increase in frequency. Missing bars are due to categories with no data in one or both of the years surveyed, and thus, no computable ratio

significant changes were noted for assessment of any of the NTS categories. (Table 5, Fig. 2).

Training and assessment based on employer

The crew members can be separated with respect to employer. Of the respondents, 49% were employed by the flight operator (HCMs and pilots) and 51% were working for the health enterprise (physicians) compared to 47 and 53%, respectively in the previous survey [8].

In 2011, health enterprise employees experienced significantly less frequent training and assessment than flight operator personnel for all NTS categories [8]. In our study, flight operator employees were reporting a significant increase in the frequency of both training and assessment of all NTS except "leadership" and "coping with fatigue" (Table 6). Even though the physicians were the group with most categories with significant increase in training and assessment in the period (Table 3), the significant differences based on employment status still exist for all categories except "leadership" (Table 6).

Discussion

Training of non-technical skills

To deliver high quality of care and patient safety, training in technical skills is important to be competent in critical care procedures [14]. Non-technical skills are essential to complement the technical skills in a work setting such as HEMS. Deficiencies in communication and teamwork are frequent contributors to adverse events in health care [15]. There is also increasing awareness about the positive influence of teamwork on clinical performance [16, 17] and clinical outcomes [18, 19].

Even though the theoretical basis and the evidence regarding educational methods to enhance patient safety using NTS training are still limited [10], both simulation and classroom-based training has been found to improve teamwork processes [15]. An interdisciplinary team training program using in-situ simulation gave a statistically significant and persistent improvement in perinatal morbidity [20]. Similar results have been found in surgical outcome after team training of operating room personnel [19]. Simulation-based team training seems to be the most prominent mode of training in the literature [15].

Duration and frequency of training varies, and there is currently limited, but emerging, evidence that provides insight into the frequency of retraining needed to maintain effective teamwork skills [15]. Significant improvement has been found for critical care providers at 6 and 12 months post-training [21], and studies on simulation based training in neonatal resuscitation seems to favour

Table 4 Pilots with simulation-based training in and assessment of non-technical skills

Question category	NTS category	2015 (*n* = 25)	2011 (*n* = 31)	*P*-value	
Simulation-based training of NTS	1. Decision-making	22/25 (88.0%)	20/31 (64.5%)	0.064	
	2. Leadership	17/25 (68.0%)	17/31 (54.8%)	0.412	
	3. Communication	20/25 (80.0%)	19/31 (61.3%)	0.155	
	4. Situation awareness	22/25 (88.0%)	18/31 (58.1%)	0.018	*
	5. Teamwork	22/25 (88.0%)	21/31 (67.7%)	0.112	
	6. Managing stress	21/25 (84.0%)	18/31 (58.1%)	0.045	*
	7. Coping with fatigue	16/25 (64.0%)	11/28 (39.3%)	0.101	
Assessment of NTS	1. Decision-making	21/25 (84.0%)	18/30 (60.0%)	0.075	
	2. Leadership	18/25 (72.0%)	18/30 (60.0%)	0.404	
	3. Communication	20/25 (80.0%)	18/30 (60.0%)	0.147	
	4. Situation awareness	21/25 (84.0%)	16/30 (53.3%)	0.022	*
	5. Teamwork	22/25 (88.0%)	19/30 (63.3%)	0.061	
	6. Managing stress	21/25 (84.0%)	17/30 (56.7%)	0.041	*
	7. Coping with fatigue	15/25 (60.0%)	11/30 (36.7%)	0.108	

Number and proportion (%) of pilots working in Norwegian helicopter emergency medical services (HEMS) who have undergone simulation-based training (question category I6) and assessment (question category I7) of seven (1–7) generic non-technical skills (NTS) in 2011 and 2015. **P*-values less than 0.05 from the two-sided Fisher exact test comparing the proportions in 2011 and 2015

Table 5 HEMS crew members (HCM) with simulation-based training in and assessment of non-technical skills

Question category	NTS category	HCM 2015 (*n* = 31)	HCM 2011 (*n* = 42)	*P*-value	
Simulation-based training of NTS	1. Decision-making	29/31 (93.5%)	30/42 (71.4%)	0.033	*
	2. Leadership	28/31 (90.3%)	30/41 (73.2%)	0.080	
	3. Communication	30/31 (96.8%)	31/42 (73.8%)	0.010	*
	4. Situation awareness	28/31 (90.3%)	31/42 (73.8%)	0.131	
	5. Teamwork	31/31 (100.0%)	34/42 (81.0%)	0.018	*
	6. Managing stress	28/31 (90.3%)	19/42 (69.0%)	0.044	*
	7. Coping with fatigue	16/31 (51.6%)	21/40 (52.5%)	1.000	
Assessment of NTS	1. Decision-making	25/31 (80,6%)	29/42 (69.0%)	0.295	
	2. Leadership	25/31 (80,6%)	26/42 (61.9%)	0.122	
	3. Communication	25/31 (80,6%)	26/42 (61.9%)	0.122	
	4. Situation awareness	24/31 (77,4%)	29/42 (69.0%)	0.596	
	5. Teamwork	27/31 (87,1%)	30/42 (71.4%)	0.154	
	6. Managing stress	25/31 (80,6%)	26/42 (61.9%)	0.122	
	7. Coping with fatigue	17/31 (54,8%)	19/39 (48.7%)	0.638	

Number and proportion (%) of HEMS crew members (HCM) working in Norwegian helicopter emergency medical services (HEMS) who have undergone simulation-based training (question category I6) and assessment (question category I7) of seven (1–7) generic non-technical skills (NTS) in 2011 and 2015.
**P*-values less than 0.05 from the two-sided Fisher exact test comparing the proportions in 2011 and 2015

low dose, high frequency training [22]. This points in the direction of at least annual training, similar to common practice for crew resource management (CRM) training in aviation.

The content and schedule of training in technical skills need to be tailored due to variations in mission profiles and exposure to different procedures [14]. Human errors, on the other hand, are not limited to inexperienced clinicians, and NTS training is therefore equally important to all. So far, a consensus regarding the content of team training has not been achieved, but the most commonly targeted teamwork competencies are communication,

Table 6 Flight operator employees and health enterprise employees with simulation-based training in and assessment of non-technical skills

Question category	NTS category	Flight 2015 (*n* = 56)	Flight 2011 (*n* = 73)	*P*-value A		Health 2015 (*n* = 53)	*P*-value B	
Simulation-based training of NTS	1. Decision-making	51/56 (91.1%)	50/73 (68.5%)	0.002	*	39/53 (73.6%)	0.022	*
	2. Leadership	45/56 (80.4%)	47/72 (65.3%)	0.075		35/53 (66.0%)	0.129	
	3. Communication	50/56 (89.3%)	50/73 (68.5%)	0.006	*	38/53 (71.7%)	0.028	*
	4. Situation awareness	50/56 (89.3%)	49/73 (67.1%)	0.003	*	37/53 (69.8%)	0.016	*
	5. Teamwork	53/56 (94.6%)	55/73 (75.3%)	0.003	*	40/53 (75.5%)	0.006	*
	6. Managing stress	49/56 (87.5%)	47/73 (64.4%)	0.004	*	28/53 (52.8%)	< 0.001	*
	7. Coping with fatigue	32/56 (57.1%)	32/68 (47.1%)	0.284		16/53 (30.2%)	0.007	*
Assessment of NTS	1. Decision-making	46/56 (82.1%)	47/72 (65.3%)	0.045	*	32/53 (60.4%)	0.019	*
	2. Leadership	43/56 (76.8%)	44/72 (61.1%)	0.085		31/53 (58.5%)	0.064	
	3. Communication	45/56 (80.4%)	44/72 (61.1%)	0.021	*	31/53 (58.5%)	0.021	*
	4. Situation awareness	45/56 (80.4%)	45/71 (63.4%)	0.049	*	29/53 (54.7%)	0.007	*
	5. Teamwork	49/56 (87.5%)	49/72 (68.1%)	0.012	*	32/53 (60.4%)	0.002	*
	6. Managing stress	46/56 (82.1%)	43/72 (59.7%)	0.007	*	20/53 (37.7%)	< 0.001	*
	7. Coping with fatigue	32/56 (57.1%)	30/69 (43.5%)	0.152		14/53 (26.4%)	0.002	*

Number and proportion (%) of Norwegian HEMS personnel employed by the flight operator and health enterprise who have undergone simulation-based training (question category I6) and assessment (question category I7) of seven (1–7) generic non-technical skills (NTS).**P*-values less than 0.05 from the two-sided Fisher exact test comparing (A) the proportions of flight operator employees in 2011 and 20 and (B) flight operator employees with health enterprise employees in 2015 situational awareness and leadership [15]. In addition to these, decision-making, teamwork, managing stress and coping with fatigue are often included in non-technical skills evaluation schemes.

Assessment versus training

Assessment is the process of observing, recording, interpreting and evaluating individual performance and serves different purposes: to audit the level of skills of individuals or units, but also to evaluate training programs [11]. A number of non-technical skills rating frameworks, behavioural marker systems, have been developed for health-care domains closely related to the air ambulance setting [23–26], but a tool for assessment of non-technical skills for HEMS such as the Aero-NOTS, has just recently been developed and yet not fully validated [27]. Generally, the frequency of assessment was lower than the frequency of simulation-based training for all three professional groups in our study. This result underlines the undone work in using assessment tools systematically in HEMS.

Training in Norwegian HEMS

Norwegian HEMS providers have a contractual mandatory training program in rescue and flight operative procedures, including recurrent flight simulator training for pilots and HCMs. Medical training, simulation-based or otherwise, depend on local initiative and commitment. In the study of Abrahamsen, physicians underwent significantly less frequent simulation-based training compared to the other groups [8]. In our study, physicians were the one group with a significant increase in most NTS categories, and thus, an important contributor to the overall increase in the frequency of training in the Norwegian HEMS. The before-mentioned initiatives with in-situ simulation [13] and the all crew training camp [12] may be one explanation to this result. The proportion of physicians training currently seems to be at the level of the other groups in 2011, but they still train significantly less than flight operative employees. Thus, a great potential for simulation-based training still exists among the HEMS physicians.

Coping with fatigue

The results from the different professional groups were inconsistent regarding each of the generic NTS, and with the limitation in response rate and sample size in our survey, these results should not be over-interpreted. For *coping with fatigue*, on the other hand, we did not find significant increase for any professional group, despite the finding from 2011 where all professional groups received limited training. This may be seen as a paradox since the non-technical performance of critical care air transfer clinicians is impaired when they are fatigued [28], and fatigue training seems to improve safety and health outcome for EMS personnel [29]. Fatigue and stress management are usually included in training programs, although it has been questioned whether it is appropriate to include these topics in assessment schemes of NTS. Both can be difficult to detect and rate unless extreme symptoms are displayed, in which other skills will be affected [11]. Another influencing factor may be the lack of a consensus on the definition of fatigue and a standardized survey instrument to measure fatigue among EMS worker groups. Only a limited number of tools used in other settings for assessment of fatigue exist, and research focused on development and testing of fatigue survey instruments tailored specifically for emergency medical services is needed [30]. The on-going research project in Norwegian HEMS in fatigue risk management will hopefully contribute to developing useful tools for fatigue training and assessment.

Limitations

Our study was part of a combined survey of both ground and air ambulance with more than 5000 invited participants, and thus, the same follow up with personal reminders to all invited as the survey of Abrahamsen [8], was not feasible. Our response rate is therefore noticeably lower, but the distribution in professional groups, prehospital experience and geographical location was largely similar (Table 1). We do not know, however, if personnel who have undergone training were more likely to respond to our survey or not, which could result in a non-responder bias and possibly more significant changes than otherwise. The results should be interpreted according to these limitations with an emphasis on the major lines and not detailed results.

In both surveys, respondents were asked to report exclusively on the frequency of interdisciplinary prehospital simulation training. We cannot, nevertheless, exclude that pilots and HCMs may have reported on mandatory flight operative training and that this may explain the better results for these groups in both surveys. We also cannot exclude that physicians may have reported on intra-hospital training.

When asked retrospective to specify the number of training sessions and assessments, some uncertainty must be expected. We have mainly based our conclusions on the dichotomized data, “no training” or “some training”, which we have assumed more reliable. Ideally, a longer period between the two surveys would be preferable. This was not possible as our study was a part of a larger research project.

Finally, as discussed earlier, in order to fully understand the effect of simulation training on patient outcome, further research is needed.

Conclusion

The frequency of simulation-based training and assessment of NTS has increased significantly in Norwegian HEMS. Physicians seem to be adjusting to the training culture of other professional groups in HEMS, but still, there is a great potential for improving training frequency and volume among the HEMS physicians. Systematic assessment of NTS, including fatigue management, should be a future focus area in HEMS.

Additional file

Additional file 1: Questionnaire (English translation). (PDF 180 kb)

Abbreviations

AeroNOTS: Aeromedical non-technical skills; HCM: HEMS Crew Member; HEMS: Helicopter Emergency Medical Service; NTS: Non-technical skills; SAR: Search and rescue

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Availability of data and materials

The datasets supporting the conclusions of this article are available from the corresponding author on reasonable request.

Authors' contributions

KR, HBA, EBA, SJMS: Study design; LIKS, KR, HBA, SJMS, GTB: data collection; KR, HL: data analysis; KR: draft of the manuscript; all authors revised the manuscript and approved the final version.

Ethics approval and consent to participate

The study was approved by the Norwegian Centre for Research Data (Ref. no. 2016/45723) and was exempted from ethical approval by the Regional Committee for Medical and Health Research Western Norway (Ref. no. 2015/2249). Consent to participate in the study was given at the start of the survey.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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ORIGINAL ARTICLE

OPEN

Sky-High Safety? A Qualitative Study of Physicians' Experiences of Patient Safety in Norwegian Helicopter Emergency Services

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Background: Patients treated and transported by Helicopter Emergency Medical Services (HEMS) are prone to both flight and medical hazards, but incident reporting differs substantially between flight organizations and health care, and the extent of patient safety incidents is still unclear.

Methods: A qualitative descriptive study based on in-depth interviews with 8 experienced Norwegian HEMS physicians from 4 different bases from February to July 2020 using inductive qualitative content analysis. The study objectives were to explore the physicians' experience with incident reporting and their perceived areas of risk in HEMS.

Results/Findings: The HEMS physicians stated that the limited number of formal incident reports was due to the "nature of the HEMS missions" and because reports were mainly relevant when deviating from procedures, which are sparse in HEMS. The physicians preferred informal rather than formal incident reporting systems and reporting to a colleague rather than a superior. The reasons were ease of use, better feedback, and less fear of consequences. Their perceived areas of risk were related to all the phases of a HEMS mission: the physician as the team leader, medication errors, the handover process, and the helicopter as a work platform.

Conclusions: The sparse, informal, and fragmented incident reporting provides a poor overview of patient safety risks in HEMS. Focusing on organizational factors and system responsibility and research on environmental and contextual factors are needed to further improve patient safety in HEMS.

Key Words: emergency medicine, hems, helicopter, patient safety, qualitative content analysis, incident reporting, organizational factors, nontechnical skills

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Transporting seriously ill or injured patients needing time-critical and advanced interventions with limited human resources and space involves a significant risk of adverse events.[1,2]

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Air ambulances introduce additional aviation-related hazards. Although not entirely comparable, aviation safety management is in many aspects considered superior to that of health care with a more supportive and nonpunitive incident reporting environment, which is openly accessible while still maintaining the immunity of involved crews.[3]

While the scientific focus on patient safety in prehospital critical care is sparse, some studies have identified factors influencing the safety climate. A Swedish study pointed out preparedness, good teamwork, and communication as essential for transporting critically ill patients in long-distance air ambulance.[4] In a similar study from a Brazilian team, experience, training, and checklists were highlighted as most important.[5] In a systematic review of patient safety in emergency medical services, the included literature was divided into the following 7 themes: adverse events and medication errors, clinical judgment, communication, ground vehicle safety, aircraft safety, interfacility transport, and intubation.[6] This coincides well with the Agency for Healthcare Research and Quality definition of dimensions within patient safety culture: leadership, teamwork within and across units, communication, staffing, and reporting systems with nonpunitive feedback.[7]

A good reporting culture has been defined as 1 of 5 components of a safety culture,[8] and incident reporting systems have become the most widespread strategy for improving patient safety.[9] Studies that compared incident reporting systems in hospitals to medical record reviews showed that only 5% or less of harmful incidents were reported.[10,11] The number of reported incidents in air medical transport is low.[12–14] However, error identification varies with medical education,[15] and the difference between the observed and self-rated performance may indicate that the problem is larger than the reported numbers.[16,17] Despite a national Helicopter Emergency Service (HEMS), Norway also has no unified reporting system to provide an overview of patient safety incidents, where each air medical base reports only within its organization. Thus, a relevant question is if incident-reporting systems can be considered reliable sources for healthcare error rates.[18]

We believe that there is reason to assume an underreporting of patient-related incidents in HEMS. To study the rationale behind this reporting culture, we chose a qualitative approach with in-depth interviews of HEMS physicians with 2 objectives: first, to explore Norwegian HEMS physicians' experiences with incident reporting, and second, their perception of areas of specific risks regarding patient safety in HEMS operations.

METHOD

Study Participants

The Norwegian HEMS is a national government-funded service with 13 bases. All helicopters are staffed by a pilot and a HEMS Technical Crew Member employed by the flight operator, and a physician employed by the local health trust. All HEMS physicians are consultant anesthesiologists and share their

TABLE 1. Informants' Age and Years of HEMS Experience

Informant	Age	HEMS Experience
A	59	28
B	46	10
C	47	16
D	44	12
E	51	6
F	52	8
G	47	9
H	48	15
Median	47,5	11

HEMS duty with in-hospital clinical work in anesthesia and intensive care medicine. At the time of the study, one base also included a nurse in the crew to assist the physician. As the physician is the sole medical provider on all other bases and is responsible for the medical treatment, we only invited physicians as informants to our study.

We recruited HEMS physicians with at least 5 years of experience as the ability to identify errors seems to increase with experience.[19] Physicians with any formal leadership role at the base were intentionally not invited.

Data Collection

We approached the medical directors of all Norwegian HEMS bases and encouraged them to appoint a person of contact who was then requested to recruit 1 or 2 informants from their base. All recruited physicians were contacted directly. This procedure ensured the informants' anonymity to avoid the risk of retaliation.

To obtain broad insight and rich information, we sought to recruit from 6 to 12 informants with the same professional background but different experiences regarding incident reporting systems, helicopter types, and crew configuration. Thus, this group of informants served as a purposeful sample.[20,21] Informants were recruited until little new information emerged from the interviews and additional coding no longer seemed feasible.[22] None of the respondents declined to participate or later withdrew their consent.

All interviews took place during regular working hours at the informants' workplace from February to July 2020 but without the presence of others. The first author conducted all interviews; the first 4 using a recorder, and the last 4 informants were interviewed via video (Microsoft Skype or Microsoft Teams; Microsoft Corp, Redmond, Wash) due to COVID-19 restrictions. The mean duration of the interviews was 49 minutes (30–62 minutes). A semistructured interview guide had been developed in advance but was not presented before the interviews (see Interview Guide, English translation in Supplemental Material, http://links.lww.com/JPS/A574). The recorded video files were converted to audio files and then transcribed verbatim.

The interview guide opened with questions about the informants' experience with incident reporting systems and continued with questions about incidents or near misses they had experienced or expected could occur in the different phases of a mission. At the end of the interview, the informants were asked to summarize essential factors for patient safety in HEMS.

Qualitative Description Design

We applied a qualitative descriptive approach to our study.[23] According to Bradshaw et al,[24] quality description is an inductive process designed to describe a phenomenon and develop understanding. The researcher takes the participants' perspectives but has an active role through interviews and interpretation.[24] Quality description is especially amendable in studies with findings not far from the literal description and, thus, a lower level of interpretation.[21,25]

Data Analysis

For data analysis, we applied an inductive qualitative content analysis with a low abstraction and low interpretation degree.[26,27] A process of dividing the text into meaning units, condensing and coding, was followed by sorting the codes by similarities and differences in subcategories and eventually in 2 main categories according to the research objectives.[28] This process was repeated multiple times until the final codes and categories emerged.

Ethics

All informants received written information first through the person of contact and then directly by mail before the interviews. This information contained information about the purpose of the study and the possibility of withdrawing at any point. The study was approved by the Norwegian Data Protection Official (NSD ref. 531035, September 5, 2019) and exempted from ethical approval by the Regional Ethical Committee (REK Vest, ref. 33093, August 20, 2019).

RESULTS

Eight physicians from 4 different bases were included in the study, 7 male and 1 female, with a median age of 47.5 years and a median HEMS experience of 11 years (Table 1).

Two main categories, learning from mistakes and managing the risk, were identified corresponding to the 2 study objectives. The associating subcategories and codes are listed in Tables 2 and 3.

Learning From Mistakes

The Nature of the Mission

The physicians emphasized the different nature of the HEMS missions compared with their intrahospital work. The missions were unpredictable, not by a recipe, difficult to standardize and thus less suitable for written procedures. They expressed that error reports were mainly relevant when deviating from a procedure. Patient assessment was challenging because of time pressure and a demanding environment with noise and limited space. Decisions were often made with little information and less backup possibility. These factors contributed to their higher threshold for defining incidents as errors.

"Maybe we don't define it as an error; it is just what was possible to do in this situation."

TABLE 2. Subcategories and Codes Derived From the Data Analysis in the Category "Learning From Mistakes"

Subcategory	Code
The nature of the mission	Not by a recipe
	Just what was possible
	Part of the game
To report or not	A black hole
	A cumbersome system
	Becoming a scapegoat
	Lack of trust

TABLE 3. Subcategories and Codes Derived From the Data Analysis in the Category "Managing the Risk"

Subcategory	Code
Working as a team	The good leader
	Having the same picture
	Making the right decisions
	The difficult communication
	A plan B
	Procedures and checklists
The challenging conditions	Darkness and noise
	Time and space
	Not enough hands
The difficult collaboration	Clarifying responsibilities
	Passing on information
	Mutual understanding
	Having the same equipment and protocols

Two basic premises were pointed out to enhance reporting: recruiting members who can reflect on their mistakes and having experienced colleagues who act as role models in sharing their errors.

"Sometimes I think that we do not always pick the right people because we may pick those showing great self-confidence, but at the same time, they are star-struck by the service. And then, admitting your mistakes may be difficult."

Some, but not all, informants remembered having written formal reports themselves. They conveyed that their reports related primarily to technical failures in the medical equipment or medication errors, such as giving the wrong medication or dose. Otherwise, most decisions made during a mission, even if in retrospect wrong, were understood to be part of the game and not errors.

"In retrospect, when you get to know the diagnosis, you can argue that it was a mistake based on that diagnosis, but at that point in time, you did not have that information, so you made that assessment on an incomplete basis."

To Report or Not

The formal incident reporting system was described as a black hole, meaning the informants often did not get the investigation results from their reports. The informants seemed to prefer informal reporting at the base, which is experienced as less cumbersome and more suitable for reporting cases and making improvement suggestions.

"It's not always easy to know where to report it, and it's quicker to think that … it's probably going well, and then we talk about it on the debrief, and we're done with it. However, that's not good."

Another objection to reporting from many informants was the fear of consequences. They emphasized the long tradition that flight operative crews had in reporting errors and near misses and how this was rewarded. They perceived that the health trust system often looks for a scapegoat.

The physicians expressed general confidence in informal reporting to colleagues at their base but skepticism toward reporting to other bases because of the lack of a system and trust between them.

"We also lack cooperation across the bases. Because I do not have to make the same mistake you made, …. so it would have been nice to know about it. Maybe I don't have to do it."

Managing the Risk

Working as a Team

The physicians considered that they were responsible for the team functioning well. Qualities highlighted for a good leader were accepting and encouraging input, assigning tasks, and giving clear instructions to bring out the best in all team members. Their goal was to ensure that the whole team had the same understanding of the situation and the same priorities. To achieve this, they tried to make a joint plan en route to the scene and, if needed, gather the team to get back on track and communicate a plan B in critical procedures.

"I think it is wise to gather all before major decisions are made, like a "war council." What will we do next? What is our plan? Because then the others I work with can come up with important input that helps me make a better decision."

Written procedures and checklists are tools to accomplish this, but a common understanding was that these must be brief and specific, mainly for complicated or seldom-performed procedures. The downside of checklists mentioned was that they do not cover every option and can be time-consuming in certain critical situations.

"I think checklists are handy when there is complex stuff where we have poor or limited knowledge and training."

The Challenging Conditions

All informants pointed out different aspects of what it means to be working under the challenging conditions of a HEMS mission, from the demanding scene to the troublesome transport.

At the scene, noise, cold, and demanding access to the patient made a thorough and systematic patient assessment demanding. An incomplete assessment may lead to both undertriage and overtriage and transport to the wrong facility.

"In a chaotic work situation, it can be anything from having overlooked severe symptoms in patients due to noise. I have been in a tunnel accident, fire trucks are running,…. We cannot communicate, so it is obvious that these are very demanding working conditions where adverse events can happen."

The type and size of the helicopter and its interior were factors affecting patient safety mentioned by all informants; this was mainly due to the problematic loading and unloading of the patient and limited access to the patient or medical equipment in-flight in some of the helicopters in use.

Informants operating helicopters with rear loading underpinned this as a critical point in patient transport. The stretcher needed to be lifted high and may tilt. The patient needing an elevated upper body had to lie supine during loading, and medical equipment was difficult to monitor. They all had experienced tubes and cannulas hooking up and dislocating when sliding the stretcher into the cabin. Still, as they were aware of the possibilities, none of them had reported events that eventually had severe consequences for the patients. Nevertheless, side loading with lower height was considered safer by those with experience in both.

The medical cabin of the smallest helicopters was described as cramped and with suboptimal ergonomics and overview. If the patient should deteriorate during transport, the physicians stated that they had limited possibility of intervention. If this was expected, they often chose transport by ground although longer transport duration.

"Of course, you never want someone to have such a problem that you cannot handle in the air.… If I had had a similar incident, I think I might have chosen to transport the patient by ground ambulance to the hospital."

Most of the informants were the sole medical provider in the cabin during most patient transports, which was experienced as a problem when the patient unexpectedly became agitated, or intervention was needed, and multiple tasks needed to be done simultaneously. A recurring experience among the informants was medication errors due to a lack of an assistant to do dual control.

"Since we are alone in the back (of the helicopter), we cannot double-check medication en route…. This is perhaps what I think is the most critical risk in flight; you pick the wrong drug for injection or miscalculate the infusion."

The Difficult Collaboration

The handover process was another situation highlighted by the informants with a potential for adverse incidents. A clear point in time where the transport team took over responsibility for the patient at interhospital transfers was often missing. Situations were mentioned where the referring doctor was not present or disappeared as soon as the transport team arrived, and responsibility had to be taken over by the transport team without all vital information present.

"And often, when we have just walked in the door, it is as if the patient is ours before we have any overview."

Examples of such vital information were if tube position was checked or IV lines were flushed, and even if considered potentially harmful, they often relied on good faith.

"So we assume someone has done it. You have a lot to focus on, right? Somehow you cannot verify everything…. Sometimes, you have to trust that the sender has done these things."

A common understanding was that, when delivering the patient, the report had to be systematic and not too long, preferably with a structure common to the recipient. The hospital trauma teams could be so focused on the patient that they did not listen to the report by the transport team. To avoid this, some informants awaited moving the patients to the trauma bed until after the report.

"So I usually leave the patient on the stretcher until I have given a report. Because as soon as the patient is lying on the trauma bed, someone starts to handle him and does not listen to the report."

The report given contains information on prehospital treatment but also which measures had been refrained from being done. For the receiving team to understand this, it was emphasized that a mutual understanding of the prehospital working conditions was needed.

"What is possible to do outside and what is possible to do inside is one thing; there is also a lack of understanding of what life is like outside among those who work in-hospital."

Taking over or handing over intensive care patients was underlined as a critical phase of interhospital transfers. Different medication protocols and pumps between the hospital and transport team, for instance, increased the risk of longer infusion pauses and dosage errors.

"It can easily go wrong when taking over infusions and drugs on syringe pumps. We often have different protocols. And then, the receiving nurse must take our syringe and program a new pump, so what is the guarantee that this is programmed correctly? There are many pitfalls."

DISCUSSION

In our study, Norwegian HEMS physicians reported that they produce only a limited number of formal incident reports as they regard the variations observed and experienced as the "nature of the HEMS missions" and reports mainly relevant when deviating from procedures, which are sparse in HEMS. The HEMS doctors prefer informal rather than formal incident reporting systems. The reasons cited are ease of use, better feedback, and less fear of consequences. Four main hazard areas related to all the phases of a HEMS mission were identified in the interviews: the physician as the team leader, medication errors, the handover process, and the helicopter as a work platform.

Patient Safety Culture and Incident Reporting

Formal incident reporting was described as cumbersome and a black hole, meaning that reports rarely elicited valuable feedback or led to improvements. Pham et al[29] suggested that the perceived value of incident reporting systems must be increased by making reporting more accessible and meaningful in that reports that have a potential for quality improvement and learning are prioritized and used to evoke changes.[29] The HEMS physicians all seemed to prefer low-threshold reporting at the base that is processed by one of their own. This finding is consistent with a study of healthcare professionals in England; physicians are most likely to report adverse events to a colleague rather than a superior.[30]

Even though the informants did not report any negative personal experiences with reporting, they still perceived the incident reporting system as punitive, which seemed to be another obstacle to formal reporting. To address this, healthcare needs to provide confidentiality better, adapt to the aviation system of immunity from disciplinary actions,[3] and change the culture from looking at errors as personal failures to an opportunity to improve the system to prevent harm.[31]

The fact that the HEMS physicians have to relate to multiple incident reporting systems fragments the reporting and does not provide a comprehensive overview of hazards and areas for improvement. Therefore, it seems evident that the HEMS system needs a unified safety management and quality improvement system that includes both medical and flight operative crew with an easy option for sharing with other bases.

Areas of Risk and Factors for Enhanced Safety

The physicians highlighted their responsibility as team leaders to accommodate good communication as imperative for shared situational awareness, thus helping decision making. Previous research in air medical transport has pointed to communication problems as the most frequent cause of events.[4,12]

A common understanding among the HEMS physicians was that checklists could be helpful if brief and reserved for complicated or seldom performed procedures. Initially adapted from aviation, checklists were introduced to reduce risk in health care.[32] The effect of checklists in prehospital work is still under debate.[5,19,33,34] However, most will agree that they must be tailored to the providers' competence.[35]

In our study, the reason for medication errors was mainly the lack of an assistant to perform independent double checking in line with standard drug management safety principles. In the literature, the reported frequency of medication errors in prehospital work is significant. However, it varies in different settings and research methods.[36,37] Systematic reviews are inconclusive regarding the effect of double checking on medication errors due to the quality of the included studies.[38,39] However, in a before-after study, overall medication errors decreased by 49% and for fentanyl by 71% after introducing a team-based medication administration cross-check procedure in a ground EMS service. Research is still insufficient on whether these results can be transferred to physician-staffed HEMS.

Informants using helicopters with rear loading and limited cabin space stated that they preferred ground transport when in-flight intubation or resuscitation during transport was anticipated. Studies have shown that in-flight intubation is as fast and safe as on-ground intubation, given a helicopter interior and staffing that facilitate this.[40,41] The possibility of intervention during flight could reduce both on-scene and transportation time and, thus, time for definitive care.

In collaboration with other health personnel, the handover process was perceived as challenging. Transferring information was often suboptimal, and different medication protocols and syringe pumps made errors with vital infusions more likely. Previous research has also found that the transition of care is associated with several risk factors; inadequate communication, lack of vital information, and adverse drug events.[42] Joint procedures and collaborative training should be relevant initiatives.

System and Individual Responsibility

Of the factors associated with risk that emerged in the interviews, some will be an individual responsibility while others are a pure system responsibility. However, also personal errors may be caused by organizational factors. The physician's qualities as a team leader require a systematic approach to recurrent training in nontechnical skills.[43,44] Checklist use is an individual decision, but a prerequisite is that they exist and are fully implemented.[35] The choice of staffing could impact medication errors and, together with the choice of helicopter type, the possibility of intervening during transport. Applying a more system-centered approach focusing on latent risk factors such as training, equipment, staffing, procedures, and organization[45] seems required to bring HEMS forward to a more proactive safety culture.[46]

The Relation to Standards and the Need for Further Research

There seemed to be a common understanding among the physicians that in-hospital standards and procedures are often not applicable in the prehospital setting and that this needs to be understood by their hospital colleagues. Although several international standards on transportation medicine have been published,[47–50] Eiding et al[19] also called for a national standard to ensure the same quality and safety for treatment prehospital as in-hospital. Thus, whether incidents affecting patient care outside the hospital can be regarded as part of a "normal variation" not leading to formal incident reports due to the exceptional environment and context of prehospital care is questionable and remains to be investigated.

LIMITATIONS

We invited experts in a field with a common background of experience. The informants in such a study are not recruited by randomization but by purposive sampling, and this should not be seen as a limitation but strength of the study.[20,23] In HEMS services with other health care professionals than physicians, different experiences and reporting cultures may exist.[30]

The main investigator and interviewer is an experienced HEMS physician, which may have influenced the analysis of the interviews and the interpretation of the results. On the other hand, it may just as well be considered a strength as it aids in taking the insider view and thus facilitates follow-up questions and richer descriptions from the informants.[24]

The study was performed in a Norwegian context. A transfer of the results to other services with different helicopter types, crew configurations, and incident reporting systems should be made with caution.[51] However, we assume that results regarding nontechnical skills also apply to other HEMS services.

Because of travel restrictions during the COVID-19 pandemic, half of the interviews were performed via video. Both interviewees and interviewer experienced this well-functioning and we do not consider this a limitation to our study.

CONCLUSIONS

In this study, Norwegian HEMS physicians preferred informal incident reporting to colleagues because of ease of use, better feedback, and less fear of personal consequences. The overall limited incident reporting was explained by the lack of procedures and the inherent unpredictability of HEMS missions. The role as team leader and the handover process was highlighted as challenging, in addition to helicopter cabin size, rear loading, and the lack of an assistant. Future studies need to investigate the bold statement that incidents in prehospital care are part of the normal and expected variation.

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Appendix

Questionnaire Study I

Questionnaire Study II

Interview guide Study III

Approvals

Questionnaire Study I

This survey will gather information from medical directors of HEMS services in Europe, North America, Australia, New Zealand and Japan. The main questions are: What is your regular crew? Do you use extra personnel by demand and how is it organized? At the end we encourage you to give your personal evaluation of the crew configuration of your service.

Who should answer?

Medical directors with medical professional responsibility for a HEMS service. If you are not, please forward the invitation mail with link to survey to the right person!

If you are responsible for more than one HEMS base, please fill out one form for every service even if most of your answers will be identical.

Questions with check boxes allow multiple answers while bullet lists only one answer. Most of the questions demand an answer. If you do not find a suitable alternative or are not able to answer a question, please tick "Other" and use the corresponding comment fields. You will be asked about some missions statistics so your annual report from 2013 is good to have within reach.

To start the survey, click "Next". Thank you for participating!

Kristen Rasmussen, MD
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BASIC INFORMATION ABOUT YOUR SERVICE

- Main country (or countries) where your service is operating?

- ☐ Albania
- ☐ Andorra
- ☐ Armenia
- ☐ Australia
- ☐ Austria
- ☐ Belgium
- ☐ Bosnia and Herzegovina
- ☐ Bulgaria
- ☐ Canada
- ☐ Croatia
- ☐ Cyprus
- ☐ Czech Republic
- ☐ Denmark
- ☐ Estonia
- ☐ Finland
- ☐ France
- ☐ Georgia
- ☐ Germany
- ☐ Greece
- ☐ Hungary

- ☐ Iceland
- ☐ Ireland
- ☐ Italy
- ☐ Japan
- ☐ Latvia
- ☐ Liechtenstein
- ☐ Lithuania
- ☐ Luxembourg
- ☐ Macedonia
- ☐ Malta
- ☐ Moldova
- ☐ Monaco
- ☐ Montenegro
- ☐ Netherlands
- ☐ New Zealand
- ☐ Norway
- ☐ Poland
- ☐ Portugal
- ☐ Romania
- ☐ Serbia
- ☐ Slovakia
- ☐ Slovenia
- ☐ Spain
- ☐ Sweden
- ☐ Switzerland
- ☐ United Kingdom
- ☐ USA
- ☐ Other; please specify:__________________

- Is your base located at a hospital, an airport or other?

- ☐ Hospital
- ☐ Airport
- ☐ Other; please specify:__________________

- What is the (estimated) population in the area that your service covers?

____

PRIMARY RESPONSE AREA

Primary response area is defined as area your service covers for on scene-calls, as the only service or together with other services.

- What is the (estimated) size of your primary response area?

Give your answer in either square miles or square km.

- ☐ Square km__________________
- ☐ Square miles__________________

- Do you characterize your primary response area as urban, rural or mixed urban/rural?

- ☐ Urban
- ☐ Rural
- ☐ Mixed urban/rural
- ☐ Other; please specify:__________________

- Do you operate 24H or daytime only?

If different operating hours ex. Summer and Winter, please specify under "Other".

- ☐ 24H
- ☐ Daytime only
- ☐ Other; please specify:__________________

- What kind of missions do you perform?

- ☐ VFR only
- ☐ IFR
- ☐ NVG
- ☐ Mountain rescue
- ☐ SAR land/coastline
- ☐ SAR off shore
- ☐ Hoist operations
- ☐ Static rope operations
- ☐ Other; please specify:__________________

VFR = Visual Flight Rules
IFR = Instrument Flight Rules
NVG = Night Vision Goggles
SAR = Search And Rescue

- How is your service financed?

If more please indicate primary source of funding.

- ☐ Charity
- ☐ Governmental
- ☐ Health insurance
- ☐ Other; please specify:__________________

- What helicopter type(s) do you use?

If more types, please indicate all types used in 2013.

- ☐ AW109
- ☐ AW109 Grand
- ☐ AW119 (Koala)
- ☐ AW139
- ☐ Bell 206
- ☐ Bell 407
- ☐ Bell 412
- ☐ Bell 427/429
- ☐ BK117
- ☐ EC120
- ☐ EC130
- ☐ EC135
- ☐ EC145
- ☐ Dauphine/SA365
- ☐ EC155
- ☐ AS 350/355
- ☐ MD Explorer
- ☐ Sikorsky S76

☐ Other; please specify:______________________________________

- Do you have additional comments on basic information about your service?

In the following questions we define "completed missions" as all missions except aborted and rejected missions. Missions without patient contact may be included, such as rescue missions.

- What was the number of missions in 2013?

Total number of completed missions: ____________
Number of completed on-scene missions (primary missions): ____________
Number of completed inter-hospital transfers: ____________
Number of completed pediatric transports (under 10 years of age): ____________
Number of transports with the use of incubator: ____________
Number of transports with the use of IABP (Intra-Aortic Balloon Pump): ____________
Number of transports with the use of ECMO (Extra-Corporal Membrane Oxygenation): ____________
Number of rescue missions with winch or static rope completed in 2013 (excluded training missions): ____________

- What other special transports of critically ill or injured patients requiring special equipment, personnel and/or care (except regular intensive care transfer and IABP, ECMO and incubator) did your service perform in 2013?

- Do you have additional comments on service statistics?

REGULAR CREW

Regular crew is defined as crew you use on all missions or the minimum crew you use on missions.

- What is the total number of your regular crew on a mission?

(Pilot(s), medical crew and other on-board support personnel)

____

- Do you operate with one to two pilots?

☐ 1 pilot
☐ 2 pilots

- Do you use other non-medical/technical personnel (ex. hoist operator, navigator) in your regular crew?

- ☐ No
- ☐ Yes; please specify:__________________

In the following questions we ask you about personnel with defined medical responsibilities or duties in the regular crew.

- What categories of medical personnel do you use in your regular crew?

	No	Yes
Physician	☐	☐
Nurse	☐	☐
EMT/Paramedic	☐	☐
Respiratory Therapist	☐	☐
HEMS Crew/Rescue Man	☐	☐
Other medical member(s) of regular crew; please specify:	______________________________	

- EMT/Paramedic: Emergency Medical Technician/Paramedic with no responsibility for flight op. or rescue missions
- HEMS crew/Rescue Man: Different medical background **with** additional flight op. and/or rescue mission responsibility

How many do you have of each category in your regular crew?

Number of each category on board:

Physician	_____
Nurse	_____
EMT/Paramedic	_____
Respiratoty Therapists	_____
HEMS Crew/Rescue Man	_____
Other medical member(s) of regular crew:	_____

- What education level do your physicians have?

- ☐ Board certified specialists only
- ☐ In training only
- ☐ Both

- What speciality are your physicians trained in?

- ☐ Anesthesiology
- ☐ Emergency medicine
- ☐ Surgery
- ☐ Internal medicine
- ☐ Pediatrics
- ☐ Other, specify:__________________

- Where do your physicians work?

Please choose the most common work combination.

- ☐ Only HEMS
- ☐ HEMS and hospital
- ☐ HEMS and ground EMS

❑ HEMS and other

If you use nurses in yours service, what formal education and certification do they have?

- Registered Nurses have college or university education corresponding a bachelor´s degree.
- Certified nurses are RN that have passed an additional exam to be certified.
- Nurse Anesthetists, Intensive Care Nurses and Neonatal Nurses should have college or university education corresponding a master´s degree.

- What education and certification do your nurses have?

❑ RN only
❑ Certified Flight Nurse – CFRN
❑ Certified Emergency Nurse – CEN
❑ Certified Critical Care Nurse – CCRN
❑ Certified Pediatric Nurse – CPEN
❑ Certified Transport Nurse – CTRN
❑ Nurse Anesthetist
❑ Intensive Care Nurse
❑ Neonatal Nurse
❑ Other, please specify:__________________

- Where do your nurses work?

Please choose the most common work combination.

❑ Only HEMS
❑ HEMS and hospital
❑ HEMS and ground EMS
❑ HEMS and other

The definition of "Emergency Medical Technicians" (EMT) and "paramedic" varies through the world and also within countries. To differ this group is divided in 3 levels after competence in airway management.

If your EMTs/Paramedics have additional responsibilities as pilot assistant, they are defined as HEMS Crew according to JAR Ops.

- What level of airway competence do the EMTs/Paramedics have in our service?

RSI = Rapid Sequence Induction

❑ Only supraglottic airway device
❑ Endotracheal intubation but not RSI
❑ Endotracheal intubation including RSI
❑ May use mechanical ventilator

- What are your HEMS Crew/Rescue Men´s highest level of medical education?

RSI = Rapid Sequence Induction

❑ No medical education
❑ EMT/Paramedic with supraglottic airway skills
❑ EMT/Paramedic with endotracheal intubation skills but not RSI
❑ EMT/Paramedic with endotracheal intubation skills including RSI
❑ Registred Nurse - RN
❑ Certified Flight Nurse – CFRN

- ☐ Certified Emergency Nurse – CEN
- ☐ Certified Critical Care Nurse – CCRN
- ☐ Certified Pediatric Nurse – CPEN
- ☐ Certified Transport Nurse – CTRN
- ☐ Nurse Anesthetist
- ☐ Intensive Care Nurse
- ☐ Neonatal Nurse
- ☐ Other, please specify:__________________

- What are your HEMS Crew/Rescue Men´s responsibilities?

- ☐ Medical assistance
- ☐ Cockpit asisstance
- ☐ Rescue operations
- ☐ Other; please specify:__________________

- Medical crew seating en route to scene (<u>no patient on board</u>) with regular crew:

	Cockpit	Cabin	May vary
Physician	☐	☐	☐
Nurse	☐	☐	☐
HEMS Crew/Rescue Man	☐	☐	☐
EMT/Paramedic	☐	☐	☐
Respiratory Therapist	☐	☐	☐
Other medical member(s) of regular crew:	☐	☐	☐

- Do you have additional comments on medical crew seating en route to scene (no patient on board) with regular crew?

- Medical crew seating <u>during patient transport</u> with regular crew:

	Cockpit	Cabin	May vary
Physician	☐	☐	☐
Nurse	☐	☐	☐
HEMS Crew/Rescue Man	☐	☐	☐
EMT/Paramedic	☐	☐	☐
Respiratory Therapist	☐	☐	☐
Other medical member(s) of regular crew:	☐	☐	☐

- Do you have additional comments on medical crew seating during patient transport with regular crew?

- Do you use same seating on all patient transports or seating by demand?

- ☐ Same
- ☐ By demand

- Is seating dependent on weather conditions?

- ☐ No
- ☐ Yes

- Is seating dependent on day or night?

- ☐ No
- ☐ Yes

- Do you have other comments on regular crew?

Additional medical personnel by demand

Many services may use extra personnel for some missions. This may be before start of mission, personnel from referring hospital or from scene of accident or other. In the next part of the survey, we ask you to provide us with what kind of additional personnel your service uses if any.

Excluded are extra personnel for educational purposes, supervision or trainees etc.

- Do you use extra medical personnel by demand (as part of patient care, not for education)?

- ☐ No
- ☐ Yes

- What type of extra medical personnel did you use in 2013?

- ☐ Physician
- ☐ Nurse
- ☐ EMT/Paramedic
- ☐ Respiratory Therapist
- ☐ Midwife
- ☐ Perfusionist
- ☐ Other, specify:_________________

- If you used physicians as extra personnel, do you use certified specialist only, "in training" physicians only or both?

- ☐ Board certified specialists only
- ☐ In training only
- ☐ Both

- What specialty were the extra physicians trained in?

- ☐ Anesthesiology
- ☐ Emergency medicine
- ☐ Surgery
- ☐ Internal medicine
- ☐ Pediatrics
- ☐ Other, specify:_________________

- If you used extra nurses in 2013, what education or certification did they have?

- ☐ RN only
- ☐ Certified Flight Nurse – CFRN

- ☐ Certified Emergency Nurse – CEN
- ☐ Certified Critical Care Nurse – CCRN
- ☐ Certified Pediatric Nurse – CPEN
- ☐ Certified Transport Nurse – CTRN
- ☐ Nurse Anesthetist
- ☐ Intensive Care Nurse
- ☐ Neonatal Nurse
- ☐ Other, please specify:__________________

- When extra personnel are used, when do they join the regular crew?

- ☐ Before start of mission
- ☐ From scene on primary missions
- ☐ From referring hospital

- If you use extra personnel from scene, do you use EMS personnel or people not working in EMS?

EMS= emergency medical service/ambulance service.

- ☐ EMS personnel
- ☐ Non-EMS personnel

- Do you have comments on extra personnel?

Evaluation of Crew Model

- What are the reasons for the choice of crew configuration?

Please rank the 3 most important reasons from 1 to 3.

Recruitment of special personnel	____________
Aircraft configuration	____________
Economical	____________
Scientific evidence	____________
Governmental politics	____________
Tradition	____________
Legal issues	____________
Company politics	____________

- Do you have additional comments on reasons for choice of crew configuration?

You will now find some statements regarding flight safety, crew resource management (CRM) and patient care in HEMS. Please indicate the statement that represents your service best!

- When using <u>regular crew</u> at your service, how do you evaluate <u>flight safety</u>?

	Totally unacceptable	Unacceptable	Slightly unacceptable	Neutral	Slightly acceptable	Acceptable	Perfectly acceptable	Not relevant for our service
En route without patient on board:	☐	☐	☐	☐	☐	☐	☐	
During patient transport in general:	☐	☐	☐	☐	☐	☐	☐	
During daylight missions:	☐	☐	☐	☐	☐	☐	☐	
During night missions:	☐	☐	☐	☐	☐	☐	☐	☐
During primary missions/on scene calls:	☐	☐	☐	☐	☐	☐	☐	☐
During: special transports:	☐	☐	☐	☐	☐	☐	☐	☐
During rescue missions:	☐	☐	☐	☐	☐	☐	☐	☐
During inter-hospital transfers:	☐	☐	☐	☐	☐	☐	☐	☐

- When using <u>regular crew</u> at your service, how do you evaluate <u>patient safety</u>?

	Totally unacceptable	Unacceptable	Slightly unacceptable	Neutral	Slightly acceptable	Acceptable	Perfectly acceptable	Not relevant for our service
During patient transport in general:	☐	☐	☐	☐	☐	☐	☐	
During daylight missions:	☐	☐	☐	☐	☐	☐	☐	
During night missions:	☐	☐	☐	☐	☐	☐	☐	☐

- When using <u>extra personnel</u> for special transports, I find <u>flight safety</u> to be:

☐ Totally unacceptable
☐ Unacceptable
☐ Slightly unacceptable
☐ Neutral
☐ Slightly acceptable
☐ Acceptable
☐ Perfectly acceptable
☐ Not relevant for our service

- When using <u>extra personnel</u> for rescue missions, I find <u>flight safety</u> to be:

☐ Totally unacceptable
☐ Unacceptable
☐ Slightly unacceptable
☐ Neutral
☐ Slightly acceptable
☐ Acceptable
☐ Perfectly acceptable
☐ Not relevant for our service

- When using <u>extra personnel</u> for special transports or rescue missions etc., I find <u>crew resource management</u> (CRM) to be:

☐ Totally unacceptable
☐ Unacceptable
☐ Slightly unacceptable
☐ Neutral
☐ Slightly acceptable
☐ Acceptable
☐ Perfectly acceptable
☐ Not relevant for our service

- Regarding following characteristics, the helicopter type in our service is a limitation for us on:

	No missions	A few missions	Some missions	Many missions	All missions
Cabin size	☐	☐	☐	☐	☐

External size	❑	❑	❑	❑	❑
Endurance	❑	❑	❑	❑	❑
Power performance	❑	❑	❑	❑	❑

- How satisfied are you with the choice of crew configuration at your service from the following aspects:

	Not at all satisfied	Slightly satisfied	Moderately satisfied	Very satisfied	Extremely satisfied
Flight safety	❑	❑	❑	❑	❑
Patient safety	❑	❑	❑	❑	❑
Crew cooperation	❑	❑	❑	❑	❑
Economic efficiency	❑	❑	❑	❑	❑
Mission efficiency	❑	❑	❑	❑	❑

- In your opinion, what are the <u>disadvantages</u> of the choice of crew configuration in your service?

- In your opinion, what are the <u>advantages</u> of the choice of crew configuration in your service?

- If you could choose freely, what do you consider as optimal medical crew configuration for your service?

(Number of each to be given on next page.)

	No	Yes
Physician	❑	❑
Nurse	❑	❑
EMT/Paramedic	❑	❑
Respiratory Therapist	❑	❑
HEMS Crew/Rescue Man	❑	❑

Other medical member(s) of regular crew; please specify: ______________________

- How many of each category do you wish to have in your regular crew?

Number of each category on board:

Physician ____

Nurse ____

EMT/Paramedic ____

Respiratory Therapist _____
HEMS Crew/Rescue Man _____
Other medical member(s) of regular crew: _____

- Do you have additional comments on evaluation of crew configuration?

- Do you have comments on this survey in general?

Thank you for participating in this survey!

You may print your questionnaire by clicking on the printer symbol below. To exit the survey, just close your browser.

Questionnaire Study II

Thank you for taking the time to respond to this **national survey** from the University of Stavanger.

The survey maps **your opinion** on patient safety, adverse events and incident reporting in your prehospital service. Your response will be treated strictly confidentially and your identity will not be traceable. The questionnaire should take approximately 15 minutes to complete.

Read the statements carefully. Be honest when answering. For each of the statements choose the one that fits best.

With regards
Leif Inge K. Sørskår
University of Stavanger

I have received information about the study and I am willing to participate

☐ Yes
☐ No

J: Background information

What is your primary work area? Select ONE Answer or specify. (If more primary work areas, choose the option that best fits what you want to answer.)

☐ Ground EMS/ambulance
☐ Physician manned rapid response car/ambulance
☐ Ambulance boat
☐ Helicopter emergency medical service (HEMS)
☐ Search and rescue helicopter (SAR)
☐ Fixed wing air ambulance
☐ Other, please specify: _____

A: Your work area/unit and patient safety

Definitions:

- ***"Your local unit"*** *is defined as the unit where you primarily work. EXAMPLE: An ambulance station, a pre-hospital base or department or similar located in the same geographical location.*
- *An* ***"adverse event"*** *is defined as an accidental event due to medical examination and/or treatment.*

Please indicate your agreement or disagreement with the following statements regarding your own local unit.

	Strongly disagree	Disagree	Neither	Agree	Strongly agree
People support one another in our local unit	☐	☐	☐	☐	☐
We have enough staff to handle the workload	☐	☐	☐	☐	☐
When a lot of work needs to be done quickly, we work together as a team to get the work done	☐	☐	☐	☐	☐
In our local unit, people treat each other with respect	☐	☐	☐	☐	☐
Staff in our local unit work longer hours than is best for patient care	☐	☐	☐	☐	☐
We are actively doing things to improve patient safety	☐	☐	☐	☐	☐
We use more agency/temporary staff than is best for patient care	☐	☐	☐	☐	☐
Staff feel like their mistakes are held against them	☐	☐	☐	☐	☐
Mistakes have led to positive changes here	☐	☐	☐	☐	☐
It is just by chance that more serious mistakes do not happen in our local unit.	☐	☐	☐	☐	☐
When one area in this unit gets really busy, others help out	☐	☐	☐	☐	☐
When an event is reported, it feels like the person is being written up, not the problem	☐	☐	☐	☐	☐
After we make changes to improve patient safety, we evaluate their effectiveness	☐	☐	☐	☐	☐
We work in "crisis mode" trying to do too much, too quickly	☐	☐	☐	☐	☐

Patient safety is never sacrificed to get more work done	☐	☐	☐	☐	☐
Staff worry that mistakes they make are kept in their personnel file	☐	☐	☐	☐	☐
We have patient safety problems in our local unit	☐	☐	☐	☐	☐
Our procedures and systems are good at preventing errors from happening	☐	☐	☐	☐	☐
I will ask my colleagues to stop work I consider is done in an unsafe manner	☐	☐	☐	☐	☐
I will report if I become aware of a dangerous situation	☐	☐	☐	☐	☐

B: Safety of employees

Please indicate your agreement or disagreement with the following statements regarding your own local unit.

	Strongly disagree	Disagree	Neither	Agree	Strongly agree
My colleagues will stop me if I work in an unsafe manner	☐	☐	☐	☐	☐
I will stop doing my job if I think it might be dangerous for me or others to continue	☐	☐	☐	☐	☐

C: Your supervisor/manager

Definition:
*The terms **"with us"** and **"management"** refer to the local unit where you primarily work, and to the management in this unit, respectively.*

Please indicate your agreement or disagreement with the following statements about your immediate supervisor/manager or person to whom you directly report in your local unit.

	Strongly disagree	Disagree	Neither	Agree	Strongly agree
My local supervisor/manager says a good word when he/she sees a job done according to established patient safety procedures	☐	☐	☐	☐	☐
My local supervisor/manager considers staff suggestions for improving patient safety	☐	☐	☐	☐	☐
Whenever pressure builds up, my local supervisor/manager wants us to work faster, even if it means taking shortcuts	☐	☐	☐	☐	☐
My local supervisor/manager ignores patient-safety problems that happen over and over	☐	☐	☐	☐	☐

D: Communication

How often do the following things happen in your work area/local unit?

	Strongly disagree	Disagree	Neither	Agree	Strongly agree
We are given feedback about changes put into place based on event reports	☐	☐	☐	☐	☐
Staff will freely speak up if they see something that may negatively affect patient care	☐	☐	☐	☐	☐
We are informed about errors that happen in this unit	☐	☐	☐	☐	☐
Staff feel free to question the decisions or actions of those with more authority	☐	☐	☐	☐	☐
In my local unit we discuss ways to prevent errors from happening again	☐	☐	☐	☐	☐
Staff are afraid to ask questions when something does not seem right	☐	☐	☐	☐	☐

E: Your evaluation of the patient safety

Please give your work area/local unit an overall grade on patient safety.

- ☐ Excellent
- ☐ Very Good
- ☐ Acceptable
- ☐ Poor
- ☐ Very poor

F: Frequency of events reported

In your work area/local unit, when the following incidents happen, how often are they reported?

	Never	Rarely	Sometimes	Most of the time	Always
When a mistake is made, but is caught and corrected before affecting the patient, how often is this reported?	☐	☐	☐	☐	☐
When a mistake is made, but has no potential to harm the patient, how often is it reported?	☐	☐	☐	☐	☐
When a mistake is made that could harm the patient, but does not, how often is this reported?	☐	☐	☐	☐	☐

G: Number of events reported

In the past 12 months, how many event reports have you filled out and submitted?

- ☐ No rapports
- ☐ 1-2 rapports
- ☐ 3-5 rapports
- ☐ 6-10 rapports
- ☐ 11-20 rapports
- ☐ 21 rapports or more

H: The pre-hospital system

Please indicate your agreement or disagreement with the following statements about your pre-hospital system. (Ground EMS, HEMS dispatch center, emergency department, GP on call etc.)

	Strongly disagree	Disagree	Neither	Agree	Strongly agree
Hospital management provides a work climate that promotes patient safety	☐	☐	☐	☐	☐
Pre-hospital units do not coordinate well with each other	☐	☐	☐	☐	☐
Things "fall between the cracks" when transferring patients from one unit to another	☐	☐	☐	☐	☐
There is good cooperation among units that need to work together	☐	☐	☐	☐	☐
Important patient care information is often lost during patient handover	☐	☐	☐	☐	☐
It is often difficult to work with staff from other units in the prehospital system	☐	☐	☐	☐	☐
Problems often occur in the exchange of information across prehospital units	☐	☐	☐	☐	☐
The actions of hospital management show that patient safety is a top priority	☐	☐	☐	☐	☐
Hospital management seems interested in patient safety only after an adverse event happens	☐	☐	☐	☐	☐
Prehospital units work well together to provide the best care for patients	☐	☐	☐	☐	☐
Handovers are problematic for patients in this prehospital system	☐	☐	☐	☐	☐

I: Education and training

Do you feel that your pre-hospital skills are deficient related to challenges you have to face in your prehospital work?

	Deficient	NOT deficient
Decision-making	☐	☐
Leadership	☐	☐
Communication	☐	☐
Situation awareness	☐	☐
Teamwork	☐	☐
Managing stress	☐	☐
Coping with fatigue	☐	☐

How many times during 2015 did you participate in multidisciplinary pre-hospital simulation-based training of one or more of the skills below, along with your professional partners?

	0 times	1-2 times	3-5 times	More than 5 times
Decision-making	☐	☐	☐	☐
Leadership	☐	☐	☐	☐
Communication	☐	☐	☐	☐
Situation awareness	☐	☐	☐	☐
Teamwork	☐	☐	☐	☐
Managing stress	☐	☐	☐	☐
Coping with fatigue	☐	☐	☐	☐

How many times during 2015 were the following of your pre-hospital skills systematically observed and evaluated?

	0 times	1-2 times	3-5 times	More than 5 times
Decision-making	☐	☐	☐	☐
Leadership	☐	☐	☐	☐
Communication	☐	☐	☐	☐
Situation awareness	☐	☐	☐	☐
Teamwork	☐	☐	☐	☐
Managing stress	☐	☐	☐	☐
Coping with fatigue	☐	☐	☐	☐

Where is your primary prehospital unit located? Select ONE option or please specify.

☐ Nordlandssykehuset HF
☐ Universitetssykehuset Nord-Norge HF
☐ Helgelandssykehuset HF
☐ Finnmarkssykehuset HF
☐ St. Olavs Hospital HF
☐ Helse Nord-Trøndelag HF
☐ Helse Møre og Romsdal HF
☐ Helse Fonna HF
☐ Helse Førde HF
☐ Helse Stavanger HF
☐ Helse Bergen HF

- ☐ Oslo Universitetssykehus HF
- ☐ Vestre Viken HF
- ☐ Sørlandet sykehus HF
- ☐ Sykehuset Innlandet HF
- ☐ Sykehuset Telemark HF
- ☐ Sykehuset Vestfold HF
- ☐ Sykehuset Østfold HF
- ☐ Other, please specify: _____

What is your staff position? Select one answer that best describes your staff position.

- ☐ EMT with authorization
- ☐ Paramedic (in-house training)
- ☐ Paramedic (university college)
- ☐ HEMS Crew Member (HCM)
- ☐ Nurse anaesthetist (with EMT authorization)
- ☐ Nurse anaesthetist (w/o EMT authorization)
- ☐ Intensive care nurse (with EMT authorization)
- ☐ Intensive care nurse (w/o EMT authorization)
- ☐ Nurse (with EMT authorization)
- ☐ Nurse (w/o EMT authorization)
- ☐ Physician in training, anaesthesiology
- ☐ Physician, anaesthesiologist
- ☐ Other, please specify: _____

In your staff position, do you typically have direct interaction or contact with patients?

- ☐ YES, I typically have direct interaction or contact with patients.
- ☐ NO, I typically do NOT have direct interaction or contact with patients.

How long have you worked in the pre-hospital system?

- ☐ Less than 1 year
- ☐ 1 to 5 years
- ☐ 6 to 10 years
- ☐ 11 to 15 years
- ☐ 16 to 20 years
- ☐ 21 years or more

How many consecutive hours do your regularly scheduled on-call duty last at most?

- ☐ Up to 8 hours
- ☐ 9 - 12 hours
- ☐ 13 - 16 hours
- ☐ 17 - 24 hours
- ☐ 25 - 48 hours
- ☐ 49 - 72 hours
- ☐ 4 to 7 days
- ☐ More than 7 days – please specify: _____

How long have you worked in your current specialty or profession?

- ☐ Less than 1 year
- ☐ 1 to 5 years
- ☐ 6 to 10 years
- ☐ 11 to 15 years
- ☐ 16 to 20 years
- ☐ 21 years or more

K: Your comments

Which are the three most prevalent adverse events you have observed or caused yourself in the pre-hospital environment?

Which are the three measures that you think could improve pre-hospital patient safety?

Please feel free to write any comments about patient safety, error, or event-reporting in your pre-hospital system.

Thank you for completing the survey!

Interview guide Study III

University of Stavanger

Semi-structured Interview Guide

- What is your age?
- How long have you been working in the air ambulance service?
- Where are you working now?
- Have you been working, or are you working at several bases?
- What is the staffing at your previous and present bases?

In this conversation, I would like to hear your thoughts on patient safety in the air ambulance service, what factors you think can affect this, and your experiences from your everyday work in the service.

1. Research suggests that there is an under-reporting of errors and near misses in medical treatment in the air ambulance service. What do you think about this?
2. If this is the case, what do you think is the reason for so little reporting?
3. Have you yourself reported errors or near misses on your shifts? If not, why?
4. Do you know of others at your base who have reported errors?
5. Do you know of errors or near misses at the accident scene or when picking up the patient at the referring hospital, or can you imagine errors that could happen there and what could be the cause? What can make it go better next time?
6. Do you know of errors or near misses during loading or unloading the helicopter, or can you imagine mistakes that could happen there and what could be the cause? What can make it go better next time?
7. Do you know of mistakes or near misses during transport, or can you imagine mistakes that could happen there and what could be the cause? What can make it go better next time?
8. Do you know of errors or near misses during handover in the hospital, or can you imagine errors that could happen there and what could be the cause? What can make it go better next time?
9. In your opinion, what do you think is most important for better patient safety in the air ambulance service?

Conclusion

- How do you think it was to be interviewed about this?
- Is there anything you would like to add at the end?

Universitetet i Stavanger

Intervjuguide

a. Hva er din alder?

b. Hvor lenge har du arbeidet i luftambulansetjenesten?

c. Hvor jobber du nå?

d. Har du jobbet eller jobber du på flere baser?

e. Hva er bemanningen der har jobbet tidligere og jobber nå?

I denne samtalen vil jeg gjerne høre om dine tanker rundt pasientsikkerhet i luftambulansetjenesten, om hvilke forhold du tenker kan påvirke dette og om dine erfaringer fra egen arbeidshverdag i tjenesten.

1. Forskning antyder at det er en underrapportering av feil og nestenuhell i den medisinske behandlingen i luftambulansetjenesten. Hva tenker du om dette?

2. I så fall, hva tror du er årsak til at så lite meldes?

3. Har du selv meldt fra om feil eller nestenuhell på dine vakter? Hvis ikke, hvorfor?

4. Kjenner du til at andre der du arbeider har meldt om feil?

5. Kjenner du til feil eller nestenuhell som har skjedd på skadested/hentested eller kan du tenke deg feil som kan skje der og hva som kan være årsaken?
   Hva skal til for at det går bedre neste gang?

6. Kjenner du til feil eller nestenuhell som har skjedd under inn- eller utlasting i helikopteret eller kan du tenke deg feil som kan skje der og hva som kan være årsaken?
   Hva skal til for at det går bedre neste gang?

7. Kjenner du til feil eller nestenuhell som har skjedd under transport eller kan du tenke deg feil som kan skje der og hva som kan være årsaken?
   Hva skal til for at det går bedre neste gang?

8. Kjenner du til feil eller nestenuhell som har skjedd under overlevering på sykehus eller kan du tenke deg feil som kan skje der og hva som kan være årsaken?
   Hva skal til for at det går bedre neste gang?

9. Hva tenker du alt i alt er det viktigste for god pasientsikkerhet i luftambulansetjenesten?

Avslutning

- Hvordan synes du det var å bli intervjuet om dette?

- Er det noe du vil tilføye til slutt?

Approvals Study I

Sv: REK vest 2014/760 Pasientsikkerhet i luftambulansetjenesten

post@helseforskning.etikkom.no <post@helseforskning.etikkom.no>
on. 23.04.2014 13:25
Til:Rasmussen, Kristen <kristen.rasmussen@norskluftambulanse.no>

Vår ref. nr.: 2014/760
Prosjekttittel: "Pasientsikkerhet i luftambulansetjenesten"
Prosjektleder: Kristen Rasmussen

Kjære Kristen Rasmussen,

Jeg viser til Framleggingsvurdering mottatt 08.04.2014.

Generelt om fremleggingsplikt for REK
Helseforskningsloven gjelder for medisinsk og helsefaglig forskning på mennesker, humant biologisk materiale eller helseopplysninger. Medisinsk og helsefaglig forskning defineres som "virksomhet som utføres med vitenskapelig metodikk for å skaffe til veie ny kunnskap om sykdom og helse", jf. helseforskningsloven § 4 bokstav a. Slike prosjekter må søke REK.

Om studien
Formålet med studien er å kartlegge eksisterende bemanningsmodeller benyttet i internasjonale luftambulansetjenester. Det vil bli samlet inn informasjon om de enkelte luftambulansebasers organisering, bemanning og samlede aktivitet i 2013. I tillegg vil de bli spurt om en begrunnelse for valg av bemanningsmodell og en egenevaluering i forhold til ulike aspekt ved tjenesten som flysikkerhet, pasientsikkerhet, samarbeid innad i crewet og økonomi.

Formålet med dennes studien kan ikke sies å være søken etter ny kunnskap *om helse og sykdom som sådan, men mer en studie av helsetjenesten. Individuelle helseopplysninger skal ikke innhentes.* Min vurdering er dermed at dere ikke trenger å søke REK.

Jeg gjør oppmerksom på at konklusjonen er å anse som veiledende jfr. forvaltningsloven § 11. Dersom du likevel ønsker å søke REK vil søknaden bli behandlet i komitémøte, og det vil bli fattet et enkeltvedtak etter forvaltningsloven.

Du bør kontakte personvernombudet/Datatilsynet for å finne ut om prosjektet skal meldes dit.

Med vennlig hilsen
Camilla Gjerstad
rådgiver
post@helseforskning.etikkom.no
T: 55978499

Regional komité for medisinsk og helsefaglig forskningsetikk REK vest-Norge (REK vest)
http://helseforskning.etikkom.no

SPREK banner 20100316.jpg

Norsk samfunnsvitenskapelig datatjeneste AS
NORWEGIAN SOCIAL SCIENCE DATA SERVICES

NSD

Harald Hårfagres gate 29
N-5007 Bergen
Norway
Tel: +47-55 58 21 17
Fax: +47-55 58 96 50
nsd@nsd.uib.no
www.nsd.uib.no
Org.nr. 985 321 884

Kristen Rasmussen
Institutt for helsefag Universitetet i Stavanger
Ullandhaug
4036 STAVANGER

Vår dato: 20.05.2014 Vår ref: 38659 / 3 / LB Deres dato: Deres ref:

TILBAKEMELDING PÅ MELDING OM BEHANDLING AV PERSONOPPLYSNINGER

Vi viser til melding om behandling av personopplysninger, mottatt 30.04.2014. Meldingen gjelder prosjektet:

38659	*Medical crew in helicopter emergency medical service survey*
Behandlingsansvarlig	*Universitetet i Stavanger, ved institusjonens øverste leder*
Daglig ansvarlig	*Kristen Rasmussen*

Personvernombudet har vurdert prosjektet og finner at behandlingen av personopplysninger er meldepliktig i henhold til personopplysningsloven § 31. Behandlingen tilfredsstiller kravene i personopplysningsloven.

Personvernombudets vurdering forutsetter at prosjektet gjennomføres i tråd med opplysningene gitt i meldeskjemaet, korrespondanse med ombudet, ombudets kommentarer samt personopplysningsloven og helseregisterloven med forskrifter. Behandlingen av personopplysninger kan settes i gang.

Det gjøres oppmerksom på at det skal gis ny melding dersom behandlingen endres i forhold til de opplysninger som ligger til grunn for personvernombudets vurdering. Endringsmeldinger gis via et eget skjema, http://www.nsd.uib.no/personvern/meldeplikt/skjema.html. Det skal også gis melding etter tre år dersom prosjektet fortsatt pågår. Meldinger skal skje skriftlig til ombudet.

Personvernombudet har lagt ut opplysninger om prosjektet i en offentlig database, http://pvo.nsd.no/prosjekt.

Personvernombudet vil ved prosjektets avslutning, 31.03.2015, rette en henvendelse angående status for behandlingen av personopplysninger.

Vennlig hilsen

Katrine Utaaker Segadal

Lene Christine M. Brandt

Kontaktperson: Lene Christine M. Brandt tlf: 55 58 89 26
Vedlegg: Prosjektvurdering

Avdelingskontorer / *District Offices:*
OSLO: NSD. Universitetet i Oslo, Postboks 1055 Blindern, 0316 Oslo. Tel: +47-22 85 52 11. nsd@uio.no
TRONDHEIM: NSD. Norges teknisk-naturvitenskapelige universitet, 7491 Trondheim. Tel: +47-73 59 19 07. kyrre.svarva@svt.ntnu.no
TROMSØ: NSD. SVF, Universitetet i Tromsø, 9037 Tromsø. Tel: +47-77 64 43 36. nsdmaa@sv.uit.no

Personvernombudet for forskning

Prosjektvurdering - Kommentar

Prosjektnr: 38659

Utvalget får skriftlig informasjon om prosjektet og behandlingen av personopplysninger. De som ønsker å delta samtykker ved besvart spørreskjema. Informasjonen er tilfredsstillende utformet såfremt det presiseres at det er Universitetet i Stavanger som er behandlingsansvarlig institusjon. Videre må ordet "anonymt" tas bort fra avsnittet "Anonymity and safety information", både i overskriften og i selve avsnittet (delen om at deltakelse er frivillig beholdes). Endelig er det tilstrekkelig å opplyse om at prosjektet er meldt til Personvernombudet for forskning (ikke godkjent av REK når de finner prosjektet "ikke søknadspliktig").

Personvernombudet ber om å få tilsendt revidert informasjonsskriv før det distribueres til utvalget. Skrivet sendes til: personvernombudet@nsd.uib.no

Rambøll/SurveyXact er databehandler for prosjektet. Personvernombudet forutsetter at det foreligger en databehandleravtale mellom databehandler og Universitetet i Stavanger for den behandling av data som finner sted, jf. personopplysningsloven § 15. For råd om hva databehandleravtalen bør inneholde, se Datatilsynets veileder på denne siden: http://www.datatilsynet.no/verktoy-skjema/Skjema-maler/Databehandleravtale---mal/

Personvernombudet legger til grunn at forsker etterfølger Universitetet i Stavanger sine interne rutiner for datasikkerhet. Forventet prosjektslutt er 31.03.2015. Ifølge prosjektmeldingen skal innsamlede opplysninger da anonymiseres. Anonymisering innebærer å bearbeide datamaterialet slik at ingen enkeltpersoner kan gjenkjennes. Det gjøres ved:
- å slette direkte personopplysninger (som navn/koblingsnøkkel)
- og slette/omskrive indirekte personopplysninger (identifiserende sammenstilling av bakgrunnsopplysninger som f.eks. bosted/arbeidssted, alder og kjønn)

Vi gjør oppmerksom på at også databehandler (Rambøll/SurveyXact), må slette personopplysninger tilknyttet prosjektet i sine systemer. Dette inkluderer eventuelle logger og koblinger mellom IP-/epostadresser og besvarelser.

Approvals Study II

Vår ref. nr.: 2015/2249
Prosjekttittel: "Prehospital sikkerhetskultur"
Prosjektleder: Leif Inge K. Sørskår

Kjære Leif Inge K. Sørskår,

Jeg viser til Framleggingsvurdering mottatt 18.11.2015.

Generelt om fremleggingsplikten for REK
Helseforskningsloven gjelder for medisinsk og helsefaglig forskning på mennesker, humant biologisk materiale eller helseopplysninger. Medisinsk og helsefaglig forskning defineres som virksomhet som utføres med vitenskapelig metodikk for å skaffe til veie ny kunnskap om helse og sykdom. Slike studier må søke REK.

Vurdering av prosjektet
Etter min oppfatning er dette prosjektet ikke fremleggingspliktig for REK.

Formålet med studien er å kartlegge holdninger til pasientsikkerhet i ambulansetjenesten. Prosjektet vil kartlegge sikkerhetsklimaet innenfor ambulansetjenesten ved å se på bl.a. kommunikasjon, ledelse, beslutningstaking og situasjonsoppmerksomhet. Studien gjennomføres som en nasjonal spørreundersøkelse blant alle ansatte i ambulansetjenesten og luftambulansetjenesten i Norge. REK oppfatter at formålet med studien faller utenfor helseforskningsloven. Forskningsformålet er å studere sikkerhetsklima og holdninger hos ansatte i helsetjenesten, men ikke å søke ny kunnskap om sykdom og helse som sådan, slik det er definert i helseforskningsloven. Du trenger derfor ikke å søke REK.

Du bør kontakte personvernombudet for om studien må meldes dit.

Vi gjør oppmerksom på at konklusjonen er å anse som veiledende, jfr. forvaltningslovens § 11. Dersom du likevel ønsker å søke REK, må du fylle ut skjema for «Prosjektsøknad». Fullstendig søknad vil bli behandlet i komitémøte, og det vil bli fattet enkeltvedtak etter forvaltningsloven.

Med vennlig hilsen
Camilla Gjerstad
rådgiver
post@helseforskning.etikkom.no
T: 55978499

Regional komité for medisinsk og helsefaglig forskningsetikk REK vest-Norge (REK vest)
http://helseforskning.etikkom.no

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Norsk samfunnsvitenskapelig datatjeneste AS
NORWEGIAN SOCIAL SCIENCE DATA SERVICES

Harald Hårfagres gate 29
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Tel: +47-55 58 21 17
Fax: +47-55 58 96 50
nsd@nsd.uib.no
www.nsd.uib.no
Org.nr. 985 321 884

Leif Inge K. Sørskår
Institutt for industriell økonomi, risikostyring og planlegging Universitetet i Stavanger

4036 STAVANGER

Vår dato: 04.01.2016 Vår ref: 45723 / 3 / HIT Deres dato: Deres ref:

TILBAKEMELDING PÅ MELDING OM BEHANDLING AV PERSONOPPLYSNINGER

Vi viser til melding om behandling av personopplysninger, mottatt 18.11.2015. All nødvendig informasjon om prosjektet forelå i sin helhet 27.11.2015. Meldingen gjelder prosjektet:

45723	*Måling av prehospital sikkerhetskultur ved bruk av Hospital Survey On Patient Safety Culture (HSOPSC)*
Behandlingsansvarlig	*Universitetet i Stavanger, ved institusjonens øverste leder*
Daglig ansvarlig	*Leif Inge K. Sørskår*

Personvernombudet har vurdert prosjektet og finner at behandlingen av personopplysninger er meldepliktig i henhold til personopplysningsloven § 31. Behandlingen tilfredsstiller kravene i personopplysningsloven.

Personvernombudets vurdering forutsetter at prosjektet gjennomføres i tråd med opplysningene gitt i meldeskjemaet, korrespondanse med ombudet, ombudets kommentarer samt personopplysningsloven og helseregisterloven med forskrifter. Behandlingen av personopplysninger kan settes i gang.

Det gjøres oppmerksom på at det skal gis ny melding dersom behandlingen endres i forhold til de opplysninger som ligger til grunn for personvernombudets vurdering. Endringsmeldinger gis via et eget skjema, http://www.nsd.uib.no/personvern/meldeplikt/skjema.html. Det skal også gis melding etter tre år dersom prosjektet fortsatt pågår. Meldinger skal skje skriftlig til ombudet.

Personvernombudet har lagt ut opplysninger om prosjektet i en offentlig database, http://pvo.nsd.no/prosjekt.

Personvernombudet vil ved prosjektets avslutning, 31.12.2016, rette en henvendelse angående status for behandlingen av personopplysninger.

Vennlig hilsen

Katrine Utaaker Segadal

Hildur Thorarensen

Kontaktperson: Hildur Thorarensen tlf: 55 58 26 54
Vedlegg: Prosjektvurdering

Dokumentet er elektronisk produsert og godkjent ved NSDs rutiner for elektronisk godkjenning.

Avdelingskontorer / *District Offices:*
OSLO: NSD. Universitetet i Oslo, Postboks 1055 Blindern, 0316 Oslo. Tel: +47-22 85 52 11. nsd@uio.no
TRONDHEIM: NSD. Norges teknisk-naturvitenskapelige universitet, 7491 Trondheim. Tel: +47-73 59 19 07. kyrre.svarva@svt.ntnu.no
TROMSØ: NSD. SVF, Universitetet i Tromsø, 9037 Tromsø. Tel: +47-77 64 43 36. nsdmaa@sv.uit.no

Personvernombudet for forskning

Prosjektvurdering - Kommentar

Prosjektnr: 45723

Utvalget informeres skriftlig om prosjektet og samtykker til deltakelse. Informasjonsskriv og samtykkeerklæring er noe mangelfullt utformet. Vi ber derfor om at følgende endres/tilføyes:
- delsetningen "Alle svar forblir anonyme" slettes, da dette ikke stemmer når datamaterialet inneholder indirekte identifiserende opplysninger. Det bør dermed endres til f.eks. "Alle svar behandles konfidensielt".

Personvernombudet legger til grunn at forsker etterfølger Universitetet i Stavanger sine interne rutiner for datasikkerhet. Dersom personopplysninger skal sendes elektronisk, bør opplysningene krypteres tilstrekkelig.

SurveyXact er databehandler for prosjektet. Universitetet i Stavanger skal inngå skriftlig avtale med SurveyXact om hvordan personopplysninger skal behandles, jf. personopplysningsloven § 15. For råd om hva databehandleravtalen bør inneholde, se Datatilsynets veileder: http://www.datatilsynet.no/Sikkerhet-internkontroll/Databehandleravtale/.

Forventet prosjektslutt er 31.12.2016. Ifølge prosjektmeldingen skal innsamlede opplysninger da anonymiseres. Anonymisering innebærer å bearbeide datamaterialet slik at ingen enkeltpersoner kan gjenkjennes. Det gjøres ved å:
- slette direkte personopplysninger (som navn/koblingsnøkkel)
- slette/omskrive indirekte personopplysninger (identifiserende sammenstilling av bakgrunnsopplysninger som f.eks. bosted/arbeidssted, alder og kjønn)

Vi gjør oppmerksom på at også databehandler (SurveyXact) må slette personopplysninger tilknyttet prosjektet i sine systemer. Dette inkluderer eventuelle logger og koblinger mellom IP-/epostadresser og besvarelser.

Approvals Study III

Svar på fremleggingsvurdering, ikke fremleggingspliktig

insights-no-reply@machina.no
på vegne av
Jessica.Svard@uib.no
ti. 20.08.2019 14:05
Til: Kristen Rasmussen - Stiftelsen Norsk Luftambulanse <kristen.rasmussen@norskluftambulanse.no>

Pasientsikkerhet i luftambulansetjenesten: en kvalitativ undersøkelse

Vår ref. nr.: 33093

Jeg viser til framleggingsvurdering innsendt 18.08.2019. REK vest ved sekretariatet vurderte saken.

REK sin forståelse av prosjektet
Denne studien vil søke å identifisere områder ved virksomheten i luftambulansetjenesten der det er særlig risiko for uønskede hendelser av betydning for pasientsikkerhet.

Metode: Kvalitative individuelle intervjuer av 10-12 erfarne leger fra ulike luftambulansebaser i Norge. Intervjuene blir tatt opp på bånd og senere nedskrevet i anonymisert form. Samtykke skal innhentes fra alle deltakere.

Vurdering
Helseforskningsloven gjelder for medisinsk og helsefaglig forskning på mennesker, humant biologisk materiale eller helseopplysninger, jf. hfl § 2. Medisinsk og helsefaglig forskning defineres som virksomhet som utføres med vitenskapelig metodikk for å skaffe til veie ny kunnskap om helse og sykdom, jf. hfl § 4.

REK vest ved sekretariatet vurderer at prosjektet er forskning som ikke søker ny kunnskap om helse og sykdom. Det er dermed ikke søknadspliktig til REK.

Jeg gjør oppmerksom på at konklusjonen er veiledende, jf. forvaltningsloven § 11.

Sikt

Vurdering av behandling av personopplysninger

Referansenummer	Vurderingstype	Dato
531035	Standard	05.09.2019

Tittel
Pasientsikkerhet i luftambulansetjenesten: en kvalitativ studie

Behandlingsansvarlig institusjon
Universitetet i Stavanger / Det helsevitenskapelige fakultet

Prosjektansvarlig
Stephen JM Sollid

Prosjektperiode
01.09.2019 - 31.12.2020

Kategorier personopplysninger
Alminnelige

Lovlig grunnlag
Samtykke (Personvernforordningen art. 6 nr. 1 bokstav a)

Behandlingen av personopplysningene er lovlig så fremt den gjennomføres som oppgitt i meldeskjemaet. Det lovlige grunnlaget gjelder til 31.12.2020.

Meldeskjema

Kommentar
BAKGRUNN
Det er sendt fremleggingsvurdering til REK. REK har vurdert at prosjektet ikke er fremleggingspliktig (ref. 33093 REK vest).

Det er vår vurdering at behandlingen av personopplysninger i prosjektet vil være i samsvar med personvernlovgivningen så fremt den gjennomføres i tråd med det som er dokumentert i meldeskjemaet med vedlegg den 05.09.2019, samt i meldingsdialogen mellom innmelder og NSD. Behandlingen kan starte.

MELD VESENTLIGE ENDRINGER
Dersom det skjer vesentlige endringer i behandlingen av personopplysninger, kan det være nødvendig å melde dette til NSD ved å oppdatere meldeskjemaet. Før du melder inn en endring, oppfordrer vi deg til å lese om hvilke type endringer det er nødvendig å melde: https://nsd.no/personvernombud/meld_prosjekt/meld_endringer.html

Du må vente på svar fra NSD før endringen gjennomføres.

TYPE OPPLYSNINGER OG VARIGHET
Prosjektet vil behandle alminnelige kategorier av personopplysninger frem til 31.12.2020.

TAUSHETSPLIKT
Vi gjør oppmerksom på at helsepersonell/ansatte i luftambulansen har taushetsplikt. Det er derfor viktig at intervjuene gjennomføres slik at det ikke samles inn opplysninger som kan identifisere enkeltpersoner eller avsløre taushetsbelagt informasjon. Forsker og informant har et felles ansvar for at det ikke kommer taushetsbelagte opplysninger inn i datamaterialet. Forsker må stille spørsmål på en slik måte at taushetsplikten kan overholdes. Det må utvises varsomhet ved bruk av eksempler, og vær oppmerksom på at ikke bare navn, men også identifiserende bakgrunnsopplysninger må utelates, f.eks. alder, kjønn, tid, sted og eventuelle spesielle hendelser.

LOVLIG GRUNNLAG
Prosjektet vil innhente samtykke fra de registrerte til behandlingen av personopplysninger. Vår vurdering er at prosjektet legger opp til et samtykke i samsvar med kravene i art. 4 og 7, ved at det er en frivillig, spesifikk, informert og utvetydig bekreftelse som kan dokumenteres, og som den registrerte kan trekke tilbake. Lovlig grunnlag for behandlingen vil dermed være den registrertes samtykke, jf. personvernforordningen art. 6 nr. 1 bokstav a.

PERSONVERNPRINSIPPER
NSD vurderer at den planlagte behandlingen av personopplysninger vil følge prinsippene i personvernforordningen om:

- lovlighet, rettferdighet og åpenhet (art. 5.1 a), ved at de registrerte får tilfredsstillende informasjon om og samtykker til behandlingen
- formålsbegrensning (art. 5.1 b), ved at personopplysninger samles inn for spesifikke, uttrykkelig angitte og berettigede formål, og ikke behandles til nye, uforenlige formål
- dataminimering (art. 5.1 c), ved at det kun behandles opplysninger som er adekvate, relevante og nødvendige for formålet med prosjektet
- lagringsbegrensning (art. 5.1 e), ved at personopplysningene ikke lagres lengre enn nødvendig for å oppfylle formålet

DE REGISTRERTES RETTIGHETER
Så lenge de registrerte kan identifiseres i datamaterialet vil de ha følgende rettigheter: åpenhet (art. 12), informasjon (art. 13), innsyn (art. 15), retting (art. 16), sletting (art. 17), begrensning (art. 18), underretning (art. 19), dataportabilitet (art. 20).

NSD vurderer at informasjonen om behandlingen som de registrerte vil motta oppfyller lovens krav til form og innhold, jf. art. 12.1 og art. 13.

Vi minner om at hvis en registrert tar kontakt om sine rettigheter, har behandlingsansvarlig institusjon plikt til å svare innen en måned.

FØLG DIN INSTITUSJONS RETNINGSLINJER
NSD legger til grunn at behandlingen oppfyller kravene i personvernforordningen om riktighet (art. 5.1 d), integritet og konfidensialitet (art. 5.1. f) og sikkerhet (art. 32).

NTNU er databehandler i prosjektet. NSD legger til grunn at behandlingen oppfyller kravene til bruk av databehandler, jf. art 28 og 29.

For å forsikre dere om at kravene oppfylles, må dere følge interne retningslinjer og/eller rådføre dere med behandlingsansvarlig institusjon.

OPPFØLGING AV PROSJEKTET
NSD vil følge opp ved planlagt avslutning for å avklare om behandlingen av personopplysningene er avsluttet.

Lykke til med prosjektet!

Kontaktperson hos NSD: Lise A. Haveraaen
Tlf. Personverntjenester: 55 58 21 17 (tast 1)