

Effect of the emergency dataset on prehospital emergency care for internal medical emergencies – Results of a simulation study

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Summary

Background

Under the German E-Health Act, patients are entitled to have important emergency data stored on their electronic health card in the form of an emergency dataset. In the T.I.M.E. project, the effect of the emergency dataset on prehospital treatment was investigated by comparing diagnoses and therapeutic decisions in simulated emergency scenarios both with and without an emergency dataset.

Methods

In a simulation study, a total of 72 emergency physicians were each confronted with two different emergency situations. Patients and their relatives were represented by actors. The simulation study was divided into two sub-studies, each of which was conducted with a cross-over design so that the emergency physicians had an emergency dataset available in only one of the two situations. Scenarios in which information could be found in the patient's surroundings (e.g., medication packages, doctors' letters) or in which no further information was available served as a control. The emergency operations and subsequent handover were recorded on video and analysed with regard to predefined outcome variables.

Results

When an emergency dataset was available, information crucial to further

treatment was recognised much more frequently (78 % vs. 18 %). No influence could be determined on treatment options which had in advance been defined as undesirable (49 % vs. 43 %). There was no evidence of an influence of the emergency dataset on the duration of the emergency mission. The preferred storage medium for the emergency dataset was the electronic health card (74 %) followed in popularity by a simple paper version (68 %).

Conclusions

Without delaying treatment, the emergency dataset helps emergency physicians gain access to information that can be decisive in providing adequate (prehospital) care. The actual effect on the quality of care should be investigated using data from everyday medical practice.

Introduction

A number of different outlooks on telemedicine were tied to the introduction of the German electronic health card (e-Health Card, eHC). Emergency data management (EDM) is a central component of the e-Health Card, and the legal basis for creating an emergency dataset (EDS) was established with the introduction of the Safe Digital Communication and Implementation in Healthcare Act¹ (E-Health Act) on 01.01.2016. In alignment with the German Medical

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Competing interests

The authors declare no competing interests.

Keywords

Telemedicine – Emergency Treatment – Emergency Medical Services – Comparative Study – Information Technology

Association, the EDS contains the following data, defined as being relevant to emergency care [1,2]:

- Diagnoses
- Medication
- Allergies and intolerances
- Special notes (e.g., pregnancy, implants)
- Additional voluntary information provided by the insured party (e.g., blood group)
- Contact details (treating physicians, emergency contacts).

In addition, remarks on where any personal declarations – such as advance directives including a living will or power of attorney, or documenting intent with regard to organ donation – are filed, can be saved to the card [3]. Whilst, technically speaking, information on personal declarations are stored in a separate data file, the term emergency dataset will be used in this paper to include both sets of data. Storing emergency data on the eHC is optional and therefore voluntary for the insured party. The data can be retrieved by any physician using their electronic Health Professional Card (eHPC) without any collaboration by the patient [1,3]; as such, access is ensured even in an emergency scenario (e.g., altered level of consciousness).

Despite the determinations in the E-Health Act, EDM is not currently employed in any practical sense. The implementation of the necessary telematics infrastructure is currently being prepared; the intention is that the electronic medication schedule (eMS) and emergency dataset can be saved to the eHC by the middle of 2020 [3]. As such, previous papers on the EDS have concentrated on content validity [4], developing concepts for fulfilling data protection requirements and measures ensuring the authenticity of the data [1]. An exploratory study saw emergency physicians and emergency medical personnel attribute significant subjective benefit to the EDS when benefit was estimated by evaluating exemplary EDS on the basis of fictitious emergency scenarios [4]. When a panel of medical experts made up of emergency phy-

sicians was consulted on the EDS in the context of a risk analysis, almost 90 % of the panel agreed that the availability of emergency data was (more) likely to increase the medical quality of emergency care [5].

The aim of the “T.I.M.E. – Timely Information in Medical Emergencies” project is to increase the quality, safety and efficacy of emergency care through use of innovative and user-oriented information and communication solutions. This paper evaluates the use and limitations of the EDS within the scope of a realistic simulated scenario to determine its potential practical use.

Methods

Study design

A simulation study consisting of two sub-trials was implemented to research the effect of the EDS on prehospital care for emergency patients. Care given when the EDS was available was analysed and compared with scenarios in which relevant past medical history was instead to be found in the patient’s immediate surroundings (trial 1) or in which no additional information was available (trial 2). Three different emergency scenarios were developed and simulated with the aid of actors, who took on the roles of the patient and their relatives, acting in accordance with a script. The main outcome measure was avoidance of undesirable or contraindicated therapeutic interventions. The duration of treatment by the emergency physician and awareness of past medical history relevant to treatment were secondary endpoints. Proband was emergency physicians from the greater area of North Rhine-Westphalia with a minimum of one year’s practical experience in physician staffed emergency services. Their approach to the emergency scenario and their handover at a fictitious hospital were documented on video and subsequently analysed on the basis of predefined criteria. Ethics approval was obtained from the ethics commission of the Westphalia-Lippe Medical Asso-

ciation and the University of Münster prior to commencing the study (2016-369-f-S).

Both sub-trials took place at the training centre at Münster University Hospital on two consecutive days in both September 2016 and October 2017. Taking into account limited resources and available space, the number of participants was limited in the planning phase to 36 emergency physicians per trial. No proband was involved in the T.I.M.E. project in any other capacity and each proband could only participate in one trial. Various considerations led to a so-called AB/BA crossover design being implemented in the study; as such, each proband partook – in random order – in one scenario with and one without an EDS. The small number of participants made it desirable that each participant should participate in more than one scenario. Taking into consideration the probability of a significant learning effect, the number of scenarios was, however, limited to two per participant. Because it was also expected that the unaccustomed exam situation was likely to have an influence on the participant – especially in the first of two scenarios – the EDS was only provided in one scenario; whether in the first or second of the two was randomised. Which two of three possible scenarios the proband partook in was also randomised. As such, each proband took part in their randomly allotted scenarios in random order either “without EDS-with EDS” (i.e., the EDS was provided to the proband in the second scenario only) or “with EDS-without EDS” (i.e., the EDS was provided in the first scenario only). When provided, the EDS was always in written form on paper.

In the **first trial** of the simulation study, scenarios in which the EDS was made available were compared with scenarios in which no EDS was available but information relevant to patient care could be found in the patient’s surroundings in the shape of doctors’ letters, medication schedules or drug packaging. All actors were instructed not to provide the probands with crucial information. In

this first trial, probands were provided with instructions regarding the general procedure, but not on the content and bearing of the EDS. There were concerns that emergency physicians might otherwise concentrate on the EDS and that the care given might then deviate too much from that routinely provided.

Following evaluation of the first trial the decision was taken to undertake a second, modified trial based on the results of the first trial. In this **second trial**, probands were provided with instructions regarding the EDS during the preparatory session; contrary to expectations, it had been shown during the first trial that some probands had not appreciated the significance of the EDS and had therefore ignored it. Furthermore, in this second trial the control scenarios which did not include an EDS also did not provide for any additional information in the patient's surroundings; this setup was judged to be a situation commonly encountered in everyday practice by emergency physicians. Information crucial to emergency care could thus only be elicited by examination and questioning.

Procedure

Three simulations ran concurrently in separate rooms. An individual proband partook in two different consecutive scenarios. In each scenario the proband was assisted by a team of two paramedics; whilst these were trained and acted on instructions given by the emergency physician, they – like the other actors involved – otherwise acted in accordance with a script. In contrast to real-life scenarios, the emergency physicians received no additional support from the paramedics; as such, treatment decisions were taken by the physician alone, and not by the team. Each proband received a brief emergency shout via mp3 player immediately prior to entering the scenario together with the paramedics. On entering the simulation room, they came upon the patient and the patient's relative. One single additional person – the so-called moderator – was present in the room to provide the proband with

those vitals which could not otherwise be simulated (e.g., blood pressure, status of the pupils, heart and lung sounds). The proband now provided prehospital care to the patient. In those scenarios randomised to include the EDS, the EDS was handed over to the emergency physician by the patient's relative when the physician either asked for information regarding the patient or at the latest two minutes after the scenario had commenced.

For later evaluation, each scenario was filmed using two cameras and the communication between the proband, patient and relative was recorded using headsets or pin-on microphones. The simulation was terminated when transport to hospital was commenced. The proband was then removed to a sound-proof room in which they spoke the handover of the patient into a further camera and subsequently recorded the shout using the appropriate DIVI emergency medical record [6].

Following a brief interval, the second simulation was undertaken. The procedure was identical to that of the first, other than that the availability of the EDS and the scenario itself differed. Following the handover of the patient after the second scenario, probands were asked to fill out a brief survey of their assessment of the EDS, which scenarios they had taken part in (only in the second trial) and a number of personal details (age, sex, working experience). To avoid influencing other participants, probands were requested not to communicate with one another other regarding the content of the simulation study during breaks or until the trial had concluded.

Following the conclusion of each of the two trials which made up the simulation study, the video recordings and emergency medical records were evaluated on the basis of a predefined questionnaire by an emergency physician involved in the study (L.W.) and a further independent physician (consultant anaesthetist and emergency physician). The data gathered in this fashion formed the basis of the statistical analysis.

Scenarios

This section outlines the three scenarios which were used in both sub-trials of the simulation study. The respective situations are presented here as they presented themselves to the emergency physician – all further information was unknown to the proband on arrival at the patient's side.

Scenario A: 74-year-old female with headache

- **Patient:** 74-year-old with severe aortic stenosis beknown to her GP
- **Situation:** Patient complains of severe headache over the past hour with a concomitant humming sensation in the ears. An acquaintance had called emergency services.
- **Vitals:** BP 235/110 mmHg, P 102 bpm
- **Relevant past history:** severe aortic stenosis, loud systolic murmur radiating to the carotid arteries.
- **Undesired medical intervention:** Reduction of blood pressure using urapidil (not cautiously titrated)
- **ECG:** Atrial fibrillation (pre-existing)
- **Key drug:** Phenprocoumon adjusted to INR
- **Allergies:** Severe metamizole (Novalgine) allergy.

Scenario B: 64-year-old male with acute coronary syndrome

- **Patient:** 64-year-old with coronary heart disease associated with known hypertension, smoking and diabetes mellitus treated with oral agents. Previous PCI with stent implantation 2 years ago. Erectile dysfunction beknown to the patient's GP, treated with sildenafil p.r.n.
- **Situation:** Sudden occurrence of severe retrosternal pain in the early morning, radiating to the neck and associated with dyspnoea. The patient's wife had called emergency services.
- **Vitals:** BP 180/90 mmHg, P 110 bpm
- **Relevant past history:** sexual intercourse, ingestion of sildenafil at approx. 22:00 h the previous evening.

- **Undesired medical intervention:** Administration of nitrate spray
- **ECG:** Sinus rhythm, incomplete left bundle branch block, no other ST-segment deviation
- **Key drug:** Sildenafil 50 mg p.r.n.
- **Allergies:** Hay fever.

Scenario C: 66-year-old female with bronchial carcinoma and impaired consciousness

- **Patient:** 66-year-old with metastasised bronchial carcinoma, in home-based palliative care. A valid advance directive precluding medical intensive care (including CPR and intubation) exists.
- **Situation:** Acute, severe respiratory distress with ensuing impaired consciousness. The patient's grandchild had called emergency services.
- **Vitals:** BP 185/105 mmHg, P 128 bpm, SpO₂ 73 %
- **Relevant past history:** Advance directive limiting medical care.
- **Undesired medical interventions:** Intubation, ventilation
- **Key drug:** Sustained-release morphine 10 mg 1-0-1, (regular morphine 5 mg p.r.n.)
- **Allergies:** Cefuroxime.

Statistical analysis

The two sub-trials, which essentially differed in their choice of control, were planned and evaluated separately. Statistical analysis included every simulation which was undertaken and as such all 72 probands who took part in one of the two trials. The primary endpoint was defined as undertaking of a prehospital intervention predetermined for the respective scenario to be undesired or contraindicated (yes/no). The analysis of the primary measure was performed using Prescott's test [7] – a two-sided exact test – to a significance level of $\alpha = 5\%$. To determine whether or not the period influenced the results, a sensitivity analysis using the Mainland-Gart-Test [8] was employed. In addition, an analysis was undertaken using generalised estimating equations (GEE), taking into account not only the presence of an EDS (yes/no) and the period

(1st/2nd run), but also the scenario (A/B/C) or working experience of the proband [9].

The analyses described for the primary endpoint were also employed for binary secondary endpoints. In the case of metric secondary endpoints, the intra-individual difference between the first and second simulations was determined and compared for the two groups “without EDS-with EDS” and “with EDS-without EDS” using the Mann-Whitney-U-Test [9].

The primary endpoints were tested using confirmatory analysis, whilst all further analysis was exploratory. All evaluations were performed using SAS-System 9.4 (SAS Inc., Cary/NC, USA).

Power analysis

A power analysis was employed prior to each trial to determine whether sufficient power could be achieved with 36 probands and the described AB/BA-crossover design. During planning of the first trial, it was assumed that undesired interventions would be rendered in 25–50 % of cases where the EDS was not available and that this rate would decrease to 5–10 % when the EDS was provided. Based on these assumptions the power was determined by computer simulation (100,000 runs) in R-Version 3.2.5 [10] to be 79.90 %. Planning for the second trial took the altered control and results of the first trial into account, adjusting the expected rate of undesired interventions to 50–60 % without the EDS and 15–20 % with the EDS. Appropriately adjusted computer simulation resulted in a power of 87.26 %.

Results

First trial

The 36 participants in the first trial of the simulation study were 15 males and 21 females with an average age of 40.2 ± 8.1 years (mean \pm standard deviation). They had a median of 5.5 years' experience in physician staffed emergency services (lower quartile-upper quartile Q1–Q3: 3.5 to 9.5 years); 25 of 36 physicians worked in anaesthesia.

A medical intervention which was to be avoided as contraindicated or on the basis of an advance directive was defined as the primary endpoint for each scenario. Information needed to take the appropriate decision was available in this first trial either from the EDS or from the patient's surroundings. In 15 of 36 trial runs without the EDS and 15 of 36 with the EDS these contraindicated interventions were undertaken and, as such, the EDS demonstrated no effect ($p = 1$). The results of the two randomised groups, on the basis of which Prescott's test was performed, are set out in Table 1. No difference could be shown between the first and second runs ($p = 1$), but there were significant differences between the three scenarios ($p = 0.0002$). As such, the undesired intervention was undertaken significantly more often in scenario A than in B and C (21/24 vs. 7/24 and 2/24); there was no suggestion of any effect of the EDS. The degree of working experience of the proband conferred no effect on undertaking the undesired intervention (data not depicted).

Table 1

Results of the analysis of the primary endpoint – i.e., undertaking a prehospital intervention predetermined to be undesired – for the first trial in the simulation study. **EDS:** emergency dataset.

1 st trial	Group	
	EDS in 2 nd run (n = 18 probands)	EDS in 1 st run (n = 18 probands)
Undesired intervention in both runs	3	2
Undesired intervention in the 1 st run only	4	5
Undesired intervention in the 2 nd run only	5	6
Undesired intervention not undertaken in either run	6	5

With regard to the duration of prehospital care, as measured from arrival of the emergency physician at the patient’s side to the decision to transport the patient to hospital, no statistically noticeable difference could be determined for the EDS ($p=0.17$). For runs without the EDS the transport to hospital was initiated after an average of 6.16 ± 1.23 minutes; where the EDS was available, that time was 5.80 ± 1.29 minutes. No statistically noticeable differences were observed between the periods or the scenarios. When interpreting these times, no inference should be made with regard to real-life intervention times, as no actual hands-on treatment was given. Instead, during simulations, the results of medicating the patient were announced by the moderator without delaying for the realistic duration of the intervention.

Second trial

26 males and 10 females with an average age of 39.5 ± 7.1 years participated in the second trial. As in the first trial, the largest proportion (22/36) of those

physicians worked in anaesthesia and had a median of 5.0 (Q1–Q3: 2.0–10.0) years’ experience in physician staffed emergency services.

This second trial was also not able to demonstrate any protective effect of the EDS with regard to undesired interventions. Such interventions were undertaken in 16/36 runs with and 20/36 runs without the EDS (see Table 2, $p=0.53$). Once again, there was no evidence of any effect of the period ($p=0.66$) or the working experience of the proband on the results. The differences between scenarios were confirmed ($p=0.02$). Undesirable interventions were undertaken 16 times in both scenarios A and B, and 4 times in scenario C; once again, no effect of the EDS on the results was demonstrated. It was also confirmed that no statistically relevant effect of the EDS on the duration of prehospital care (without EDS: median 4.33 minutes (Q1–Q3: 3.54–4.98), with EDS 4.32 minutes (Q1–Q3: 3.73–5.06), $p=0.48$) could be shown.

Documentation of relevant past history

During planning of the second trial, a decision was taken to include acknowledgment of past history relevant to contraindicated interventions as a secondary endpoint, with the intention of more closely examining the reasoning behind treatment decisions. Relevant past history was treated as acknowledged if it was documented in the emergency medical record by the proband or passed on during verbal handover of the patient. This second trial demonstrated a statistically noticeable correlation between the availability of the EDS and documentation of relevant past history ($p<0.0001$). Past history relevant in respect of the contraindications was documented more often when the EDS was available. As such, the relevant information was documented in 26 of 36 runs with the EDS (8x each in scenarios A and B and 10x in scenario C), whilst it was not documented in any of the 36 runs without the EDS (Table 3). However, no correlation between documenting the past history and avoiding undesired interventions was detected. The undesired intervention was undertaken in 12 of the 26 runs (46 %) in which the relevant past history was known. With regard to the 46 runs in which the contraindications were not documented, the undesired intervention was undertaken in 24/46 (52 %) cases.

Following the second run, probands were asked to fill in a questionnaire asking them whether they had been aware of the relevant past history and for the reasoning behind their decisions. In 5 of 8 runs of scenario A in which aortic stenosis was documented, urapidil was administered without regard for aortic stenosis (i.e., not carefully titrated). Proband’s reasoning made it apparent that in most (4 of 5) cases, the decision was actively taken for treatment of the patient’s headache and that aortic stenosis was not recognised as a risk when administering urapidil. The responses with regard to scenario B showed that probands often did not ask after sildenafil use even when the EDS was available. As such, 4 of 8 probands who had

Table 2
Results of the analysis of the primary endpoint – i.e., undertaking a prehospital intervention pre-determined to be undesired – for the second trial in the simulation study. **EDS:** emergency dataset.

2 nd trial	Group	
	EDS in 2 nd run (n = 18 probands)	EDS in 1 st run (n = 18 probands)
Undesired intervention in both runs	6	1
Undesired intervention in the 1 st run only	4	9
Undesired intervention in the 2 nd run only	4	5
Undesired intervention not undertaken in either run	4	3

Table 3
Documentation of the relevant past history with respect to the undesired intervention in the second trial of the simulation study. **EDS:** emergency dataset.

2 nd trial	Group	
	EDS in 2 nd run (n = 18 probands)	EDS in 1 st run (n = 18 probands)
Relevant past history not documented in either run	4	6
Relevant past history documented in the 2 nd run only	14	0
Relevant past history documented in the 1 st run only	0	12
Relevant past history documented in both runs	0	0

Table 4

Documentation of the relevant past history with respect to the undesired intervention in the first trial of the simulation study. EDS: emergency dataset.

1 st trial	Group	
	EDS in 2 nd run (n = 18 probands)	EDS in 1 st run (n = 18 probands)
Relevant past history not documented in either run	1	3
Relevant past history documented in the 2 nd run only	10	2
Relevant past history documented in the 1 st run only	0	9
Relevant past history documented in both runs	7	4

documented the patient's p.r.n. use of sildenafil also documented that they had not been aware of the patient's recent use of the drug. In those cases in which probands were aware of sildenafil use, but administered nitrates despite that knowledge, the probands were unaware of the contraindication for administration of nitrates following sildenafil use. In scenario C the undesired intervention – intubation – was only performed infrequently (4 of 24 trial runs, 2 with and 2 without an EDS), and only in one case despite knowledge of the patient's advance directive.

Recognising relevant past history was significantly impeded in the second trial by the lack of information to be gleaned from the patient's surroundings in those runs without the EDS. It was for this reason that this endpoint was retrospectively analysed using data from the first trial, in which the relevant information was available from the patient's surroundings. When the EDS was available, relevant past history was documented in 30 of 36 cases, while it was only documented in 13 of 36 cases in which the EDS was not available ($p = 0.0002$, Table 4). This confirms the results of the later trial – past history relevant to treatment was ascertained more frequently when the EDS was available. Probands were not surveyed with regard to their decisions in the first trial.

Surveying the emergency physicians

When surveyed following completion of the simulation study, 62 % of emergency physicians (22/33 in the first and

20/35 in the second trial) estimated that availability of the EDS had decreased the duration of prehospital care. 28 % (6/33 and 13/35) were of the opinion that the EDS had had no influence on the duration of prehospital care, whilst a further 4 % (2/33 and 1/35) felt that the EDS was associated with an increased duration of care.

Probands were asked to specify their preferred medium for future storage of the EDS; multiple answers were permitted. Probands in the first trial preferred an EDS on paper (28/32) followed by storage on the e-Health Card (25/32). Probands in the second trial favoured storage on the e-health Card (25/36) followed by a paper version (18/36) or other forms (10/36) such as mobile telephones or online storage. Taking both trials together showed storage on the e-Health Card (74 %) or a simple paper form (68 %) to be the favoured mediums for storing the EDS, with many emergency physicians desiring a combination of both formats (47 %).

Discussion

Our research investigates whether use of the emergency dataset during simulated emergencies attended by emergency physicians has an influence on prehospital care. To this end, we developed various emergency scenarios in which emergency physicians rendered prehospital care either aided or unaided by the EDS.

The simulation study could not demonstrate any effect of the EDS on avoidance of predetermined undesired

interventions during prehospital care. When viewed in isolation, however, this endpoint does not do the complexities of emergency care justice. Analysis of the simulation examines only this one intervention, rather than all the steps involved in prehospital care. This simplification was intentional and aimed at ascertaining quantifiable results – but interpretation of those results should not concentrate on this aspect alone. In the second trial, treatment decisions were probed when the probands undertook the undesired intervention. This step showed manifold reasoning behind their decisions. In scenario A (patient suffering severe headache, severe aortic stenosis) probands were often not aware of the risk involved when administering urapidil in the presence of aortic stenosis. In such patients, hypertension can cause a decrease in cardiac output due to a decrease in the transvalvular pressure gradient. However, treatment with urapidil must be exercised with great caution: the decrease in peripheral vascular resistance associated with α -blockade can result in a critical decrease in coronary vascular perfusion. Awareness of aortic stenosis in this patient could thus help avoid critical complications during care or lead to appropriate consideration at risk-benefit-analysis.

In scenario B (acute coronary syndrome following use of sildenafil) on the other hand, the problem was more typically that contemporary use of sildenafil was not specifically asked after, even when the emergency physician was aware of the patient's discretionary use of the drug.

Both trials showed clearly that documents such as the EDS play no role in emergency physicians' everyday practice today. Because of this, simulation studies can only provide limited insight into the real-world use of the EDS, despite attempts to make scenarios realistic. In the first trial, participants were not informed about the EDS due to concerns that this would lead to probands concentrating too intensely on the EDS, making the simulated scenario more of an abstract situation rather

than a simulation of a real emergency. As such, the simulation represented an unfamiliar exam situation, which was nevertheless intended to bear significant similarity to real-life care in emergencies. Simulations were performed under “lab conditions”, limited to three different scenarios and – in contrast to real-life situations – did not offer the option of taking team decisions. When viewing video recordings of the first trial, the two assessors – both of whom work as emergency physicians – were nevertheless of the opinion that the simulation was realistic, but that probands were often not able to place the EDS and so ignored or even mistrusted it. It was for this reason that probands were given instructions regarding the significance and content of the EDS prior to the second trial. Despite this, the EDS was not always observed by probands in that second trial. During the simulation the emergency physicians behaved as they would in a real-life situation: as the EDS is not yet a part of that reality it was not automatically factored in despite prior instructions regarding its use. This too is a reason why the simulation study can provide only a circumscribed overview of the utility of introducing the EDS. An evaluation of the actual usefulness will require further studies and observation once the EDS has arrived in real-life everyday care across the country.

Despite its various limitations, the simulation study does permit potential positive effects of the EDS to be inferred. A clear effect on the documentation of details of patients’ past medical history relevant to (prehospital) care was shown. Regardless of whether information was to be found in the patients’ surroundings (trial 1) or was only available through very specific history taking and clinical examination (trial 2), the emergency physician was aware of and documented relevant information significantly more often when the EDS was available. This may have further positive effects on continuing treatment following the handover of the patient at hospital. The

EDS does not provide the emergency physician with instructions and cannot inhibit the physician from taking specific treatment decisions. It can, however, reliably convey information on which those treatment decisions can be based. That information can be relayed to the receiving hospital, making it known upon the arrival of the patient.

The majority of physicians participating in the simulation study estimated that the duration of treatment was decreased through use of the EDS. In contrast, however, analysis of actual measured times showed no relevant difference. As set out above, the measured times cannot be equated to the duration of real-life treatment. It can, however, be asserted that no relevant difference in treatment duration between those scenarios with and those without the EDS could be detected. As such, treatment times are not measurably decreased, but they are also not prolonged by studying the EDS.

Conclusion

The utility of the EDS in prehospital care for emergency patients was examined by means of two trials in the context of a simulation study. Despite the limitations of simulation studies, a clear effect of the EDS on the documentation of relevant past history could be ascertained, whilst no effect on avoidance of undesired prehospital interventions could be demonstrated. To maximise the utility of the EDS following its introduction it needs to achieve a higher profile amongst emergency medical personnel and emergency physicians.

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References

1. Zimmer L: Notfalldaten-Management mit der elektronischen Gesundheitskarte. Datenschutz und Datensicherheit - DuD 2014;38:394–398
2. gematik GmbH. <https://www.gematik.de/anwendungen/notfalldaten/> (accessed 13th July 2020)
3. Haserück A: Elektronischer Heilberufsausweis: Eintrittskarte zur Datenautobahn. Deutsches Ärzteblatt 2020;117:A-1365 B-1165
4. Born J, Albert J, Bohn A, Butz N, Fuchs K, Loos S et al: Der Notfalldatensatz für die elektronische Gesundheitskarte. Notfall + Rettungsmedizin 2017;20:32–37
5. Evers-Wölk M, Weinberger N, Sonk M, Uhl A, Winkelmann M: Fachanwendung Notfalldatenmanagement (NFDm): Risikoanalyse. Berlin; 2017
6. Moëcke H, Dirks B, Friedrich HJ, Hennes HJ, Lackner CK, Messelken M et al: DIVI emergency medicine protocol, version 4.0. Der Anaesthetist 2000;49:211–213
7. Prescott RJ: The Comparison of Success Rates in Cross-Over Trials in the Presence of an Order Effect. Journal of the Royal Statistical Society. Series C (Applied Statistics) 1981;30:9–15. www.jstor.org/stable/2346652
8. Gart JJ: An Exact Test for Comparing Matched Proportions in Crossover Designs. Biometrika 1969;56:75–80. www.jstor.org/stable/2334692
9. Jones B, Kenward MG: Design and Analysis of Cross-Over Trials. 3rd ed. Boca Raton: Chapman and Hall/CRC; 2015
10. Core Team R: A language and environment for statistical computing. Wien, Österreich: R Foundation for Statistical Computing; 2016.

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