BMJ Open

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Journal:	*BMJ Open*
Manuscript ID	bmjopen-2020-041942
Article Type:	Original research
Date Submitted by the Author:	21-Jun-2020
Complete List of Authors:	Bergrath, Sebastian; RWTH Aachen University Medical Faculty, Department of Anaesthesiology; Kliniken Maria Hilf GmbH, Emergency Department Brokmann, Jörg; University Hospital Aachen, Emergency Department Beckers, Stefan ; University Hospital Aachen, Department of Anaesthesiology Felzen, Marc; University Hospital Aachen, Department of Anesthesiology Czaplik, Michael; Medical Faculty, RWTH Aachen, Anesthesiology Rossaint, Rolf; RWTH Aachen University Medical Faculty, Department of Anaesthesiology
Keywords:	ACCIDENT & EMERGENCY MEDICINE, Telemedicine < BIOTECHNOLOGY & BIOINFORMATICS, Organisational development < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Change management < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

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Implementation analysis and systemic effects on emergency resources by routine application of a full-scale prehospital telemedicine system

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Ethics committee: University Hospital RWTH Aachen, Germany, registration number EK 109/15

Trial registration: clinicaltrials.gov (NCT04127565)

Word count: 2700

Word count Abstract: 284

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Abstract

Objectives To review the implementation strategy from a first research project to routine care of a worldwide unique physician staffed prehospital telemedicine system. Systemic influences of this implementation on emergency medical service (EMS) resource utilisation should be evaluated.

Design Retrospective pre-post implementation study

Setting Two interdisciplinary research projects and the EMS of a German urban region.

Interventions Development and implementation of a full-scale prehospital telemedicine system.

Endpoints Evaluation of the implementation strategy. Pre- vs. post-implementation analysis of resource utilisation regarding ground- and helicopter based physician staffed emergency missions.

Results The first research project revealed positive effects on guideline adherence and patient safety in two simulation studies, general feasibility was demonstrated in a clinical study. After technical optimisation, safety and positive effects were demonstrated in a multicentre trial. Routine care implementation in the city of Aachen, Germany was conducted stepwise from April 2014 to March 2015. Systemic parameters of all EMS missions between pre-implementation (April 2013 to March 2014) and post-implementation (April 2015 to March 2016): On-scene EMS physician usage decreased from 7,882/25,187 missions (31.3%) to 6,360/26,462 (24.0%), p<0.0001. The need for neighbouring physician-staffed units dropped from 234/25,187 (0.93%) to 119/26,462 (0.45%), p<0.0001, as well as the need for helicopter EMS from 198/25,187 (0.79%) to 100/26,462 (0.38%), p<0.0001. In the post implementation period 2,347 telemedical interventions were conducted out of a total number of 26,462 emergency missions (8.87%).

Conclusion A stepwise implementation strategy allowed the transfer from research to routine care. We detected a reduced need for conventional on-scene physician care by ground and helicopter based EMS. This holds the potential for increased availability of EMS physicians for life-threatening emergencies by shifting of physician interventions from conventional to telemedical care.

Trial registration: clinicaltrials.gov/NCT04127565, retrospectively registered

Keywords: Emergency medicine, emergency medical service physician, telemedicine, telecare, quality of care.

Strengths and limitations of the study

- The study may help other researchers to adopt their implementation strategy from research projects to routine care in telemedicine projects.
- It is the first study that researched the influence on resource utilisation in EMS by implementation of a mobile telemedicine system in a complete urban region.
- A connection to other influencing factors such as diagnoses and patient characteristics could not be evaluated.

Introduction

Emergency medical services (EMS) in developed countries are facing increasing numbers of emergency missions. Besides possible negative effects on the patient outcome due to prolonged response intervals, there are economic consequences due to increased use and provision of resources. Therefore, modern concepts are required to ensure a high quality of care without a steep increase in costs. Telehealthcare interventions are spreading in both acute and chronic medical conditions. Despite rapidly increasing technological capabilities, barriers that restrict implementation remain, including legal, political, and social issues.[1] There are also barriers to be justified by the behavior of the medical staff and the patients.[2] It is well known that in ST-segment elevation, myocardial infarction telemedical transmission of the 12-lead-ECG and consultation of a cardiologist leads to reduced intervals to myocardial reperfusion.[3,4] The telemedical procedure even reduces in-hospital mortality in patients with ST-segment elevation myocardial infarction.[5] However, widespread use is still lacking. Beside acute coronary syndromes, telemedical interventions in the prehospital phase and scientific data are rare and many projects are not transferred into routine care after cessation of the project financing.[6,7] In acute stroke, studies have shown the feasibility of video transmission from the ambulance, but this technique has not been rolled out in a grand scale, while inter-hospital teleconsultation in acute stroke is implemented in ever more hospital systems and can be considered routine.[8–11] Overall, only a few EMS agencies use telemedical techniques.[7]

Against this background, we conducted two interdisciplinary research projects to develop and evaluate a comprehensive mobile teleconsultation system that supports on-scene paramedics from a remote site by experienced physicians in all kinds of emergency situations. After successful technical and organizational development, as well as scientific evaluation, this system was implemented stepwise into

routine care, financed by health insurance. The implementation strategy from the initial project idea to routine care of this worldwide, unique, physician-staffed telemedicine system should be assessed. To evaluate the systemic effects of this new concept in emergency care, the influence of this implementation on systemic resources and EMS parameters should be evaluated.

Methods

Implementation strategy

The implementation process from the project idea (2006/2007) to routine care (2014-2016) was dissected into all relevant steps and milestones. These steps were analysed descriptively with the respective rationale and resume of the main results.

Organisational setup

In the city of Aachen, Germany (255,967 residents; December 2017), the EMS service is within the responsibilities of the fire department. Up to eleven emergency ambulances are staffed with 2-year trained paramedics of the fire brigade and three EMS agencies. Additionally, two ground-based EMS physician units are run on a 24/7 basis to assist the ambulances if advanced life-support procedures (e.g., rapid sequence induction) are necessary. All physicians are certified EMS physicians with at least 3 years of training in anaesthesia and critical care and a certificate in advanced life support and pre-hospital trauma life support. In cases of non-availability due to duplicity events, physician-staffed units from adjacent districts or helicopter emergency medical services are used as back up. All paramedics were trained on the telemedicine system and its use was based on trained and published standard operating procedures.

Study design and evaluation of systemic effects

After two interdisciplinary research projects, transfer of the telemedical procedures into routine care was considered possible. To evaluate systemic influences of the implementation into routine care, we compared systemic EMS data of the 1-year pre-implementation period (April 2013–March 2014) with a similar interval after full implementation (April 2015–March 2016) in a pre-post intervention study. All EMS missions in the city of Aachen (Germany) were included. To assess EMS resource utilization, the

number of advanced life support missions carried out by on-scene EMS physicians was compared between the two periods as the primary outcome. The cumulative number of on-scene and telemedical interventions by physicians was analysed as secondary outcome. The non-availability of EMS physicians due to overlapping emergency calls was analysed by evaluating the number of advanced life support missions carried out by EMS physician units from adjacent EMS districts and by helicopter EMS.

Characteristics of telemedically-supported emergencies in routine care

Data of telemedically-supported emergency missions were analysed descriptively in the post-implementation period. Conducted medical procedures of this 1-year phase were evaluated by analysis of the electronic documentation system.

Data sources

We analysed the database of electronically documented telemedical interventions (Telemedical Documentation, P3 telehealthcare, Aachen, Germany) as well as the database of the regional EMS dispatch centre (COBRA4, ISE, Aachen, Germany). Numbers of callouts and telemedical supports, as well as conducted procedures, could be evaluated this way.

Ethics and study registration

Data screening and analyses were conducted after approval by the local ethics committee (University Hospital RWTH Aachen, registration number EK 109/15). All cases were pseudonymized for analysis to enable data privacy. Systemic data of the EMS dispatch centre contained no personal data and, therefore, there was no need for pseudonymisation. Study registration was performed retrospectively at clinicaltrials.gov (NCT04127565).

Statistical methods

Categorical data are presented as frequencies and percentages. Systemic parameters were compared with contingency tables using the Chi-squared test with Yates correction. All statistical analyses were performed using GraphPad Prism 7.0 (GraphPad Software, La Jolla, CA, USA). Due to the exploratory character of the study, p-values < 0.05 were considered significant.

Results

Implementation process

The whole process of final implementation could be divided into three main phases: two research projects, followed by integration into health insurance-financed routine emergency care. Table 1 outlines this process, including summarized research findings.[12–17] Local and national political stakeholders, health insurance companies, and EMS providers of different levels (paramedics to EMS directors/stakeholders) were integrated from the first interdisciplinary workshop.[13] Iterative development with integration of end-users allowed design and development and continuous adaption of the technical system, as well as the organizational model. In the first research project, a mobile telemedicine system with multiple applications was developed for the first time. General feasibility and positive effects on guideline-adherence in stroke patients could be shown.[9,18] Although the second project did not allow a randomized controlled trial due to practical and ethical concerns, the results of this prospective observational multi-centre trial did convince political stakeholders and health insurances to transfer this concept into routine care in a model region.[16,17,19] Before routine care implementation, milestones with interim analyses and workshops were defined between the fire department, the accompanying university (RWTH Aachen University, Germany), and the health insurance. Periodic quality reporting enabled data and safety monitoring as well as continuous information of decision-makers and financiers.

Technical development and capabilities in routine care

While in the first project, the transmission unit was integrated into a backpack (2009) with a total weight of 18 kg (self-development of research partners), the general technical development enabled miniaturization and integration of a smartphone for system monitoring and still picture transmission during the second project. Within 5 years, a stepwise professionalization and miniaturization led to a total weight of 1.7 kg and made the system practicable for routine emergency medical care. The technical performance improved over time to a sufficient standard.[18,20] In routine care, the following technical capabilities were enabled by a project related spin-off company (P3 telehealthcare, Aachen, Germany): two-way audio connection, real-time vital data transmission (numerical values and waveforms), 12-lead-ECG and still-picture transmission on-demand, as well as video streaming from inside the ambulance. The connection between the ambulances and the teleconsultation centre was accomplished by mobile

Table 1. Implementation strategy in steps and milestones

Phase	Process steps	Summary	References
Research Project No 1 (Med-on-aix) 2007-2010	1. Stakeholder workshops	Discussion and definition of requirements und expectations as well as misgivings; Integration of data privacy experts	[13]
	2. Technical Design and development	Development of specification booklet by medical users; integration of users into all steps of technical development	[13]
	3. Mock up tests	Technical field tests with a precursor system	
	4. Legal opinion by expert	Legal opinion about the specific legal questions of mobile telemedical care and delegation of medical procedures to paramedics	
	5. Simulation study I	Improved guideline adherence in STEMI and major trauma in full scale simulation	[12]
	6. Simulation study II (RCT)	Comparable quality of care between telemedically supported paramedics and on-scene physician teams.	[14]
	7. Development of economic models	Workshop-based with integration of politics, health insurances, technical partners and medical users.	
	8. Clinical feasibility study, prospective observational study	General feasibility was shown; video transmission in stroke and improvement of data transfer into the hospital were demonstrated.	[9, 18]
	9. User survey	Interviews and questionnaire-survey of users. Future potential is seen but technical performance and usability were criticised.	[21]
Research project No 2 (TemRas) 2010-2013	10. Technical adaption	Iterative development cycles with integration of medical users. Miniaturization of the technical system.	
	11. Technical field testing	Field testing by technicians and by emergency care providers.	[22]
	12. Development and execution of a training concept for providers	Parallel training concept for paramedics and future tele-EMS-physicians.	[15]
	13. Prospective multi-center trial in 5 EMS districts over one year	Safety, feasibility and evaluation of quality of care in 425 telemedical emergency missions	[15-17]
	14. Integration of health insurances and discussion of results and economic potential	Discussion of the scientific results and portability into a routine care setting. Model calculation of costs and savings potential.	
Integration into routine emergency care 2014-2015	15. Agreement with health insurances about seed funding	Seed funding of a first real-life phase, limited depending on interim results.	
	16. Technical adaption	Technical adaption and further miniaturization, integration of state-of-the-art monitor-defibrillator.	
	17. Integration and stepwise implementation into routine care (April 2014 - March 2015)	Start with 3 equipped ambulances and 12.75-hour daytime service; 24-hour coverage after 3 months and stepwise integration of 11 ambulances within one year. Implementation of telemedical contents into the yearly training concept for paramedics. Evaluation of technical performance by end-users and assessment of quality of care. Scientific evaluation of guideline adherence.	[20, 24-26]
	18. Discussion of interim results with politics, German health secretary and health insurances	Quarterly performance and quality reports. Discussion of interim results with health insurances, stakeholders and politics after 6 months in a workshop.	
	19. Full implementation since April 2015	Provision of 24/7 coverage, all ambulances technically equipped. Quarterly quality reports and real-time supervision of tele-EMS physicians. Scientific evaluation of guideline adherence.	[24]

EMS, emergency medical service; RCT, randomized controlled trial; STEMI, ST-segment elevation myocardial infarction

transmission units (peeq-Box, P3 telehealthcare, Aachen, Germany) connected to the monitor-defibrillator unit (C^3, GS Stemple Elektromedizinische Geräte, Kaufering, Germany). Inside the ambulance, the transmission unit was connected with a wireless local network provided by an In-Car computer. Parallelized and encrypted audio and data transmission from the emergency site and en-route were enabled this way. In the teleconsultation centre, a context-sensitive documentation software provided checklists and algorithms based on current international guidelines in addition to the technical display of all transmitted data (Telemedical Documentation, P3 telehealthcare, Aachen, Germany).

Systemic effects of telemedical support in routine care

Before the implementation of the telemedical real-time support, 25,187 EMS missions with emergency ambulances were conducted (April 2013–March 2014). Of these, 7882 (31.3%) were supported by an conventional on-scene EMS physician. After 1287 telemedical-supported missions during the 1-year training and implementation phase (April 2014 to March 2015), the system was completely implemented, enabling 24/7 availability. The total number of emergency ambulance missions increased to 26,462 after the implementation (April 2015–March 2016). Of these, 2347 (8.87%) were supported telemedically. Their characteristics are summarized in Table 2. The number of missions that were supported by on-scene EMS physicians decreased to 6360 (24%) of these cases ($p < 0.0001$). The rate of ground-based EMS staffed units from neighbouring districts that were utilized due to shortage of own resources dropped from 234/25,187 (0.93%) to 119/26,462 (0.45%) ($p < 0.0001$). A helicopter-based EMS physician was summoned in 198 of the 25,187 (0.79%) cases pre-intervention and this number decreased to 100 of 26,462 (0.38%) missions after the implementation ($p < 0.0001$). The total number of physician-guided prehospital interventions increased from 7882/25,187 (31.3%, conventional on-scene care) to 8707/26,462 (32.9%, telemedical and conventional on-scene care) in this 1-year phase ($p < 0.0001$).

Table 2. Characteristics of telemedically supported missions

Characteristics	Number (fraction)
Telemedically supported emergency missions	2,347
- solely telemedically supported, without additional on-scene physician	2,145 (91.4%)
Telemedically supported cases with delegation of medication	1,541 (65.66%)
- cases with opioid delegation	497 (21.18%)
- delegated single medications	4,419
Telemedically supported inter-hospital transfers	315

Discussion

The stepwise implementation with the integration of different end-users, politics, stakeholders, and health insurers allowed a successful transfer from the research project phase to routine care in an urban model region. After implementation, the utilisation of conventional on-scene care by EMS-physicians decreased significantly.

Although comprehensive scientific results were not available at the time point of discussion about further continuation, the continuous involvement of decision-makers and models for economic effects encouraged commitment from financiers. Periodic quality reporting and further scientific evaluation in routine care enabled stable integration and further expansion. By using this obstinately and continuous information strategy and integration of decision-makers barriers to implementation could be overcome, although a randomized controlled trial was not possible during the process. For the end-users, a satisfactory technical performance and usability were identified as the key elements for implementation during user interviews and via questionnaire.[21] Only in the course of the three phases were we were able to meet these user requirements.[18,20,22] While integrating new telemedical procedures, including the expansion of skills of paramedics, the users' perspectives can differ noticeably between paramedics and physicians. In a Scottish project of mobile tele-ultrasound on-board of ambulances, physicians feared distraction from the key roles and assessed this technique as too difficult for paramedics, while in contrast

the paramedics felt valued and assessed this new task as their role in prehospital care.[23] Although no evaluable data were available, we can report similar concerns by physicians while most paramedics felt valued with the new tasks for the most part. During routine care, positive effects on quality of care, as well as on guideline adherence, were shown for acute coronary syndromes, pain reduction in trauma and non-trauma emergencies, and blood pressure management in hypertensive emergencies.[24–26] However, the whole process from the research idea to implementation lasted one decade. This demonstrates that political decision-makers cannot be convinced with scientific results alone but also require ideas and models that allow future economic potential. General technical development and social development regarding mobile technologies accelerated the process in the last years.

The frequency of telemedical interventions increased from the integration phase to the routine phase. In more than half of the telemedically-supported rescue missions, medications (including opioids) were delegated by the tele-EMS-physician to the paramedics on-scene. With this pre-post intervention study about systemic resource needs, our predicted model was shown to be true. During routine care with all its unadjusted influences, the new process of telemedically-supported paramedic care proved its grand potential to reduce the number of on-scene interventions by EMS physicians. A reduction of approximately 2500 on-scene interventions in one year led to the significantly increased availability of ground-based physician intervention units, as shown by the reduced need for neighbouring units and helicopter-based EMS. However, a significant increase in overall physician interventions was found when adding on-scene and telemedical interventions in the post-implementation period. Although standard operating procedures existed for the most common emergencies, a lower threshold for telemedical support compared to the summoning of a physician-staffed EMS unit is our interpretation for this increase. A low-threshold use of telemedical procedures may improve the quality of care, but carries the risk of negating the possible cost savings.

Additionally, it must be kept in mind that during low acuity, telemedical interventions a parallel incoming call with high acuity can be answered, in contrast to parallel on-scene interventions at different sites. Furthermore, the overall duration, as well as the net time consumption of the physician, is significantly shorter with telemedicine compared to conventional on-scene care.[24–26] With 2500 telemedical cases in one year, the responsible tele-EMS physician is not fully occupied. Therefore, one tele-EMS physician would be able to be in charge of at least a second region with the same amount of emergency calls. With this model in mind, an economic business model would be possible. The increased

availability of the limited resources of on-scene physicians holds the potential to reduce the response intervals, which can be lifesaving in life-threatening emergencies, such as major trauma or cardiopulmonary resuscitation.

Limitations

New technologies and interventions in work processes can lead to different behaviours of end-users. This study cannot determine if the use of the telemedical concepts was widespread throughout all the EMS personnel or limited to some subgroups. No personal data of the EMS personnel could be evaluated while following the ethics committee's statement. In a project about clinical decision support systems for paramedics, inequalities in the attitude towards the technology were found.[27] Furthermore, this study was not designed to evaluate any medical outcomes. Detailed economic calculations were not possible because the telemedicine system was financed for the city of Aachen (Germany) in a first step during the study period. Health insurances and project participants arranged a further integration of more EMS districts so that the function as a tele-EMS physician can be utilized more efficiently. Only then will a pre-post analysis of costs between regular and regular plus telemedically-supported EMS produce meaningful findings.

Conclusions

Transfer from research projects to health insurance-financed routine care was successful with an implementation strategy that considered political and economic aspects throughout. Telemedical support for paramedics is an effective new element for prehospital emergency care due to the shifting of missions from classic on-scene physician to telemedically-supported missions. Consecutively, the availability of physician-staffed EMS units increased significantly. This will probably lead to shorter response times in life-threatening situations/missions. In the future, remote telemedical support holds a noticeably economic potential due to spatial independence and shorter workload time for the responsible physician. With implementation into routine care, we achieved a prerequisite for future randomized controlled trials comparing on-scene versus telemedical care in a whole model region.[28]

Contributors SB, JCB, SKB, MC and RR made substantial contributions to conception and design of the current study. All authors were mainly involved in project, study design, data analysis and publication of the results of the mentioned research projects Med-on-aix and TemRas. SB, MC and SKB performed data acquisition. Literature search was carried out by SB, JCB, SKB and RR. Data analysis and interpretation were conducted by all authors. Statistical tests were carried out by SB and MC. All authors made substantial contributions to the manuscript, while SB and RR drafted the first complete version. All authors read and approved the final manuscript.

Funding There was no funding for the current study, and the authors received no financial support for the research, authorship, and/or publication of this article. The first mentioned research project ("Med-on-aix") was funded by the German Federal Ministry of Economics and Technology (BMWi), [Project-No.: 01MB07022]. The second project ("TemRas") was funded by the European Union and the Ministry of Innovation, Science and Research of Northrhine Westphalia, Germany (MIWF) [Project-No.: PtJ-Az. 0909im002b, Funding code 005-1003-0034].

Competing interests The authors report no specific funding in relation to this research. JCB, MC, and RR are shareholders of the docs in clouds company, Aachen, Germany (telemedical service and consulting). All other authors declare no conflicts of interest.

Ethics approval The study was approved by the ethics committee of the RWTH Aachen University, Germany, registration number EK 109/15.

Patient consent Not required by ethics committee.

Data sharing statement No additional data is available. The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

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STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	4-5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	4
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	4-5
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	5
Bias	9	Describe any efforts to address potential sources of bias	
Study size	10	Explain how the study size was arrived at	5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	5
		(*b*) Describe any methods used to examine subgroups and interactions	5
		(*c*) Explain how missing data were addressed	
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	

Continued on next page

Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	6-9
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	8-9
		(b) Indicate number of participants with missing data for each variable of interest	
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	8
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	8
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	8-9
Discussion			
Key results	18	Summarise key results with reference to study objectives	9
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	11
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	9-11
Generalisability	21	Discuss the generalisability (external validity) of the study results	11
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	12

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

Standards for Reporting Implementation Studies:

Bergrath et al. Implementation analysis and systemic effects on emergency resources by routine application of a full-scale prehospital telemedicine system

The primary focus of implementation science is the implementation strategy (column 1) and the expectation is that this will always be completed.

The evidence about the impact of the intervention on the targeted population should always be considered (column 2) and either health outcomes reported or robust evidence cited to support a known beneficial effect of the intervention on the health of individuals or populations.

The StaRI standards refers to the broad range of study designs employed in implementation science. Authors should refer to other reporting standards for advice on reporting specific methodological features. Conversely, whilst all items are worthy of consideration, not all items will be applicable to, or feasible within every study.

Checklist item		Reported on page #	Implementation Strategy	Reported on page #	Intervention
			"Implementation strategy" refers to how the intervention was implemented		"Intervention" refers to the healthcare or public health intervention that is being implemented.
Title and abstract					
Title	**1**	1	Identification as an implementation study, and description of the methodology in the title and/or keywords		
Abstract	**2**	2	Identification as an implementation study, including a description of the implementation strategy to be tested, the evidence-based intervention being implemented, and defining the key implementation and health outcomes.		
Introduction					
Introduction	**3**	3-4	Description of the problem, challenge or deficiency in healthcare or public health that the intervention being implemented aims to address.		
Rationale	**4**	4	The scientific background and rationale for the implementation strategy (including any underpinning theory/framework/model, how it is expected to achieve its effects and any pilot work).	4	The scientific background and rationale for the intervention being implemented (including evidence about its effectiveness and how it is expected to achieve its effects).

Aims and objectives	**5**	4	The aims of the study, differentiating between implementation objectives and any intervention objectives.		
Methods: description					
Design	**6**	4-5	The design and key features of the evaluation, (cross referencing to any appropriate methodology reporting standards) and any changes to study protocol, with reasons		
Context	**7**	4	The context in which the intervention was implemented. (Consider social, economic, policy, healthcare, organisational barriers and facilitators that might influence implementation elsewhere).		
Targeted 'sites'	**8**	4	The characteristics of the targeted 'site(s)' (e.g locations/personnel/resources etc.) for implementation and any eligibility criteria.	4-5	The population targeted by the intervention and any eligibility criteria.
Description	**9**	4 -5	A description of the implementation strategy	4-5	A description of the intervention
Sub-groups	**10**	N/A	Any sub-groups recruited for additional research tasks, and/or nested studies are described		
Methods: evaluation					
Outcomes	**11**	4-5	Defined pre-specified primary and other outcome(s) of the implementation strategy, and how they were assessed. Document any pre-determined targets	5	Defined pre-specified primary and other outcome(s) of the intervention (if assessed), and how they were assessed. Document any pre-determined targets
Process evaluation	**12**	4	Process evaluation objectives and outcomes related to the mechanism by which the strategy is expected to work		
Economic evaluation	**13**	N/A	Methods for resource use, costs, economic outcomes and analysis for the implementation strategy	N/A	Methods for resource use, costs, economic outcomes and analysis for the intervention
Sample size	**14**	5	Rationale for sample sizes (including sample size calculations, budgetary constraints, practical considerations, data saturation, as appropriate)		
Analysis	**15**	6	Methods of analysis (with reasons for that choice)		
Sub-group analyses	**16**	N/A	Any a priori sub-group analyses (e.g. between different sites in a multicentre study, different clinical or demographic populations), and sub-groups recruited to specific nested research tasks		

Results					
Characteristics	**17**	6-9	Proportion recruited and characteristics of the recipient population for the implementation strategy	6-9	Proportion recruited and characteristics (if appropriate) of the recipient population for the intervention
Outcomes	**18**	6-8	Primary and other outcome(s) of the implementation strategy	6-8	Primary and other outcome(s) of the Intervention (if assessed)
Process outcomes	**19**	6-7	Process data related to the implementation strategy mapped to the mechanism by which the strategy is expected to work		
Economic evaluation	**20**	N/A	Resource use, costs, economic outcomes and analysis for the implementation strategy	N/A	Resource use, costs, economic outcomes and analysis for the intervention
Sub-group analyses	**21**	N/A	Representativeness and outcomes of subgroups including those recruited to specific research tasks		
Fidelity/ adaptation	**22**	6-8	Fidelity to implementation strategy as planned and adaptation to suit context and preferences	6-8	Fidelity to delivering the core components of intervention (where measured)
Contextual changes	**23**	N/A	Contextual changes (if any) which may have affected outcomes		
Harms	**24**	N/A	All important harms or unintended effects in each group		
Discussion					
Structured discussion	**25**	9-11	Summary of findings, strengths and limitations, comparisons with other studies, conclusions and implications		
Implications	**26**	9-11	Discussion of policy, practice and/or research implications of the implementation strategy (specifically including scalability)	9-11	Discussion of policy, practice and/or research implications of the intervention (specifically including sustainability)
General					
Statements	**27**	12	Include statement(s) on regulatory approvals (including, as appropriate, ethical approval, confidential use of routine data, governance approval), trial/study registration (availability of protocol), funding and conflicts of interest		

BMJ Open

Implementation of a full-scale prehospital telemedicine system: evaluation of process and systemic effects in a pre-post intervention study

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2020-041942.R1
Article Type:	Original research
Date Submitted by the Author:	16-Dec-2020
Complete List of Authors:	Bergrath, Sebastian; RWTH Aachen University Medical Faculty, Department of Anaesthesiology; Kliniken Maria Hilf GmbH, Emergency Department Brokmann, Jörg; University Hospital Aachen, Emergency Department Beckers, Stefan ; University Hospital Aachen, Department of Anaesthesiology Felzen, Marc; University Hospital Aachen, Department of Anesthesiology Czaplik, Michael; Medical Faculty, RWTH Aachen, Anesthesiology Rossaint, Rolf; RWTH Aachen University Medical Faculty, Department of Anaesthesiology
Primary Subject Heading:	Emergency medicine
Secondary Subject Heading:	Health informatics, Health services research
Keywords:	ACCIDENT & EMERGENCY MEDICINE, Telemedicine < BIOTECHNOLOGY & BIOINFORMATICS, Organisational development < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Change management < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

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Implementation of a full-scale prehospital telemedicine system: evaluation of process and systemic effects in a pre-post intervention study

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Ethics committee: University Hospital RWTH Aachen, Germany, registration number EK 109/15

Trial registration: clinicaltrials.gov (NCT04127565)

Word count: 2792

Word count Abstract: 283

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Abstract

Objectives To review the implementation strategy from a first research project to routine care of a worldwide unique physician staffed prehospital telemedicine system. The objective was to evaluate systemic influences on emergency medical service (EMS) resource utilisation.

Design Retrospective pre-post implementation study

Setting Two interdisciplinary research projects and the EMS of a German urban region.

Interventions Development and implementation of a full-scale prehospital telemedicine system.

Endpoints Descriptive evaluation of the implementation strategy. Primary endpoint: number of ground- and helicopter-based physician staffed emergency missions before and after implementation.

Results The first research project revealed positive effects on guideline adherence and patient safety in two simulation studies, general feasibility was demonstrated in a clinical study. After technical optimisation, safety and positive effects were demonstrated in a multicentre trial. Routine care implementation in the city of Aachen, Germany was conducted stepwise from April 2014 to March 2015. Systemic parameters of all EMS missions between pre-implementation (April 2013 to March 2014) and post-implementation (April 2015 to March 2016): On-scene EMS physician usage decreased from 7,882/25,187 missions (31.3%) to 6,360/26,462 (24.0%), p<0.0001. The need for neighbouring physician-staffed units dropped from 234/25,187 (0.93%) to 119/26,462 (0.45%), p<0.0001, as well as the need for helicopter EMS from 198/25,187 (0.79%) to 100/26,462 (0.38%), p<0.0001. In the post implementation period 2,347 telemedical interventions were conducted out of a total number of 26,462 emergency missions (8.87%).

Conclusion A stepwise implementation strategy allowed the transfer from project phase to routine care. We detected a reduced need for conventional on-scene physician care by ground and helicopter-based EMS. This holds the potential for increased availability of EMS physicians for life-threatening emergencies by shifting of physician interventions from conventional to telemedical care.

Trial registration: clinicaltrials.gov/NCT04127565, retrospectively registered

Keywords: Emergency medicine, emergency medical service physician, telemedicine, telecare, quality of care.

Strengths and limitations of the study

- The strength of the study is the description of the different methods of implementation of a prehospital telemedicine system with the transfer from project phase to routine care.
- We drew real life data from an EMS dispatch centre to evaluate the effect on emergency medical service resource utilisation by implementation of a telemedical support system.
- This is the first study that researched the effects aforementioned implementation in a whole urban region.
- The limitation is that other influencing factors like adapted dispatch criteria may have also influenced the results and this could not be calculated out.
- Influences on patient outcome could not be evaluated which is another relevant limitation of our findings.

Introduction

Emergency medical services (EMS) are facing increasing numbers of emergency missions. Besides possible negative effects on the patient outcome due to prolonged response intervals, there are economic consequences due to increased use and provision of resources.[1,2] Therefore, modern concepts are required to ensure a high quality of care without a steep increase in costs. Telehealthcare interventions are spreading in both acute and chronic medical conditions.[3–5] Despite rapidly increasing technological capabilities, barriers that restrict implementation remain, including legal, political, and social issues.[6] There are also barriers to be justified by the behaviour of the medical staff and the patients.[7] It is well known that in ST-segment elevation, myocardial infarction telemedical transmission of the 12-lead-ECG and consultation of a cardiologist leads to reduced intervals to myocardial reperfusion.[8,9] The telemedical procedure even reduces in-hospital mortality in patients with ST-segment elevation myocardial infarction.[10] However, widespread use is still lacking. Beside acute coronary syndromes, telemedical interventions in the prehospital phase and scientific data are rare and many projects are not transferred into routine care after cessation of the project financing.[11,12] In acute stroke, studies have shown the feasibility of video transmission from the ambulance, but this technique has not been rolled out in a grand scale, while inter-hospital teleconsultation in acute stroke is implemented in ever more hospital

systems and can be considered routine.[13–16] Overall, only a few EMS agencies use telemedical techniques.[12]

Against this background, we conducted two interdisciplinary research projects to develop and evaluate a comprehensive mobile teleconsultation system that supports on-scene paramedics from a remote site by experienced physicians in all in all kinds of emergency medical clinical situations. After successful technical and organizational development, as well as scientific evaluation, this system was implemented stepwise into routine care, financed by health insurance. In Germany the EMS is generally financed by statutory health insurances and private health insurances after negotiation of needs and budget. The aim of the study was to evaluate the implementation strategy from the initial project idea to routine care of this worldwide, unique, physician-staffed telemedicine system. To evaluate the systemic effects of this new concept in emergency care, the influence of this implementation on EMS resources should be evaluated.

Methods

Implementation strategy

The implementation process from the project idea (2006/2007) to routine care (2014-2016) was dissected into all relevant steps and milestones. These steps were analysed descriptively with the respective rationale and resume of the main results.

Organisational setup

In the city of Aachen, Germany (255,967 residents; December 2017), the EMS service is within the responsibilities of the fire department. Up to eleven emergency ambulances are staffed with 2-year trained paramedics of the fire brigade and three EMS agencies. Additionally, two ground-based EMS physician units are run on a 24/7 basis to assist the ambulances if advanced life-support procedures (e.g., rapid sequence induction) are necessary. All physicians are certified EMS physicians with at least 3 years of training in anaesthesia and critical care and a certificate in advanced life support and pre-hospital trauma life support. In cases of non-availability due to duplicity events, physician-staffed units from adjacent districts or helicopter emergency medical services are used as back up. All paramedics were trained on the telemedicine system and its use was based on trained and published standard operating procedures.

Study design and evaluation of systemic effects

After two interdisciplinary research projects, transfer of the telemedical procedures into routine care was considered possible. To evaluate systemic influences of the implementation into routine care, we compared EMS data of the 1-year pre-implementation period (April 2013–March 2014) with a similar interval after full implementation (April 2015–March 2016) in a pre-post intervention study: To assess EMS resource utilization, the number of emergency missions carried out by on-scene EMS physicians was compared between the two periods as the primary outcome. The cumulative number of on-scene and telemedical interventions by physicians was analysed as secondary outcome. The non-availability of EMS physicians due to overlapping emergency calls was analysed by evaluating the number of emergency missions carried out by EMS physician units from adjacent EMS districts and by helicopter EMS. All EMS missions in the city of Aachen (Germany) were included.

With full implementation the dispatch criteria were changed and supported with an electronical list of symptoms and possible diagnoses (n=213 scenarios). In the pre-implementation period, it was at the discretion of the dispatcher to send an EMS physician unit whenever he judged a situation as potentially life threatening. Due to availability of 24/7 telemedical support the following emergency scenarios were not dispatched with an on-scene EMS physician anymore: acute stroke with patient awake, painful conditions with patient awake, mild dyspnea, hypertensive urgency, terminated seizure. In the pre-implementation period these conditions were routinely dispatched with an on-scene EMS physician, although no electronic support was available.

Characteristics of telemedically-supported emergencies in routine care

Data of telemedically-supported emergency missions were analysed descriptively in the post-implementation period: type of emergency mission (emergency missions vs. inter-hospital transfer), delegated medications and medical severity.

Data sources

We analysed the database of electronically documented telemedical interventions (Telemedical Documentation, P3 telehealthcare, Aachen, Germany) as well as the database of the regional EMS dispatch centre (COBRA4, ISE, Aachen, Germany). Numbers of callouts and telemedical supports, as well as

conducted procedures, could be evaluated this way. Patient data could not be connected between these two systems.

Patient and Public Involvement

No patient was involved. The public was regularly informed by local media (newspaper, radio and local television) but had no influence on the project and study design.

Ethics and study registration

Data screening and analyses were conducted after approval by the local ethics committee (University Hospital RWTH Aachen, registration number EK 109/15). All cases were pseudonymized for analysis to enable data privacy. Systemic data of the EMS dispatch centre contained no personal data and, therefore, there was no need for pseudonymisation. Study registration was performed retrospectively at clinicaltrials.gov (NCT04127565).

Statistical methods

Categorical data are presented as frequencies and percentages. Systemic parameters were compared with contingency tables using the Chi-squared test with Yates correction. All statistical analyses were performed using GraphPad Prism 7.0 (GraphPad Software, La Jolla, CA, USA). Due to the exploratory character of the study, p-values < 0.05 were considered significant.

Results

Implementation process

The whole process of final implementation could be divided into three main phases: two research projects, followed by integration into health insurance-financed routine emergency care, which is already standard for all conventional EMS resources in Germany. We have now been able to ensure that telemedical care was also be financed in this way. Table 1 outlines this process, including summarized research findings.[17–22] Local and national political stakeholders, health insurance companies, and EMS providers of different levels (paramedics to EMS directors/stakeholders) were integrated from the first interdisciplinary workshop.[18]

Iterative development with integration of end-users allowed design and development and continuous adaption of the technical system, as well as the organizational model. In the first research project, a mobile telemedicine system with multiple applications was developed for the first time. General feasibility and positive effects on guideline-adherence in stroke patients could be shown.[14,23] Although the second project did not allow a randomized controlled trial due to practical and ethical concerns, the results of this prospective observational multi-centre trial did convince political stakeholders and health insurances to transfer this concept into routine care in a model region.[21,22,24] Before routine care implementation, milestones with interim analyses and workshops were defined between the fire department, the accompanying university (RWTH Aachen University, Germany), and the health insurance. Periodic quality reporting enabled data and safety monitoring as well as continuous information of decision-makers and financiers.

Technical development and capabilities in routine care

While in the first project, the transmission unit was integrated into a backpack (2009) with a total weight of 18 kg (self-development of research partners), the general technical development enabled miniaturization and integration of a smartphone for system monitoring and still picture transmission during the second project. Within 5 years, a stepwise professionalization and miniaturization led to a total weight of 1.7 kg and made the system practicable for routine emergency medical care. The technical performance improved over time to a sufficient standard.[23,25] In routine care, the following technical capabilities were enabled by a project related spin-off company (P3 telehealthcare, Aachen, Germany): two-way audio connection, real-time vital data transmission (numerical values and waveforms), 12-lead-ECG and still-picture transmission on-demand, as well as video streaming from inside the ambulance. The connection between the ambulances and the teleconsultation centre was accomplished by mobile

Table 1. Implementation strategy in steps and milestones

Phase	Process steps	Summary	References
Research Project (Med-on-aix) 2007-2010	1. Stakeholder workshops	Discussion and definition of requirements und expectations as well as misgivings; Integration of data privacy experts	[18]
	2. Technical Design and development	Development of specification booklet by medical users; integration of users into all steps of technical development	[18]
	3. Mockup tests	Technical field tests with a precursor system	
	4. Legal opinion by expert	Legal opinion about the specific legal questions of mobile telemedical care and delegation of medical procedures to paramedics	
	5. Simulation study I	Improved guideline adherence in STEMI and major trauma in full scale simulation	[17]
	6. Simulation study II (RCT)	Comparable quality of care between telemedically supported paramedics and on-scene physician teams.	[19]
	7. Development of economic models	Workshop-based with integration of politics, health insurances, technical partners and medical users.	
	8. Clinical feasibility study, prospective observational study	General feasibility was shown; video transmission in stroke and improvement of data transfer into the hospital were demonstrated.	[14,23]
	9. User survey	Interviews and questionnaire-survey of users. Future potential is seen but technical performance and usability were criticised.	[26]
Research project (TemRas) 2010-2013	10. Technical adaption	Iterative development cycles with integration of medical users. Miniaturization of the technical system.	
	11. Technical field testing	Field testing by technicians and by emergency care providers.	[27]
	12. Development and execution of a training concept for providers	Parallel training concept for paramedics and future tele-EMS-physicians.	[20]
	13. Prospective multi-centre trial in 5 EMS districts over one year	Safety, feasibility and evaluation of quality of care in 425 telemedical emergency missions	[21,22,24]
	14. Integration of health insurances and discussion of results and economic potential	Discussion of the scientific results and portability into a routine care setting. Model calculation of costs and savings potential.	
Integration into routine emergency care 2014-2015	15. Agreement with health insurances about seed funding	Seed funding of a first real-life phase, limited depending on interim results.	
	16. Technical adaption	Technical adaption and further miniaturization, integration of state-of-the-art monitor-defibrillator.	
	17. Integration and stepwise implementation into routine care (April 2014 - March 2015)	Start with 3 equipped ambulances and 12.75-hour daytime service; 24-hour coverage after 3 months and stepwise integration of 11 ambulances within one year. Implementation of telemedical contents into the yearly training concept for paramedics. Evaluation of technical performance by end-users and assessment of quality of care. Scientific evaluation of guideline adherence.	[25,28–30]
	18. Discussion of interim results with politics, German health secretary and health insurances	Quarterly performance and quality reports. Discussion of interim results with health insurances, stakeholders and politics after 6 months in a workshop.	
	19. Full implementation since April 2015	Provision of 24/7 coverage, all ambulances technically equipped. Quarterly quality reports and real-time supervision of tele-EMS physicians. Scientific evaluation of guideline adherence.	[28]

EMS, emergency medical service; RCT, randomized controlled trial; STEMI, ST-segment elevation myocardial infarction

transmission units (peeq-Box, P3 telehealthcare, Aachen, Germany) connected to the monitor-defibrillator unit (C^3, GS Stemple Elektromedizinische Geräte, Kaufering, Germany). Inside the ambulance, the

transmission unit was connected with a wireless local network provided by a conventional In-Car computer. Parallelized and encrypted audio and data transmission from the emergency site and en-route were enabled this way. In the teleconsultation centre, a physician responsible for the telemedical consultations was located. In the centre, a context-sensitive documentation software provided checklists and algorithms based on current international guidelines in addition to the technical display of all transmitted data (Telemedical Documentation, P3 telehealthcare, Aachen, Germany).

Systemic effects of telemedical support in routine care

Before the implementation of the telemedical real-time support, 25,187 EMS missions with emergency ambulances were conducted (April 2013–March 2014). Of these, 7882 (31.3%) were supported by an conventional on-scene EMS physician. After 1287 telemedical-supported missions during the 1-year training and implementation phase (April 2014 to March 2015), the system was completely implemented, enabling 24/7 availability. The total number of emergency ambulance missions increased to 26,462 after the implementation (April 2015–March 2016). Of these, 2347 (8.87%) were supported telemedically. Their characteristics are summarized in Table 2. The number of missions that were supported by on-scene EMS physicians decreased from 7882 (31.3%, pre-intervention) to 6360 (24%, post-intervention) of all cases, $p < 0.0001$. The rate of ground-based EMS staffed units from neighbouring districts that were utilized due to shortage of own resources dropped from 234/25,187 (0.93%) to 119/26,462 (0.45%), $p < 0.0001$. A helicopter-based EMS physician was summoned in 198 of the 25,187 (0.79%) cases pre-intervention and this number decreased to 100 of 26,462 (0.38%) missions after the implementation ($p < 0.0001$). The total number of physician-guided prehospital interventions increased from 7882/25,187 (31.3%, only conventional on-scene care) to 8707/26,462 (32.9%, telemedical and conventional on-scene care) in this 1-year phase ($p < 0.0001$).

Table 2. Characteristics of telemedically supported missions after full implementation

Characteristics	**Number (fraction)**
Telemedically supported emergency missions	2,347
- solely telemedically supported, without additional on-scene physician	2,145/2,347 (91.4%)
Telemedically supported cases with delegation of medication	1,541/2,347 (65.66%)
- cases with opioid delegation - delegated single medications	497/2,347 (21.18%) 4,419 drug administrations in 1,541 missions
M-NACA score of telemedically supported missions: n=2,262/2,347 missions scored (96.4%)	
M-NACA II – no hospital admission necessary	165
M-NACA III – transport to hospital required	1,298
M-NACA IV – possible vital danger	613
M-NACA V – acute vital danger	180
M-NACA VI – successful cardiopulmonary resuscitation	1
M-NACA VII – death at scene	5
Telemedically supported inter-hospital transfers	315

M-NACA, modified National Advisory Committee or Aeronautics severity score [31]

Discussion

The stepwise implementation with the integration of different end-users, politics, stakeholders, and health insurers allowed a successful transfer from the research project phase to routine care in an urban model region. After implementation, the utilisation of conventional on-scene care by EMS-physicians decreased significantly, but beside the implementation of a telemedicine system the dispatch criteria were modified und structured.

Although comprehensive scientific results were not available at the time point of discussion about further continuation, the continuous involvement of decision-makers and models for economic effects encouraged commitment from financiers. Periodic quality reporting and further scientific evaluation in routine care enabled stable integration and further expansion. By using this obstinately and continuous information strategy and integration of decision-makers barriers to implementation could be overcome, although a randomized controlled trial (RCT) was judged to be not possible by the researchers during the process. There was the unanimous opinion that an RCT would have created too many barriers within the framework of the projects that would have endangered the concept idea. Furthermore, in the discussion with the ethics committee a RCT was viewed critically due to the novelty of the system. For the end-users, a satisfactory technical performance and usability were identified as the key elements for implementation during user interviews and via questionnaire.[26] Only in the course of the three phases were we were able to meet these user requirements.[23,25,27] While integrating new telemedical procedures, including the expansion of skills of paramedics, the users' perspectives can differ noticeably between paramedics and physicians. In a Scottish project of mobile tele-ultrasound on-board of ambulances, physicians feared distraction from the key roles and assessed this technique as too difficult for paramedics, while in contrast the paramedics felt valued and assessed this new task as their role in prehospital care.[32] Although no evaluable data were available, we can report similar concerns by physicians while most paramedics felt valued with the new tasks for the most part. During routine care, positive effects on quality of care, as well as on guideline adherence, were shown for acute coronary syndromes, pain reduction in trauma and non-trauma emergencies, and blood pressure management in hypertensive emergencies.[28–30] However, the whole process from the research idea to implementation lasted one decade. This demonstrates that political decision-makers cannot be convinced with scientific results alone but also require ideas and models that allow future economic potential. General technical development and social development regarding mobile technologies accelerated the process in the last years.

The frequency of telemedical interventions increased from the integration phase to the routine phase. In more than half of the telemedically-supported rescue missions, medications (including opioids) were delegated by the tele-EMS-physician to the paramedics on-scene. During routine care with all its unadjusted influences, the new process of telemedically-supported paramedic care proved its grand potential to reduce the number of on-scene interventions by EMS physicians. However, the reduced numbers of on-scene EMS physician interventions cannot be explained with the implementation of the

telemedical system alone. The EMS dispatch criteria were structured and modified with the aim to reduce primary alarms of EMS physician units. However, such dispatch criteria probably would not have been acceptable by personnel and patients without the availability of the telemedical system. Administration of opioids by paramedics is not allowed in Germany without the (telemedical) delegation by a physician. A reduced primary alarm ratio in painful conditions would therefore have been unethical without the telemedical concept. Another factor that might led to reduced EMS physician alarms are training effects of the ambulance personnel. With improved performance in i.v.-lines, analgesia and sedation over time, the paramedics were able to perform advanced care with telemedical support alone. The reduction of approximately 2500 on-scene interventions in one year led to the significantly increased availability of ground-based physician intervention units, as shown by the reduced need for neighbouring units and helicopter-based EMS. However, a significant increase in overall physician interventions was found when adding on-scene and telemedical interventions in the post-implementation period. Although standard operating procedures existed for the most common emergencies, a lower threshold for telemedical support compared to the summoning of a physician-staffed EMS unit is our interpretation for this increase. A low-threshold use of telemedical procedures may improve the quality of care, but carries the risk of negating the possible cost savings.

Additionally, it must be kept in mind that during low acuity, telemedical interventions a parallel incoming call with high acuity can be answered, in contrast to parallel on-scene interventions at different sites. Furthermore, the overall duration, as well as the net time consumption of the physician, is significantly shorter with the physician in the telemedicine centre compared to conventional on-scene care by EMS physicians.[28–30] With 2500 telemedical cases in one year, the responsible tele-EMS physician is not fully occupied. Therefore, one tele-EMS physician would be able to be in charge of at least a second region with the same amount of emergency calls. With this model in mind, an economic business model would be possible. The increased availability of the limited resources of on-scene physicians holds the potential to reduce the response intervals, which can be lifesaving in life-threatening emergencies, such as major trauma or cardiopulmonary resuscitation.

Limitations

New technologies and interventions in work processes can lead to different behaviours of end-users. This study cannot determine if the use of the telemedical concepts was widespread throughout all the EMS personnel or limited to some subgroups. No personal data of the EMS personnel could be evaluated while following the ethics committee's statement. In a project about clinical decision support systems for paramedics, inequalities in the attitude towards the technology were found.[33] Furthermore, this study was not designed to evaluate any medical outcomes, which is the major limitation of this study. Therefore, it cannot be answered if outcomes changed by implementing a telemedicine system with modified primary dispatch criteria. Detailed economic calculations were not possible because the telemedicine system was financed for the city of Aachen (Germany) in a first step during the study period. Health insurances and project participants arranged a further integration of more EMS districts so that the function as a tele-EMS physician can be utilized more efficiently. Only then will a pre-post analysis of costs between regular and regular plus telemedically-supported EMS produce meaningful findings.

Conclusions

Transfer from research projects to health insurance-financed routine care was successful with an implementation strategy that considered political and economic aspects throughout. Telemedical support for paramedics is an effective new element for prehospital emergency care due to the shifting of missions from classic on-scene physician to telemedically-supported missions. Consecutively, the availability of physician-staffed EMS units increased significantly. This will probably lead to shorter response times in life-threatening situations/missions. In the future, remote telemedical support holds a noticeably economic potential due to spatial independence and shorter workload time for the responsible physician. With implementation into routine care, we achieved a prerequisite for future randomized controlled trials comparing on-scene versus telemedical care in a whole model region.[34]

Contributors SB, JCB, SKB, MC, MF and RR made substantial contributions to conception and design of the current study. All authors were mainly involved in project, study design, data analysis and publication of the results of the mentioned research projects Med-on-aix and TemRas. SB, MC and SKB performed data

acquisition. Literature search was carried out by SB, JCB, SKB, MF and RR. Data analysis and interpretation were conducted by all authors. Statistical tests were carried out by SB, MF and MC. All authors made substantial contributions to the manuscript, while SB and RR drafted the first complete version. All authors read and approved the final manuscript.

Funding There was no funding for the current study, and the authors received no financial support for the research, authorship, and/or publication of this article. The first mentioned research project ("Med-on-aix") was funded by the German Federal Ministry of Economics and Technology (BMWi), [Project-No.: 01MB07022]. The second project ("TemRas") was funded by the Ministry of Innovation, Science and Research of Northrhine Westphalia, Germany (MIWF) [Project-No.: PtJ-Az. 0909im002b, Funding code 005-1003-0034].

Competing interests The authors report no specific funding in relation to this research. JCB, MC, and RR are shareholders of the docs in clouds company, Aachen, Germany (telemedical service and consulting). All other authors declare no conflicts of interest.

Ethics approval The study was approved by the ethics committee of the RWTH Aachen University, Germany, registration number EK 109/15.

Patient consent Not required by ethics committee.

Data sharing statement No additional data is available. The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

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STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	4-5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	4
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	4-5
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	5
Bias	9	Describe any efforts to address potential sources of bias	
Study size	10	Explain how the study size was arrived at	5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	5
		(*b*) Describe any methods used to examine subgroups and interactions	5
		(*c*) Explain how missing data were addressed	
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	

Continued on next page

Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	6-9
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	8-9
		(b) Indicate number of participants with missing data for each variable of interest	
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	8
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	8
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	8-9
Discussion			
Key results	18	Summarise key results with reference to study objectives	9
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	11
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	9-11
Generalisability	21	Discuss the generalisability (external validity) of the study results	11
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	12

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

Standards for Reporting Implementation Studies:

Bergrath et al. Implementation analysis and systemic effects on emergency resources by routine application of a full-scale prehospital telemedicine system

The primary focus of implementation science is the implementation strategy (column 1) and the expectation is that this will always be completed.

The evidence about the impact of the intervention on the targeted population should always be considered (column 2) and either health outcomes reported or robust evidence cited to support a known beneficial effect of the intervention on the health of individuals or populations.

The StaRI standards refers to the broad range of study designs employed in implementation science. Authors should refer to other reporting standards for advice on reporting specific methodological features. Conversely, whilst all items are worthy of consideration, not all items will be applicable to, or feasible within every study.

Checklist item		Reported on page #	Implementation Strategy	Reported on page #	Intervention
			"Implementation strategy" refers to how the intervention was implemented		"Intervention" refers to the healthcare or public health intervention that is being implemented.
Title and abstract					
Title	**1**	1	Identification as an implementation study, and description of the methodology in the title and/or keywords		
Abstract	**2**	2	Identification as an implementation study, including a description of the implementation strategy to be tested, the evidence-based intervention being implemented, and defining the key implementation and health outcomes.		
Introduction					
Introduction	**3**	3-4	Description of the problem, challenge or deficiency in healthcare or public health that the intervention being implemented aims to address.		
Rationale	**4**	4	The scientific background and rationale for the implementation strategy (including any underpinning theory/framework/model, how it is expected to achieve its effects and any pilot work).	4	The scientific background and rationale for the intervention being implemented (including evidence about its effectiveness and how it is expected to achieve its effects).

Aims and objectives	**5**	4	The aims of the study, differentiating between implementation objectives and any intervention objectives.		
Methods: description					
Design	**6**	4-5	The design and key features of the evaluation, (cross referencing to any appropriate methodology reporting standards) and any changes to study protocol, with reasons		
Context	**7**	4	The context in which the intervention was implemented. (Consider social, economic, policy, healthcare, organisational barriers and facilitators that might influence implementation elsewhere).		
Targeted 'sites'	**8**	4	The characteristics of the targeted 'site(s)' (e.g locations/personnel/resources etc.) for implementation and any eligibility criteria.	4-5	The population targeted by the intervention and any eligibility criteria.
Description	**9**	4 -5	A description of the implementation strategy	4-5	A description of the intervention
Sub-groups	**10**	N/A	Any sub-groups recruited for additional research tasks, and/or nested studies are described		
Methods: evaluation					
Outcomes	**11**	4-5	Defined pre-specified primary and other outcome(s) of the implementation strategy, and how they were assessed. Document any pre-determined targets	5	Defined pre-specified primary and other outcome(s) of the intervention (if assessed), and how they were assessed. Document any pre-determined targets
Process evaluation	**12**	4	Process evaluation objectives and outcomes related to the mechanism by which the strategy is expected to work		
Economic evaluation	**13**	N/A	Methods for resource use, costs, economic outcomes and analysis for the implementation strategy	N/A	Methods for resource use, costs, economic outcomes and analysis for the intervention
Sample size	**14**	5	Rationale for sample sizes (including sample size calculations, budgetary constraints, practical considerations, data saturation, as appropriate)		
Analysis	**15**	6	Methods of analysis (with reasons for that choice)		
Sub-group analyses	**16**	N/A	Any a priori sub-group analyses (e.g. between different sites in a multicentre study, different clinical or demographic populations), and sub-groups recruited to specific nested research tasks		

Results					
Characteristics	**17**	6-9	Proportion recruited and characteristics of the recipient population for the implementation strategy	6-9	Proportion recruited and characteristics (if appropriate) of the recipient population for the intervention
Outcomes	**18**	6-8	Primary and other outcome(s) of the implementation strategy	6-8	Primary and other outcome(s) of the Intervention (if assessed)
Process outcomes	**19**	6-7	Process data related to the implementation strategy mapped to the mechanism by which the strategy is expected to work		
Economic evaluation	**20**	N/A	Resource use, costs, economic outcomes and analysis for the implementation strategy	N/A	Resource use, costs, economic outcomes and analysis for the intervention
Sub-group analyses	**21**	N/A	Representativeness and outcomes of subgroups including those recruited to specific research tasks		
Fidelity/ adaptation	**22**	6-8	Fidelity to implementation strategy as planned and adaptation to suit context and preferences	6-8	Fidelity to delivering the core components of intervention (where measured)
Contextual changes	**23**	N/A	Contextual changes (if any) which may have affected outcomes		
Harms	**24**	N/A	All important harms or unintended effects in each group		
Discussion					
Structured discussion	**25**	9-11	Summary of findings, strengths and limitations, comparisons with other studies, conclusions and implications		
Implications	**26**	9-11	Discussion of policy, practice and/or research implications of the implementation strategy (specifically including scalability)	9-11	Discussion of policy, practice and/or research implications of the intervention (specifically including sustainability)
General					
Statements	**27**	12	Include statement(s) on regulatory approvals (including, as appropriate, ethical approval, confidential use of routine data, governance approval), trial/study registration (availability of protocol), funding and conflicts of interest		

BMJ Open

Implementation of a full-scale prehospital telemedicine system: evaluation of process and systemic effects in a pre-post intervention study

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2020-041942.R2
Article Type:	Original research
Date Submitted by the Author:	14-Feb-2021
Complete List of Authors:	Bergrath, Sebastian; RWTH Aachen University Medical Faculty, Department of Anaesthesiology; Kliniken Maria Hilf GmbH, Emergency Department Brokmann, Jörg; University Hospital Aachen, Emergency Department Beckers, Stefan ; University Hospital Aachen, Department of Anaesthesiology Felzen, Marc; University Hospital Aachen, Department of Anesthesiology Czaplik, Michael; Medical Faculty, RWTH Aachen, Anesthesiology Rossaint, Rolf; RWTH Aachen University Medical Faculty, Department of Anaesthesiology
Primary Subject Heading:	Emergency medicine
Secondary Subject Heading:	Health informatics, Health services research
Keywords:	ACCIDENT & EMERGENCY MEDICINE, Telemedicine < BIOTECHNOLOGY & BIOINFORMATICS, Organisational development < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Change management < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

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Implementation of a full-scale pre-hospital telemedicine system: Evaluation of the process and systemic effects in a pre-post intervention study

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Ethics committee: University Hospital RWTH Aachen, Germany, registration number EK 109/15

Trial registration: clinicaltrials.gov (NCT04127565)

Word count: 3538 (without Tables, References, or the Abstract)

Word count Abstract: 292

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Abstract

Objectives To review the implementation strategy from a research project towards routine care of a comprehensive mobile physician-staffed pre-hospital telemedicine system. The objective is to evaluate the implementation process and systemic influences on emergency medical service (EMS) resource utilisation.

Design Retrospective pre-post implementation study

Setting Two interdisciplinary projects and the EMS of a German urban region.

Interventions Implementation of a full-scale pre-hospital telemedicine system.

Endpoints Descriptive evaluation of the implementation strategy. Primary endpoint: ground- and helicopter-based physician staffed emergency missions before and after implementation.

Results The first research project revealed positive effects on guideline adherence and patient safety in two simulation studies, with feasibility demonstrated in a clinical study. After technical optimisation, safety and positive effects were demonstrated in a multicentre trial. Routine care in the city of Aachen, Germany was conducted stepwise from April 2014 to March 2015, including modified dispatch criteria. Systemic parameters of all EMS assignments between pre-implementation (April 2013 to March 2014) and post-implementation (April 2015 to March 2016): On-scene EMS physician operations decreased from 7,882/25,187 missions (31.3%) to 6,360/26,462 (24.0%), $p < 0.0001$. The need for neighbouring physician-staffed units dropped from 234/25,187 (0.93%) to 119/26,462 (0.45%), $p < 0.0001$, and the need for helicopter EMS from 198/25,187 (0.79%) to 100/26,462 (0.38%), $p < 0.0001$. In the post-implementation period 2,347 telemedical interventions were conducted, with 26,462 emergency missions (8.87%).

Conclusion A stepwise implementation strategy allowed transfer from the project phase to routine care. We detected a reduced need for conventional on-scene physician care by ground and helicopter-based EMS, but cannot exclude unrecognized confounders, including modified dispatch criteria and possible learning effects. This creates the potential for increased availability of EMS physicians for life-threatening emergencies by shifting physician interventions from conventional to telemedical care.

Trial registration: Clinicaltrials.gov/NCT04127565, retrospectively registered.

Keywords: Emergency medicine, emergency medical service physician, telemedicine, telecare, quality of care.

Strengths and limitations of the study

- The strength of the study is the description of different methods of implementation in a pre-hospital telemedicine system, with the transfer from project phase to routine care.
- We used real-life data from an EMS dispatch centre to evaluate the effect on emergency medical service resource utilisation by implementation of a telemedical support system.
- This is the first study to examine effects the aforementioned implementation in an urban region.
- The limitation is that other influencing factors, such as adapted dispatch criteria, may have also influenced the results, which could not be calculated.
- Influences on patient outcomes could not be evaluated, another limitation of our findings.

Introduction

Emergency medical services (EMS) face increasing emergency missions. Besides possible negative effects on patient outcome due to prolonged response intervals, there are economic consequences due to increased use and provision of resources.[1,2] As such, modern concepts must ensure a high quality of care without a steep increase in costs. Telehealthcare interventions have been spreading for acute and chronic medical conditions.[3–5] Despite rapidly increasing technological capabilities, barriers that restrict implementation still remain, which include legal, political, and social issues.[6] There are barriers that must be justified by the behaviour of both medical staff and patients.[7] It is also well-known that in ST-segment elevation myocardial infarction (STEMI) telemedical transmission of the 12-lead-ECG and consultation of a cardiologist lead to reduced intervals of myocardial reperfusion.[8,9] The telemedical procedure reduces in-hospital mortality in patients with STEMI.[10] However, widespread use is lacking. Besides acute coronary syndromes, telemedical interventions in the pre-hospital phase and scientific data are rare, so that many projects are not transferred into routine care after cessation of project financing.[11,12] In acute stroke, studies have shown the feasibility of video transmission from the ambulance, but this technique has not been rolled out on a grand scale, while inter-hospital teleconsultation in acute stroke is implemented in more hospital systems and could be considered routine.[13–16] Overall, only a few EMS agencies use telemedical techniques.[12]

Against this background, we conducted two interdisciplinary research projects to develop and evaluate a comprehensive mobile teleconsultation system that supports on-scene paramedics from a remote site: this is with experienced physicians in all kinds of emergency medical situations. After successful technical and

organizational development, and scientific evaluation, this system was implemented stepwise into routine care, financed by health insurance. In Germany, the EMS is generally financed by statutory health insurances and private health insurances after negotiation of needs and budget. The aim of the study was to evaluate the implementation strategy from the initial project idea to routine care, within a unique, physician-staffed telemedicine system. To evaluate systemic effects of this new concept in emergency care, the influence of implementation on EMS resources should be evaluated.

Methods

Implementation strategy

The implementation process from the project idea (2006/2007) to routine care (2014-2016) was carefully dissected into all relevant steps and milestones. These steps were analysed descriptively with the respective rationale to be able to utilise the main results.

Organisational setup

In the city of Aachen, Germany (255,967 residents; December 2017), the EMS service is an integral part of the responsibilities of the fire department. Up to eleven emergency ambulances are run by the fire brigade and three EMS agencies. All emergency ambulances are staffed with 2-year trained paramedics. Two ground-based EMS physician units are run on a 24/7 basis to assist the ambulances if advanced life-support procedures (e.g., rapid sequence induction) are necessary. All physicians are certified EMS physicians with at least 3 years of training in anaesthesia and critical care, as well as a certificate in advanced life support and pre-hospital trauma life support. If non-availability is due to duplicated events, physician-staffed units from adjacent districts or helicopter emergency medical services will be used as backup. All paramedics are trained on the telemedicine system, based on trained and published standard operating procedures.

Study design and evaluation of systemic effects

After two interdisciplinary research projects, transfer of telemedical procedures to routine care was considered possible.[17,18] To evaluate systemic influences of implementation into routine care, we compared EMS data of the 1-year pre-implementation period (April 2013–March 2014) with a similar interval after full implementation (April 2015–March 2016) in a pre-post intervention study: To assess EMS resource utilisation, the number of emergency missions carried out by on-scene EMS physicians was compared to the

two periods as the primary outcome. The cumulative number of on-scene and telemedical interventions by physicians was analysed as a secondary outcome. Non-availability of EMS physicians due to overlapping emergency calls was analysed by the number of emergency missions by EMS physician units from adjacent EMS districts, including helicopter EMS. All EMS missions in the city of Aachen were included.

With full implementation, dispatch criteria were supported with an electronic list of symptoms and possible diagnoses (n=213 scenarios). In the pre-implementation period, it was at the discretion of the dispatcher to send an EMS physician unit whenever a situation was judged to be potentially life-threatening. Following implementation, 24/7 telemedical support was available, allowing structured adjustments of dispatch criteria by the EMS medical director. These emergency scenarios were not dispatched with an on-scene EMS physician as a general rule: acute stroke with the patient awake, painful conditions with the patient awake, mild dyspnea, hypertensive urgency, and terminated seizure. In the pre-implementation period, these conditions were dispatched with an on-scene EMS physician, although no electronic support was available.

Characteristics of telemedically-supported emergencies in routine care

Data of telemedically-supported emergency missions were analysed descriptively in the post-implementation period: type of emergency mission (emergency mission vs. inter-hospital transfer), given delegated medications and medical severity. In a documented outcome, we reviewed the case to determine if a fatal outcome was a function of a telemedical intervention.

Data sources

We analysed the database of electronically documented telemedical interventions (Telemedical Documentation, P3 Telehealthcare, Aachen, Germany) and the database of the regional EMS dispatch centre (COBRA4, ISE, Aachen, Germany). Number of calls and telemedical supports, as well as conducted procedures, could be best evaluated this way. Patient data could not be connected between these systems.

Patient and Public Involvement

Patients were not involved in the design or implementation of this project. The public was informed by local media (newspaper, radio, and local television), but had no influence on the project and study design.

Ethics and study registration

Data screening and analyses were conducted after approval by the local ethics committee (University Hospital RWTH Aachen, registration number EK 109/15). All cases were pseudonymised to ensure data privacy. Systemic data of the EMS dispatch centre contained no personal data, so there was no need for pseudonymisation. Study registration was done retrospectively at clinicaltrials.gov (NCT04127565).

Statistical methods

Categorical data are presented as frequencies and percentages. Systemic parameters were compared with contingency tables, using the Chi-squared test with Yate's correction. All statistical analyses were performed using GraphPad Prism 7.0 (GraphPad Software, La Jolla, CA, USA). Due to the exploratory nature of the study, p-values < 0.05 were considered significant.

Results

Implementation process

The process of final implementation can be divided into three main phases: two research projects, followed by integration into health insurance-financed routine emergency care, standard for all conventional EMS services in Germany. We ensured that telemedical care was also financed this way. Table 1 outlines this process, including summarised research findings.[17–22] Local and national political stakeholders, health insurance companies, and EMS providers at different levels (paramedics to EMS directors/stakeholders) were integrated from the first interdisciplinary workshop.[17] Iterative development with integration of end-users allowed for design and development, and continuous adaption of the technical system, including the organizational model. In the first research project, a mobile telemedicine system with multiple applications was first developed. General feasibility and positive effects on guideline-adherence in stroke patients are shown.[14,23] Although the second project did not allow for a randomised controlled trial due to practical, political, and ethical concerns, the results of this prospective observational multicentre trial convinced political stakeholders and health insurances to transfer this concept to routine care in a model region (Aachen, Germany).[18,22,24] With routine care implementation, milestones of interim analyses and workshops were defined between the fire department, the related university (RWTH Aachen University, Germany), and

the health insurances . Periodic reporting enabled data and safety monitoring, and continuous information by decision-makers and financiers.

Technical development and capabilities in routine care

During the first project, the transmission unit was integrated into a backpack (2009), with a weight of 18 kg (self-development of research partners), while general technical development enabled miniaturisation and integration of a smartphone for system monitoring and photo transmission in the second project. Within 5 years, a stepwise professionalisation and miniaturisation saw a total weight of 1.7 kg and made the system viable for routine emergency medical care. Technical performance improved over time to a sufficient standard.[23,25] In routine care, the following technical capabilities evolved with a project related spin-off company (P3 Telehealthcare): two-way audio connection, real-time vital data transmission (numerical values and waveforms), 12-lead-ECG and still-picture transmission on-demand, as well as video streaming from in the ambulance. The connection between ambulances and the teleconsultation centre was accomplished by mobile transmission units (peeq-Box, P3 Telehealthcare) hooked to the monitor-defibrillator unit (C^3, GS Stemple Elektromedizinische Geräte, Kaufering, Germany). In the ambulance, the transmission unit was connected to a wireless local network by a conventional in-car computer. Parallel, encrypted audio and data transmission from the emergency site, including en-route, were facilitated. In the teleconsultation centre, a physician responsible for telemedical consults was available. Context-sensitive documentation software provided checklists and algorithms of current international guidelines, and a technical display of all transmitted data (Telemedical Documentation, P3 Telehealthcare).

Systemic effects of telemedical support in routine care

Before the implementation of telemedical real-time support, 25,187 EMS assignments with emergency ambulances were conducted (April 2013–March 2014). Of these, 7,882 (31.3%) were supported by an conventional on-scene EMS physician. After 1,287 telemedical-supported missions during the first-year training and implementation phase (April 2014 to March 2015), the system was fully implemented, enabling 24/7 availability. The total number of emergency ambulance missions increased to 26,462 after this (April 2015–March 2016). Of these, 2,347 (8.87%) were supported telemedically, while their characteristics are summarised in Table 2. The only NACA VI assignment was a consultation between the on-scene EMS physician and the physician at the telemedical centre for support, during a successful resuscitation of a 13-year-old child with known cardiac disease. In two of the NACA VII missions, the

paramedics contacted the tele-EMS physician for termination of resuscitation due to latency and patient age, while the EMS-physician unit was en-route. In three other NACA VII cases, the EMS physician on-scene contacted the telemedical centre for organisational issues after the patient was pronounced dead. There were no other telemedically-supported missions in which the patient suffered cardiac arrest. Those supported by on-scene EMS physicians decreased from 7,882 (31.3%, pre-intervention) to 6,360 (24%, post-intervention) for all cases, $p < 0.0001$. The rate of ground-based EMS staffed units from neighbouring districts were utilised due to a shortage of resources, dropping from 234/25,187 (0.93%) to 119/26,462 (0.45%), $p < 0.0001$. A helicopter-based EMS physician was summoned in 198 of the 25,187 (0.79%) cases pre-intervention, which decreased to 100 of 26,462 (0.38%) after implementation ($p < 0.0001$). The total number of physician-guided pre-hospital interventions increased from 7,882/25,187 (31.3% were only conventional on-scene care) to 8,707/26,462 (32.9%, telemedical and conventional on-scene care) in the 1-year post-implementation phase ($p < 0.0001$).

Table 1. Implementation strategy in steps and milestones

Phase	Process steps	Summary	References
Research Project (Med-on-aix) 2007-2010	1. Stakeholder workshops	Discussion and definition of requirements und expectations as well as misgivings; Integration of data privacy experts	[17]
	2. Technical Design and development	Development of specification booklet by medical users; integration of users into all steps of technical development	[17]
	3. Mockup tests	Technical field tests with a precursor system	
	4. Legal opinion by expert	Legal opinion about the specific legal questions of mobile telemedical care and delegation of medical procedures to paramedics	
	5. Simulation study I	Improved guideline adherence in STEMI and major trauma in full scale simulation	[19]
	6. Simulation study II (RCT)	Comparable quality of care between telemedically supported paramedics and on-scene physician teams.	[20]
	7. Development of economic models	Workshop-based with integration of politics, health insurances, technical partners and medical users.	
	8. Clinical feasibility study, prospective observational study	General feasibility was shown; video transmission in stroke and improvement of data transfer into the hospital were demonstrated.	[14,23]
	9. User survey	Interviews and questionnaire-survey of users. Future potential is seen but technical performance and usability were criticised.	[26]
Research project (TemRas) 2010-2013	10. Technical adaption	Iterative development cycles with integration of medical users. Miniaturization of the technical system.	
	11. Technical field testing	Field testing by technicians and by emergency care providers.	[27]
	12. Development and execution of a training concept for providers	Parallel training concept for paramedics and future tele-EMS-physicians.	[21]
	13. Prospective multi-centre trial in 5 EMS districts over one year	Safety, feasibility and evaluation of quality of care in 425 telemedical emergency missions	[18,22,24]
	14. Integration of health insurances and discussion of results and economic potential	Discussion of the scientific results and portability into a routine care setting. Model calculation of costs and savings potential.	
Integration into routine emergency care 2014-2015	15. Agreement with health insurances about seed funding	Seed funding of a first real-life phase, limited depending on interim results.	
	16. Technical adaption	Technical adaption and further miniaturization, integration of state-of-the-art monitor-defibrillator.	
	17. Integration and stepwise implementation into routine care (April 2014 - March 2015)	Start with 3 equipped ambulances and 12.75-hour daytime service; 24-hour coverage after 3 months and stepwise integration of 11 ambulances within one year. Implementation of telemedical contents into the yearly training concept for paramedics. Evaluation of technical performance by end-users and assessment of quality of care. Scientific evaluation of guideline adherence.	[25,28–30]
	18. Discussion of interim results with politics, German health secretary and health insurances	Quarterly performance and quality reports. Discussion of interim results with health insurances, stakeholders and politics after 6 months in a workshop.	
	19. Full implementation since April 2015	Provision of 24/7 coverage, all ambulances technically equipped. Quarterly quality reports and real-time supervision of tele-EMS physicians. Scientific evaluation of guideline adherence.	[28]

EMS, emergency medical service; RCT, randomised controlled trial; STEMI, ST-segment elevation myocardial infarction.

Table 2. Characteristics of telemedically-supported missions after full implementation

Characteristics	Number (fraction)
Telemedically supported emergency missions	2,347
- solely telemedically supported, without additional on-scene physician	2,145/2,347 (91.4%)
Telemedically supported cases with delegation of medication	1,541/2,347 (65.66%)
- cases with opioid delegation	497/2,347 (21.18%)
- delegated single medications	4,419 drug administrations in 1,541 missions
M-NACA score of telemedically supported missions: n=2,262/2,347 missions scored (96.4%)	
M-NACA II – no hospital admission necessary	165
M-NACA III – transport to hospital required	1,298
M-NACA IV – possible vital danger	613
M-NACA V – acute vital danger	180
M-NACA VI – successful cardiopulmonary resuscitation	1
M-NACA VII – death at scene	5
Telemedically supported inter-hospital transfers	315

M-NACA, modified National Advisory Committee or Aeronautics severity score. [31]

Discussion

Stepwise implementation with the integration of different end-users, politics, stakeholders, and health insurers allowed for successful transfer from the research project phase to routine care in an urban model region. After implementation, utilisation of conventional on-scene care by EMS-physicians decreased significantly, but with the implementation of a telemedicine system, the dispatch criteria were modified und restructured, with the intention of reducing primary EMS physician unit alarms.

Although comprehensive scientific results were not available for discussion about continuation, continuous involvement of decision-makers and models for economic effects fostered commitment from financiers. Periodic quality reporting and further observational scientific evaluation in routine care enabled stable integration and expansion. While this continuous information strategy and the integration of decision-making barriers to implementation were overcome, a randomised controlled trial (RCT) was judged not to be possible by researchers during the described process. There was the unanimous opinion that an RCT would have created too many barriers within the framework of projects, which could have endangered the concept. Further, in the discussion with the ethics committee, a RCT was viewed critically due to the novelty

of the system. However, these were more political than scientific reasons, but continuation of the project should not be endangered. For end-users, a satisfactory technical performance and usability were identified as key elements for implementation during user interviews and questionnaires.[26] Only in the course of the three phases were we were able to meet user requirements.[23,25,27] While integrating new telemedical procedures, including expanded skills of paramedics, the users' perspectives differed noticeably between paramedics and physicians. In a Scottish project of mobile tele-ultrasound on-board ambulances, physicians feared distraction in key roles and assessed this as too difficult for paramedics; in contrast, paramedics felt valued, and assessed this new task as their role in pre-hospital care.[32] Although no relevant data were available, we reported similar concerns by physicians, although most paramedics felt valued with the new tasks. During routine care, positive effects on quality of care, as well as guideline adherence, were shown for acute coronary syndromes, pain reduction in trauma and non-trauma emergencies, and blood pressure management in hypertensive emergencies.[28–30] However, the process from research to implementation lasted one decade (Table 1). This demonstrates that political decision-makers are not convinced with scientific results alone, but require ideas and models that allow future economic potential. General technical and social development for mobile technologies accelerated the process in the last few years. The system's operation over the one-year post-implementation period would not be called economical, as the physician at the telemedical centre was not fully occupied. System operation was possible due to health insurance financing for a pilot region. With further expansion and integration of more EMS districts, the operation could be run economically. During all discussions with decision-makers, our aim was to expand the system after implementation in one model region. In other countries like Denmark, a "telephone-only" consultation with an EMS-physician in charge is typical, but in Germany this would not have been permitted; this was due to delegation of measures and medications to the paramedics, as based on legal concerns.[33] The transmission of vital-data, ECG, still pictures, and video from the ambulance allowed for a more detailed remote assessment compared to telephone consultation alone.

The frequency of telemedical interventions increased from the integration phase to the routine phase. In more than half of the telemedically-supported rescue missions, medications (including opioids) were delegated by the tele-EMS-physician to the paramedics on-scene. During routine care with all of its unadjusted influences and potential confounders, the process of telemedically-supported paramedic care proved its potential to reduce the number of on-scene interventions by EMS physicians. However, this cannot be explained by the implementation of the telemedical system alone. The EMS dispatch criteria were restructured and modified with the aim of reducing unnecessary primary alarms of EMS physician units.

However, such dispatch criteria would likely not have been acceptable by personnel and patients, without availability of the telemedical system. Administration of opioids by paramedics is not allowed in Germany without its (telemedical) delegation by a physician. A reduced primary alarm ratio in painful conditions would have been unethical without the telemedical concept. Another factor that might have led to reduced EMS physician alarms was training effects of ambulance personnel. With improved performance in I.V.-lines, analgesia, and sedation over time, the paramedics could perform advanced care with telemedical support alone. However, these confounders probably influenced the number of EMS physician interventions and was not the result of the telemedical implementation system alone. Implementation with restructured dispatch criteria should ideally be called "multi-interventions." In similar situations, the effect cannot be attributed to a single intervention.[34] However, we also cannot exclude other confounders, given that no other structural changes were conducted in the EMS system (e.g., number of ambulances or EMS physician units) besides modified dispatch criteria. The reduction of approximately 2,500 on-scene maneuvers in one year led to the significantly increased availability of ground-based physician intervention units, shown by the reduced need for neighbouring units and helicopter-based EMS. However, a significant increase in overall physician interventions was found by adding on-scene and telemedical interventions in the post-implementation period. Although standard operating procedures existed for most common emergencies, a lower threshold for telemedical support, in contrast to summoning a physician-staffed EMS unit, has been our interpretation for this increase. A lower threshold of telemedical procedures may improve the quality of care but carries a risk of undermining the possible cost savings.

It must be acknowledged that during low acuity telemedical interventions, a parallel incoming call with high acuity can be answered, in contrast to similar on-scene interventions at different sites. Overall duration, and net time consumption of the physician, is significantly shorter with the physician in the telemedicine centre, compared to conventional on-scene care by EMS physicians.[28–30] Increased availability of limited resources of on-scene physicians is key to reducing response intervals, which can be lifesaving in life-threatening emergencies, such as major trauma or cardiopulmonary resuscitation.

Limitations

New technologies in certain work processes can lead to different behaviours of end-users. This study cannot determine if the use of the telemedical concepts was widespread for all EMS personnel or limited to some subgroups. No personal data about EMS personnel could be evaluated while following the ethics

committee's statement. In a project about clinical decision support systems for paramedics, inequalities towards the technology were found.[35] Furthermore, our study was not designed to evaluate any medical outcomes or general safety of telemedical support, both of which are major limitations of this study. Thus, it is not clear if outcomes are changed by implementing a telemedicine system with modified primary dispatch criteria. No patient who received telemedical support suffered cardiac arrest during support or transport to the hospital. In addition, other confounders influencing the number of missions cannot be excluded with certainty. Detailed economic calculations were not possible, as the telemedicine system was financed for the city of Aachen during the study period, as a pilot region. Health insurances and project participants arranged future integration of more EMS districts, so that the function of a tele-EMS physician could be utilized more efficiently and economically. Only then, can a pre-post analysis of costs between regular and 'regular-plus' telemedically-supported EMS produce meaningful findings.

Conclusions

Transfer from research projects to health insurance-financed routine care was successful, using an implementation strategy accounting for political and economic aspects. Telemedical support for paramedics is an effective new element for pre-hospital emergency care, due to shifting missions from classic on-scene physician to telemedically-supported missions. Subsequently, the availability of physician-staffed EMS units increased significantly. This could lead to shorter response times in life-threatening situations/missions. In the future, remote telemedical support holds strong economic potential due to spatial independence and shorter workload time for the responsible physician. Yet, unrecognized confounders, with modified dispatch criteria and possible learning curves, could influence the reduced number of on-scene EMS physician missions. With more implementation to routine care, we achieved a prerequisite for future randomised controlled trials, comparing on-scene vs. telemedical care in a model region.[36] Along with a randomised controlled trial, could this question be addressed - regarding how telemedical support affects patient outcomes and whether telemedical support is generally safe.

Contributors SB, JCB, SKB, MC, MF, and RR made substantial contributions to the conception and design of the current study. All authors were mainly involved in project, study design, data analysis, and publication of results of the mentioned research projects Med-on-aix and TemRas. SB, MC, and SKB performed data acquisition. The literature search was carried out by SB, JCB, SKB, MF, and RR. Data analysis and

interpretation were conducted by all authors. Statistical tests were carried out by SB, MF, and MC. All authors made substantial contributions to the manuscript, while SB and RR drafted the first complete version. All authors read and approved the final manuscript.

Funding There was no funding for this study, so the authors received no financial support for their research, authorship, or publication of this article. The first mentioned research project ("Med-on-aix") was funded by the German Federal Ministry of Economics and Technology (BMWi), [Project-No.: 01MB07022]. The second project ("TemRas") was funded by the Ministry of Innovation, Science and Research of North Rhine Westphalia, Germany (MIWF) [Project-No.: PtJ-Az. 0909im002b, Funding code 005-1003-0034].

Competing interests The authors report no specific funding in relation to this research. JCB, MC, and RR are shareholders in Docs in Clouds GmbH (Aachen, Germany), a telemedical and consulting service. All other authors declare no conflicts of interest.

Ethics approval The study was approved by the ethics committee of the RWTH Aachen University, Germany, registration number EK 109/15.

Patient consent Not required by the ethics committee.

Data sharing statement No additional data is available. The datasets used and/or analysed during the current study are available from the corresponding author after a reasonable request.

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STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	4-5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	4
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	4-5
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	5
Bias	9	Describe any efforts to address potential sources of bias	
Study size	10	Explain how the study size was arrived at	5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	5
		(*b*) Describe any methods used to examine subgroups and interactions	5
		(*c*) Explain how missing data were addressed	
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	

Continued on next page

Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	6-9
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	8-9
		(b) Indicate number of participants with missing data for each variable of interest	
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	8
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	8
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	8-9
Discussion			
Key results	18	Summarise key results with reference to study objectives	9
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	11
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	9-11
Generalisability	21	Discuss the generalisability (external validity) of the study results	11
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	12

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

Standards for Reporting Implementation Studies:

Bergrath et al. Implementation analysis and systemic effects on emergency resources by routine application of a full-scale prehospital telemedicine system

The primary focus of implementation science is the implementation strategy (column 1) and the expectation is that this will always be completed.

The evidence about the impact of the intervention on the targeted population should always be considered (column 2) and either health outcomes reported or robust evidence cited to support a known beneficial effect of the intervention on the health of individuals or populations.

The StaRI standards refers to the broad range of study designs employed in implementation science. Authors should refer to other reporting standards for advice on reporting specific methodological features. Conversely, whilst all items are worthy of consideration, not all items will be applicable to, or feasible within every study.

Checklist item		Reported on page #	Implementation Strategy	Reported on page #	Intervention
			"Implementation strategy" refers to how the intervention was implemented		"Intervention" refers to the healthcare or public health intervention that is being implemented.
Title and abstract					
Title	**1**	1	Identification as an implementation study, and description of the methodology in the title and/or keywords		
Abstract	**2**	2	Identification as an implementation study, including a description of the implementation strategy to be tested, the evidence-based intervention being implemented, and defining the key implementation and health outcomes.		
Introduction					
Introduction	**3**	3-4	Description of the problem, challenge or deficiency in healthcare or public health that the intervention being implemented aims to address.		
Rationale	**4**	4	The scientific background and rationale for the implementation strategy (including any underpinning theory/framework/model, how it is expected to achieve its effects and any pilot work).	4	The scientific background and rationale for the intervention being implemented (including evidence about its effectiveness and how it is expected to achieve its effects).

Aims and objectives	**5**	4	The aims of the study, differentiating between implementation objectives and any intervention objectives.		
Methods: description					
Design	**6**	4-5	The design and key features of the evaluation, (cross referencing to any appropriate methodology reporting standards) and any changes to study protocol, with reasons		
Context	**7**	4	The context in which the intervention was implemented. (Consider social, economic, policy, healthcare, organisational barriers and facilitators that might influence implementation elsewhere).		
Targeted 'sites'	**8**	4	The characteristics of the targeted 'site(s)' (e.g locations/personnel/resources etc.) for implementation and any eligibility criteria.	4-5	The population targeted by the intervention and any eligibility criteria.
Description	**9**	4 -5	A description of the implementation strategy	4-5	A description of the intervention
Sub-groups	**10**	N/A	Any sub-groups recruited for additional research tasks, and/or nested studies are described		
Methods: evaluation					
Outcomes	**11**	4-5	Defined pre-specified primary and other outcome(s) of the implementation strategy, and how they were assessed. Document any pre-determined targets	5	Defined pre-specified primary and other outcome(s) of the intervention (if assessed), and how they were assessed. Document any pre-determined targets
Process evaluation	**12**	4	Process evaluation objectives and outcomes related to the mechanism by which the strategy is expected to work		
Economic evaluation	**13**	N/A	Methods for resource use, costs, economic outcomes and analysis for the implementation strategy	N/A	Methods for resource use, costs, economic outcomes and analysis for the intervention
Sample size	**14**	5	Rationale for sample sizes (including sample size calculations, budgetary constraints, practical considerations, data saturation, as appropriate)		
Analysis	**15**	6	Methods of analysis (with reasons for that choice)		
Sub-group analyses	**16**	N/A	Any a priori sub-group analyses (e.g. between different sites in a multicentre study, different clinical or demographic populations), and sub-groups recruited to specific nested research tasks		

Results					
Characteristics	**17**	6-9	Proportion recruited and characteristics of the recipient population for the implementation strategy	6-9	Proportion recruited and characteristics (if appropriate) of the recipient population for the intervention
Outcomes	**18**	6-8	Primary and other outcome(s) of the implementation strategy	6-8	Primary and other outcome(s) of the Intervention (if assessed)
Process outcomes	**19**	6-7	Process data related to the implementation strategy mapped to the mechanism by which the strategy is expected to work		
Economic evaluation	**20**	N/A	Resource use, costs, economic outcomes and analysis for the implementation strategy	N/A	Resource use, costs, economic outcomes and analysis for the intervention
Sub-group analyses	**21**	N/A	Representativeness and outcomes of subgroups including those recruited to specific research tasks		
Fidelity/ adaptation	**22**	6-8	Fidelity to implementation strategy as planned and adaptation to suit context and preferences	6-8	Fidelity to delivering the core components of intervention (where measured)
Contextual changes	**23**	N/A	Contextual changes (if any) which may have affected outcomes		
Harms	**24**	N/A	All important harms or unintended effects in each group		
Discussion					
Structured discussion	**25**	9-11	Summary of findings, strengths and limitations, comparisons with other studies, conclusions and implications		
Implications	**26**	9-11	Discussion of policy, practice and/or research implications of the implementation strategy (specifically including scalability)	9-11	Discussion of policy, practice and/or research implications of the intervention (specifically including sustainability)
General					
Statements	**27**	12	Include statement(s) on regulatory approvals (including, as appropriate, ethical approval, confidential use of routine data, governance approval), trial/study registration (availability of protocol), funding and conflicts of interest		

BMJ Open

Implementation of a full-scale pre-hospital telemedicine system: Evaluation of the process and systemic effects in a pre-post intervention study

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2020-041942.R3
Article Type:	Original research
Date Submitted by the Author:	07-Mar-2021
Complete List of Authors:	Bergrath, Sebastian; RWTH Aachen University Medical Faculty, Department of Anaesthesiology; Kliniken Maria Hilf GmbH, Emergency Department Brokmann, Jörg; University Hospital Aachen, Emergency Department Beckers, Stefan ; University Hospital Aachen, Department of Anaesthesiology Felzen, Marc; University Hospital Aachen, Department of Anesthesiology Czaplik, Michael; University Hospital Aachen, Anesthesiology Rossaint, Rolf; University Hospital Aachen, Department of Anaesthesiology
Primary Subject Heading:	Emergency medicine
Secondary Subject Heading:	Health informatics, Health services research
Keywords:	ACCIDENT & EMERGENCY MEDICINE, Telemedicine < BIOTECHNOLOGY & BIOINFORMATICS, Organisational development < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Change management < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

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Implementation of a full-scale pre-hospital telemedicine system: Evaluation of the process and systemic effects in a pre-post intervention study

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Ethics committee: University Hospital RWTH Aachen, Germany, registration number EK 109/15

Trial registration: clinicaltrials.gov (NCT04127565)

Word count: 3906 (without Tables, References, or the Abstract)

Word count Abstract: 292

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Abstract

Objectives To review the implementation strategy from a research project towards routine care of a comprehensive mobile physician-staffed pre-hospital telemedicine system. The objective is to evaluate the implementation process and systemic influences on emergency medical service (EMS) resource utilisation.

Design Retrospective pre-post implementation study

Setting Two interdisciplinary projects and the EMS of a German urban region.

Interventions Implementation of a full-scale pre-hospital telemedicine system.

Endpoints Descriptive evaluation of the implementation strategy. Primary endpoint: ground- and helicopter-based physician staffed emergency missions before and after implementation.

Results The first research project revealed positive effects on guideline adherence and patient safety in two simulation studies, with feasibility demonstrated in a clinical study. After technical optimisation, safety and positive effects were demonstrated in a multicentre trial. Routine care in the city of Aachen, Germany was conducted stepwise from April 2014 to March 2015, including modified dispatch criteria. Systemic parameters of all EMS assignments between pre-implementation (April 2013 to March 2014) and post-implementation (April 2015 to March 2016): On-scene EMS physician operations decreased from 7,882/25,187 missions (31.3%) to 6,360/26,462 (24.0%), $p < 0.0001$. The need for neighbouring physician-staffed units dropped from 234/25,187 (0.93%) to 119/26,462 (0.45%), $p < 0.0001$, and the need for helicopter EMS from 198/25,187 (0.79%) to 100/26,462 (0.38%), $p < 0.0001$. In the post-implementation period 2,347 telemedical interventions were conducted, with 26,462 emergency missions (8.87%).

Conclusion A stepwise implementation strategy allowed transfer from the project phase to routine care. We detected a reduced need for conventional on-scene physician care by ground and helicopter-based EMS, but cannot exclude unrecognized confounders, including modified dispatch criteria and possible learning effects. This creates the potential for increased availability of EMS physicians for life-threatening emergencies by shifting physician interventions from conventional to telemedical care.

Trial registration: Clinicaltrials.gov/NCT04127565, retrospectively registered.

Keywords: Emergency medicine, emergency medical service physician, telemedicine, telecare, quality of care.

Strengths and limitations of the study

- The strength of the study is the description of different methods of implementation in a pre-hospital telemedicine system, with the transfer from project phase to routine care.
- We used real-life data from an EMS dispatch centre to evaluate the effect on emergency medical service resource utilisation by implementation of a telemedical support system.
- This is the first study to examine effects the aforementioned implementation in an urban region.
- The limitation is that other influencing factors, such as adapted dispatch criteria, may have also influenced the results, which could not be calculated.
- Influences on patient outcomes could not be evaluated, another limitation of our findings.

Introduction

Emergency medical services (EMS) face increasing emergency missions. Besides possible negative effects on patient outcome due to prolonged response intervals, there are economic consequences due to increased use and provision of resources.[1,2] As such, modern concepts must ensure a high quality of care without a steep increase in costs. Telehealthcare interventions have been spreading for acute and chronic medical conditions.[3–5] Despite rapidly increasing technological capabilities, barriers that restrict implementation still remain, which include legal, political, and social issues.[6] There are barriers that must be justified by the behaviour of both medical staff and patients.[7] It is also well-known that in ST-segment elevation myocardial infarction (STEMI) telemedical transmission of the 12-lead-ECG and consultation of a cardiologist lead to reduced intervals of myocardial reperfusion.[8,9] By using the telemedical procedure in-hospital mortality in patients with STEMI can be reduced.[10] However, widespread use is lacking. Besides acute coronary syndromes, telemedical interventions in the pre-hospital phase and scientific data are rare, so that many projects are not transferred into routine care after cessation of project financing.[11,12] In acute stroke, studies have shown the feasibility of video transmission from the ambulance, but this technique has not been rolled out on a grand scale, while inter-hospital teleconsultation in acute stroke is implemented in more hospital systems and could be considered routine.[13–16] Overall, only a few EMS agencies use telemedical techniques.[12] In Germany, delegation of medications (e.g. opioids) from physicians to ambulance personnel is regulated very strictly compared to other countries like Denmark.[17,18] To enable delegation of medications without physical presence of a physician on-scene,

the responsible physician has to have a complete overview about the patient by German law, which can probably only achieved be telemedical virtual presence.

Against this background, we conducted two interdisciplinary research projects to develop and evaluate a comprehensive mobile teleconsultation system that supports on-scene paramedics from a remote site: this is with experienced physicians in all kinds of emergency medical situations. After technical and organizational development, and scientific evaluation, this system was implemented stepwise into routine care, financed by health insurance. In Germany, the EMS is generally financed by statutory health insurances and private health insurances after negotiation of needs and budget. The aim of the study was to evaluate the implementation strategy from the initial project idea to routine care, within a unique, physician-staffed telemedicine system. To evaluate systemic effects of this new concept in emergency care, the influence of implementation on EMS resources should be evaluated.

Methods

Implementation strategy

The implementation process from the project idea (2006/2007) to routine care (2014-2016) was carefully dissected into all relevant steps and milestones. These steps were analysed descriptively with the respective rationale to be able to utilise the main results.

Organisational setup

In the city of Aachen, Germany (255,967 residents; December 2017), the EMS service is an integral part of the responsibilities of the fire department. Up to eleven emergency ambulances are run by the fire brigade and three EMS agencies. All emergency ambulances are staffed with 2-year trained paramedics. Two ground-based EMS physician units are run on a 24/7 basis to assist the ambulances if advanced life-support procedures (e.g., rapid sequence induction) are necessary. All physicians are certified EMS physicians with at least 3 years of training in anaesthesia and critical care, as well as a certificate in advanced life support and pre-hospital trauma life support. If non-availability is due to duplicated events, physician-staffed units from adjacent districts or helicopter emergency medical services will be used as backup. All paramedics are trained on the telemedicine system, based on trained and published standard operating procedures.

Study design and evaluation of systemic effects

After two interdisciplinary research projects, transfer of telemedical procedures to routine care was considered possible.[19,20] To evaluate systemic influences of implementation into routine care, we compared EMS data of the 1-year pre-implementation period (April 2013–March 2014) with a similar interval after full implementation (April 2015–March 2016) in a pre-post intervention study: To assess EMS resource utilisation, the number of emergency missions carried out by on-scene EMS physicians was compared to the two periods as the primary outcome. The cumulative number of on-scene and telemedical interventions by physicians was analysed as a secondary outcome. Non-availability of EMS physicians due to overlapping emergency calls was analysed by the number of emergency missions by EMS physician units from adjacent EMS districts, including helicopter EMS. All EMS missions in the city of Aachen were included. With full implementation, dispatch criteria were supported with an electronic list of symptoms and possible diagnoses (n=213 scenarios). In the pre-implementation period, it was at the discretion of the dispatcher to send an EMS physician unit whenever a situation was judged to be potentially life-threatening. Following implementation, 24/7 telemedical support was available, allowing structured adjustments of dispatch criteria by the EMS medical director. These emergency scenarios were not dispatched with an on-scene EMS physician as a general rule: acute stroke with the patient awake, painful conditions with the patient awake, mild dyspnea, hypertensive urgency, and terminated seizure. In the pre-implementation period, these conditions were dispatched with an on-scene EMS physician, although no electronic support was available.

Interaction of tele-EMS-physician and ambulance personnel

The paramedics on-scene - or in special situations the EMS-physician on-scene - decided if telemedical support was necessary based on standard operating procedures and based on personal assessment. After initiation of the call by the personnel on-scene they described the situation and they addressed questions to the tele-EMS physician in the telemedical centre. Automatically, all real-time vital parameters (numerical values and curves), all 12-lead ECGs and all still pictures taken with a smartphone were transmitted to the telemedicine centre from the start of the teleconsultation. After verbal consent of the ambulance personnel and the patient, the tele-EMS physician was able to start a real-time video transmission from a camera embedded into the ceiling of the ambulance. Short and direct communication rules should be used to allow structured and clear messages. Delegated medications had to be communicated clearly with substance name and dosage from the tele-EMS physician to the paramedics and they had to repeat substance name

and dosage. After administration of the medication, they had to confirm it. Termination of the teleconsultation was decided jointly.

Legal framework

Delegation of medical procedures and medications to paramedics is regulated strictly in Germany. The responsible physician has to have a complete overview about the medical status of the patient. Therefore, trans-telephonic communication alone – which is routine in other countries like Denmark – is not sufficient if a broad spectrum of delegated medications should be achieved.[17,18] By using a multifunctional telemedical system which allows nearly a virtual presence via a functionalities like real-time video transmission this legal barriers can be overcome.

Characteristics of telemedically-supported emergencies in routine care

Data of telemedically-supported emergency missions were analysed descriptively in the post-implementation period: type of emergency mission (emergency mission vs. inter-hospital transfer), given delegated medications and medical severity. In a documented outcome, we reviewed the case to determine if a fatal outcome was a function of a telemedical intervention.

Data sources

We analysed the database of electronically documented telemedical interventions (Telemedical Documentation, P3 Telehealthcare, Aachen, Germany) and the database of the regional EMS dispatch centre (COBRA4, ISE, Aachen, Germany). Number of calls and telemedical supports, as well as conducted procedures, could be best evaluated this way. Patient data could not be connected between these systems.

Patient and Public Involvement

Patients were not involved in the design or implementation of this project. The public was informed by local media (newspaper, radio, and local television), but had no influence on the project and study design.

Ethics and study registration

Data screening and analyses were conducted after approval by the local ethics committee (University Hospital RWTH Aachen, registration number EK 109/15). All cases were pseudonymised to ensure data

privacy. Systemic data of the EMS dispatch centre contained no personal data, so there was no need for pseudonymisation. Study registration was done retrospectively at clinicaltrials.gov (NCT04127565).

Statistical methods

Categorical data are presented as frequencies and percentages. Systemic parameters were compared with contingency tables, using the Chi-squared test with Yate's correction. All statistical analyses were performed using GraphPad Prism 7.0 (GraphPad Software, La Jolla, CA, USA). Due to the exploratory nature of the study, p-values < 0.05 were considered significant.

Results

Implementation process

The process of final implementation can be divided into three main phases: two research projects, followed by integration into health insurance-financed routine emergency care, standard for all conventional EMS services in Germany. We ensured that telemedical care was also financed this way. Table 1 outlines this process, including summarised research findings.[19–24] Local and national political stakeholders, health insurance companies, and EMS providers at different levels (paramedics to EMS directors/stakeholders) were integrated from the first interdisciplinary workshop.[19] Iterative development with integration of end-users allowed for design and development, and continuous adaption of the technical system, including the organizational model. In the first research project, a mobile telemedicine system with multiple applications was first developed. General clinical and technical feasibility of prehospital teleconsultation and positive effects on stroke specific information transfer were shown.[14,25] Although the second project did not allow for a randomised controlled trial due to practical, political, and ethical concerns, the results of this prospective observational multicentre trial convinced political stakeholders and health insurances to transfer this concept to routine care in a model region (Aachen, Germany).[20,24,26] With routine care implementation, milestones of interim analyses and workshops were defined between the fire department, the related university (RWTH Aachen University, Germany), and the health insurances. Periodic quality reporting including review of data and screening for major events enabled data and patient safety monitoring, and continuous information by decision-makers and financiers. Clinical data for case review

were extracted out of the electronic documentation system, technical performance was monitored using questionnaires about the technical performance based on the user's perspective.[27]

Technical development and capabilities in routine care

During the first project, the transmission unit was integrated into a backpack (2009), with a weight of 18 kg (self-development of research partners), while general technical development enabled miniaturisation and integration of a smartphone for system monitoring and photo transmission in the second project. Within 5 years, a stepwise professionalisation and miniaturisation saw a total weight of 1.7 kg and made the system viable for routine emergency medical care. Technical performance improved over time to a sufficient standard.[25,27] In routine care, the following technical capabilities evolved with a project related spin-off company (P3 Telehealthcare): two-way audio connection, real-time vital data transmission (numerical values and waveforms), 12-lead-ECG and still-picture transmission on-demand, as well as video streaming from in the ambulance. The connection between ambulances and the teleconsultation centre was accomplished by mobile transmission units (peeq-Box, P3 Telehealthcare) hooked to the monitor-defibrillator unit (C^3, GS Stemple Elektromedizinische Geräte, Kaufering, Germany). In the ambulance, the transmission unit was connected to a wireless local network by a conventional in-car computer. Parallel, encrypted audio and data transmission from the emergency site, including en-route, were facilitated. In the teleconsultation centre, a physician responsible for telemedical consults was available. Context-sensitive documentation software provided checklists and algorithms of current international guidelines, and a technical display of all transmitted data (Telemedical Documentation, P3 Telehealthcare).

Systemic effects of telemedical support in routine care

Before the implementation of telemedical real-time support, 25,187 EMS assignments with emergency ambulances were conducted (April 2013–March 2014). Of these, 7,882 (31.3%) were supported by an conventional on-scene EMS physician. After 1,287 telemedical-supported missions during the first-year training and implementation phase (April 2014 to March 2015), the system was fully implemented, enabling 24/7 availability. The total number of emergency ambulance missions increased to 26,462 after this (April 2015–March 2016). Of these, 2,347 (8.87%) were supported telemedically, while their characteristics are summarised in Table 2. The only NACA VI assignment was a consultation between the on-scene EMS physician and the physician at the telemedical centre for support, during a successful resuscitation of a 13-year-old child with known cardiac disease. In two of the NACA VII missions, the

paramedics contacted the tele-EMS physician for termination of resuscitation due to latency and patient age, while the EMS-physician unit was en-route. In three other NACA VII cases, the EMS physician on-scene contacted the telemedical centre for organisational issues after the patient was pronounced dead. There were no other telemedically-supported missions in which the patient suffered cardiac arrest. Those supported by on-scene EMS physicians decreased from 7,882 (31.3%, pre-intervention) to 6,360 (24%, post-intervention) for all cases, $p < 0.0001$. The rate of ground-based EMS staffed units from neighbouring districts were utilised due to a shortage of resources, dropping from 234/25,187 (0.93%) to 119/26,462 (0.45%), $p < 0.0001$. A helicopter-based EMS physician was summoned in 198 of the 25,187 (0.79%) cases pre-intervention, which decreased to 100 of 26,462 (0.38%) after implementation ($p < 0.0001$). The total number of physician-guided pre-hospital interventions increased from 7,882/25,187 (31.3% were only conventional on-scene care) to 8,707/26,462 (32.9%, telemedical and conventional on-scene care) in the 1-year post-implementation phase ($p < 0.0001$).

Table 1. Implementation strategy in steps and milestones

Phase	Process steps	Summary	References
Research Project (Med-on-aix) 2007-2010	1. Stakeholder workshops	Discussion and definition of requirements und expectations as well as misgivings; Integration of data privacy experts	[19]
	2. Technical Design and development	Development of specification booklet by medical users; integration of users into all steps of technical development	[19]
	3. Mockup tests	Technical field tests with a precursor system	
	4. Legal opinion by expert	Legal opinion about the specific legal questions of mobile telemedical care and delegation of medical procedures to paramedics	
	5. Simulation study I	Improved guideline adherence in STEMI and major trauma in full scale simulation	[21]
	6. Simulation study II (RCT)	Comparable quality of care between telemedically supported paramedics and on-scene physician teams.	[22]
	7. Development of economic models	Workshop-based with integration of politics, health insurances, technical partners and medical users.	
	8. Clinical feasibility study, prospective observational study	General feasibility was shown; video transmission in stroke and improvement of data transfer into the hospital were demonstrated.	[14,25]
	9. User survey	Interviews and questionnaire-survey of users. Future potential is seen but technical performance and usability were criticised.	[28]
Research project (TemRas) 2010-2013	10. Technical adaption	Iterative development cycles with integration of medical users. Miniaturization of the technical system.	
	11. Technical field testing	Field testing by technicians and by emergency care providers.	[29]
	12. Development and execution of a training concept for providers	Parallel training concept for paramedics and future tele-EMS-physicians.	[23]
	13. Prospective multi-centre trial in 5 EMS districts over one year	Safety, feasibility and evaluation of quality of care in 425 telemedical emergency missions	[20,24,26]
	14. Integration of health insurances and discussion of results and economic potential	Discussion of the scientific results and portability into a routine care setting. Model calculation of costs and savings potential.	
Integration into routine emergency care 2014-2015	15. Agreement with health insurances about seed funding	Seed funding of a first real-life phase, limited depending on interim results.	
	16. Technical adaption	Technical adaption and further miniaturization, integration of state-of-the-art monitor-defibrillator.	
	17. Integration and stepwise implementation into routine care (April 2014 - March 2015)	Start with 3 equipped ambulances and 12.75-hour daytime service; 24-hour coverage after 3 months and stepwise integration of 11 ambulances within one year. Implementation of telemedical contents into the yearly training concept for paramedics. Evaluation of technical performance by end-users and assessment of quality of care. Scientific evaluation of guideline adherence.	[27,30–32]
	18. Discussion of interim results with politics, German health secretary and health insurances	Quarterly performance and quality reports. Discussion of interim results with health insurances, stakeholders and politics after 6 months in a workshop.	
	19. Full implementation since April 2015	Provision of 24/7 coverage, all ambulances technically equipped. Quarterly quality reports and real-time supervision of tele-EMS physicians. Scientific evaluation of guideline adherence.	[30]

EMS, emergency medical service; RCT, randomised controlled trial; STEMI, ST-segment elevation myocardial infarction.

Table 2. Characteristics of telemedically-supported missions after full implementation

Characteristics	Number (fraction)
Telemedically supported emergency missions	2,347
- solely telemedically supported, without additional on-scene physician	2,145/2,347 (91.4%)
Telemedically supported cases with delegation of medication	1,541/2,347 (65.66%)
- cases with opioid delegation	497/2,347 (21.18%)
- delegated single medications	4,419 drug administrations in 1,541 missions
M-NACA score of telemedically supported missions: n=2,262/2,347 missions scored (96.4%)	
M-NACA II – no hospital admission necessary	165
M-NACA III – transport to hospital required	1,298
M-NACA IV – possible vital danger	613
M-NACA V – acute vital danger	180
M-NACA VI – successful cardiopulmonary resuscitation	1
M-NACA VII – death at scene	5
Telemedically supported inter-hospital transfers	315

M-NACA, modified National Advisory Committee or Aeronautics severity score. [33]

Discussion

Stepwise implementation with the integration of different end-users, politics, stakeholders, and health insurers allowed for successful transfer from the research project phase to routine care in an urban model region. After implementation, utilisation of conventional on-scene care by EMS-physicians decreased significantly, but with the implementation of a telemedicine system, the dispatch criteria were modified und restructured, with the intention of reducing primary EMS physician unit alarms.

Although comprehensive scientific results were not available for discussion about continuation, continuous involvement of decision-makers and models for economic effects fostered commitment from financiers. Periodic quality reporting and further observational scientific evaluation in routine care enabled stable integration and expansion. While this continuous information strategy and the integration of decision-making barriers to implementation were overcome, a randomised controlled trial (RCT) was judged not to be possible by researchers during the described process. There was the unanimous opinion that an RCT would have created too many barriers within the framework of projects, which could have endangered the concept. Further, in the discussion with the ethics committee, a RCT was viewed critically due to the novelty

of the system. However, these were more political than scientific reasons, but continuation of the project should not be endangered. For end-users, a satisfactory technical performance and usability were identified as key elements for implementation during user interviews and questionnaires.[28] Only in the course of the three phases were we were able to meet user requirements.[25,27,29] While integrating new telemedical procedures, including expanded skills of paramedics, the users' perspectives differed noticeably between paramedics and physicians. In a Scottish project of mobile tele-ultrasound on-board ambulances, physicians feared distraction in key roles and assessed this as too difficult for paramedics; in contrast, paramedics felt valued, and assessed this new task as their role in pre-hospital care.[34] Although no relevant data were available, we reported similar concerns by physicians, although most paramedics felt valued with the new tasks. During routine care, positive effects on quality of care, as well as guideline adherence, were shown for acute coronary syndromes, pain reduction in trauma and non-trauma emergencies, and blood pressure management in hypertensive emergencies.[30–32] However, the process from research to implementation lasted one decade (Table 1). This demonstrates that political decision-makers are not convinced with scientific results alone but require ideas and models that allow future economic potential. General technical and social development for mobile technologies accelerated the process in the last few years. The system's operation over the one-year post-implementation period would not be called economical, as the physician at the telemedical centre was not fully occupied. System operation was possible due to health insurance financing for a pilot region. With further expansion and integration of more EMS districts, the operation could be run economically. During all discussions with decision-makers, our aim was to expand the system after implementation in one model region. In other countries like Denmark, a "telephone-only" consultation with an EMS-physician in charge is typical, but in Germany this would not have been permitted; this was due to delegation of measures and medications to the paramedics, as based on legal concerns.[17] The transmission of vital-data, ECG, still pictures, and video from the ambulance allowed for a more detailed remote assessment compared to telephone consultation alone.

The frequency of telemedical interventions increased from the integration phase to the routine phase. In more than half of the telemedically-supported rescue missions, medications (including opioids) were delegated by the tele-EMS-physician to the paramedics on-scene. During routine care with all of its unadjusted influences and potential confounders, the process of telemedically-supported paramedic care proved its potential to reduce the number of on-scene interventions by EMS physicians. However, this cannot be explained by the implementation of the telemedical system alone. The EMS dispatch criteria were restructured and modified with the aim of reducing unnecessary primary alarms of EMS physician units.

However, such dispatch criteria would likely not have been acceptable by personnel and patients, without availability of the telemedical system. Administration of opioids by paramedics is not allowed in Germany without its (telemedical) delegation by a physician. A reduced primary alarm ratio in painful conditions would have been unethical without the telemedical concept. Another factor that might have led to reduced EMS physician alarms was training effects of ambulance personnel. With improved performance in I.V.-lines, analgesia, and sedation over time, the paramedics could perform advanced care with telemedical support alone. However, these confounders probably influenced the number of EMS physician interventions and was not the result of the telemedical implementation system alone. Implementation with restructured dispatch criteria should ideally be called "multi-interventions." In similar situations, the effect cannot be attributed to a single intervention.[35] However, we also cannot exclude other confounders, given that no other structural changes were conducted in the EMS system (e.g., number of ambulances or EMS physician units) besides modified dispatch criteria. The reduction of approximately 2,500 on-scene maneuvers in one year led to the significantly increased availability of ground-based physician intervention units, shown by the reduced need for neighbouring units and helicopter-based EMS. However, a significant increase in overall physician interventions was found by adding on-scene and telemedical interventions in the post-implementation period. Although standard operating procedures existed for most common emergencies, a lower threshold for telemedical support, in contrast to summoning a physician-staffed EMS unit, has been our interpretation for this increase. A lower threshold of telemedical procedures may improve the quality of care but carries a risk of undermining the possible cost savings.

It must be acknowledged that during low acuity telemedical interventions, a parallel incoming call with high acuity can be answered, in contrast to similar on-scene interventions at different sites. Overall duration, and net time consumption of the physician, is significantly shorter with the physician in the telemedicine centre, compared to conventional on-scene care by EMS physicians.[30–32] Increased availability of limited resources of on-scene physicians is key to reducing response intervals, which can be lifesaving in life-threatening emergencies, such as major trauma or cardiopulmonary resuscitation.

Limitations

New technologies in certain work processes can lead to different behaviours of end-users. This study cannot determine if the use of the telemedical concepts was widespread for all EMS personnel or limited to some subgroups. No personal data about EMS personnel could be evaluated while following the ethics

committee's statement. In a project about clinical decision support systems for paramedics, inequalities towards the technology were found.[36] Furthermore, our study was not designed to evaluate any medical outcomes or general safety of telemedical support, both of which are major limitations of this study. Thus, it is not clear if outcomes are changed by implementing a telemedicine system with modified primary dispatch criteria. No patient who received telemedical support suffered cardiac arrest during support or transport to the hospital. In addition, other confounders influencing the number of missions cannot be excluded with certainty. Detailed economic calculations were not possible, as the telemedicine system was financed for the city of Aachen during the study period, as a pilot region. Health insurances and project participants arranged future integration of more EMS districts, so that the function of a tele-EMS physician could be utilized more efficiently and economically. Only then, can a pre-post analysis of costs between regular and 'regular-plus' telemedically-supported EMS produce meaningful findings.

Conclusions

Transfer from research projects to health insurance-financed routine care was successful, using an implementation strategy accounting for political and economic aspects. Telemedical support for paramedics is an effective new element for pre-hospital emergency care, due to shifting missions from classic on-scene physician to telemedically-supported missions. Subsequently, the availability of physician-staffed EMS units increased significantly. This could lead to shorter response times in life-threatening situations/missions. In the future, remote telemedical support holds strong economic potential due to spatial independence and shorter workload time for the responsible physician. Yet, unrecognized confounders, with modified dispatch criteria and possible learning curves, could influence the reduced number of on-scene EMS physician missions. With more implementation to routine care, we achieved a prerequisite for future randomised controlled trials, comparing on-scene vs. telemedical care in a model region.[37] Along with a randomised controlled trial, could this question be addressed - regarding how telemedical support affects patient outcomes and whether telemedical support is generally safe.

Contributors SB, JCB, SKB, MC, MF, and RR made substantial contributions to the conception and design of the current study. All authors were mainly involved in project, study design, data analysis, and publication of results of the mentioned research projects Med-on-aix and TemRas. SB, MC, and SKB performed data acquisition. The literature search was carried out by SB, JCB, SKB, MF, and RR. Data analysis and

interpretation were conducted by all authors. Statistical tests were carried out by SB, MF, and MC. All authors made substantial contributions to the manuscript, while SB and RR drafted the first complete version. All authors read and approved the final manuscript.

Funding There was no funding for this study, so the authors received no financial support for their research, authorship, or publication of this article. The first mentioned research project ("Med-on-aix") was funded by the German Federal Ministry of Economics and Technology (BMWi), [Project-No.: 01MB07022]. The second project ("TemRas") was funded by the Ministry of Innovation, Science and Research of North Rhine Westphalia, Germany (MIWF) [Project-No.: PtJ-Az. 0909im002b, Funding code 005-1003-0034].

Competing interests The authors report no specific funding in relation to this research. JCB, MC, and RR are shareholders in Docs in Clouds GmbH (Aachen, Germany), a telemedical and consulting service. All other authors declare no conflicts of interest.

Ethics approval The study was approved by the ethics committee of the RWTH Aachen University, Germany, registration number EK 109/15.

Patient consent Not required by the ethics committee.

Data sharing statement No additional data is available. The datasets used and/or analysed during the current study are available from the corresponding author after a reasonable request.

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STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	4-5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	4
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	4-5
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	5
Bias	9	Describe any efforts to address potential sources of bias	
Study size	10	Explain how the study size was arrived at	5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	5
		(*b*) Describe any methods used to examine subgroups and interactions	5
		(*c*) Explain how missing data were addressed	
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	

Continued on next page

Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	6-9
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	8-9
		(b) Indicate number of participants with missing data for each variable of interest	
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	8
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	8
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	8-9
Discussion			
Key results	18	Summarise key results with reference to study objectives	9
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	11
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	9-11
Generalisability	21	Discuss the generalisability (external validity) of the study results	11
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	12

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

Standards for Reporting Implementation Studies:

Bergrath et al. Implementation analysis and systemic effects on emergency resources by routine application of a full-scale prehospital telemedicine system

The primary focus of implementation science is the implementation strategy (column 1) and the expectation is that this will always be completed.

The evidence about the impact of the intervention on the targeted population should always be considered (column 2) and either health outcomes reported or robust evidence cited to support a known beneficial effect of the intervention on the health of individuals or populations.

The StaRI standards refers to the broad range of study designs employed in implementation science. Authors should refer to other reporting standards for advice on reporting specific methodological features. Conversely, whilst all items are worthy of consideration, not all items will be applicable to, or feasible within every study.

Checklist item		Reported on page #	Implementation Strategy	Reported on page #	Intervention
			"Implementation strategy" refers to how the intervention was implemented		"Intervention" refers to the healthcare or public health intervention that is being implemented.
Title and abstract					
Title	**1**	1	Identification as an implementation study, and description of the methodology in the title and/or keywords		
Abstract	**2**	2	Identification as an implementation study, including a description of the implementation strategy to be tested, the evidence-based intervention being implemented, and defining the key implementation and health outcomes.		
Introduction					
Introduction	**3**	3-4	Description of the problem, challenge or deficiency in healthcare or public health that the intervention being implemented aims to address.		
Rationale	**4**	4	The scientific background and rationale for the implementation strategy (including any underpinning theory/framework/model, how it is expected to achieve its effects and any pilot work).	4	The scientific background and rationale for the intervention being implemented (including evidence about its effectiveness and how it is expected to achieve its effects).

Aims and objectives	**5**	4	The aims of the study, differentiating between implementation objectives and any intervention objectives.		
Methods: description					
Design	**6**	4-5	The design and key features of the evaluation, (cross referencing to any appropriate methodology reporting standards) and any changes to study protocol, with reasons		
Context	**7**	4	The context in which the intervention was implemented. (Consider social, economic, policy, healthcare, organisational barriers and facilitators that might influence implementation elsewhere).		
Targeted 'sites'	**8**	4	The characteristics of the targeted 'site(s)' (e.g locations/personnel/resources etc.) for implementation and any eligibility criteria.	4-5	The population targeted by the intervention and any eligibility criteria.
Description	**9**	4 -5	A description of the implementation strategy	4-5	A description of the intervention
Sub-groups	**10**	N/A	Any sub-groups recruited for additional research tasks, and/or nested studies are described		
Methods: evaluation					
Outcomes	**11**	4-5	Defined pre-specified primary and other outcome(s) of the implementation strategy, and how they were assessed. Document any pre-determined targets	5	Defined pre-specified primary and other outcome(s) of the intervention (if assessed), and how they were assessed. Document any pre-determined targets
Process evaluation	**12**	4	Process evaluation objectives and outcomes related to the mechanism by which the strategy is expected to work		
Economic evaluation	**13**	N/A	Methods for resource use, costs, economic outcomes and analysis for the implementation strategy	N/A	Methods for resource use, costs, economic outcomes and analysis for the intervention
Sample size	**14**	5	Rationale for sample sizes (including sample size calculations, budgetary constraints, practical considerations, data saturation, as appropriate)		
Analysis	**15**	6	Methods of analysis (with reasons for that choice)		
Sub-group analyses	**16**	N/A	Any a priori sub-group analyses (e.g. between different sites in a multicentre study, different clinical or demographic populations), and sub-groups recruited to specific nested research tasks		

Results					
Characteristics	**17**	6-9	Proportion recruited and characteristics of the recipient population for the implementation strategy	6-9	Proportion recruited and characteristics (if appropriate) of the recipient population for the intervention
Outcomes	**18**	6-8	Primary and other outcome(s) of the implementation strategy	6-8	Primary and other outcome(s) of the Intervention (if assessed)
Process outcomes	**19**	6-7	Process data related to the implementation strategy mapped to the mechanism by which the strategy is expected to work		
Economic evaluation	**20**	N/A	Resource use, costs, economic outcomes and analysis for the implementation strategy	N/A	Resource use, costs, economic outcomes and analysis for the intervention
Sub-group analyses	**21**	N/A	Representativeness and outcomes of subgroups including those recruited to specific research tasks		
Fidelity/ adaptation	**22**	6-8	Fidelity to implementation strategy as planned and adaptation to suit context and preferences	6-8	Fidelity to delivering the core components of intervention (where measured)
Contextual changes	**23**	N/A	Contextual changes (if any) which may have affected outcomes		
Harms	**24**	N/A	All important harms or unintended effects in each group		
Discussion					
Structured discussion	**25**	9-11	Summary of findings, strengths and limitations, comparisons with other studies, conclusions and implications		
Implications	**26**	9-11	Discussion of policy, practice and/or research implications of the implementation strategy (specifically including scalability)	9-11	Discussion of policy, practice and/or research implications of the intervention (specifically including sustainability)
General					
Statements	**27**	12	Include statement(s) on regulatory approvals (including, as appropriate, ethical approval, confidential use of routine data, governance approval), trial/study registration (availability of protocol), funding and conflicts of interest		