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Patient trust and patient safety for low-priority patients: A randomized controlled trial pilot study in the prehospital chain of care

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ABSTRACT

Background: Patients who call for an ambulance but only have primary care needs do not always get appropriate care. The starting point in this study is that such patients should be assigned to as basic of care as possible, while maintaining high levels of patient trust and patient safety.
Aim: To evaluate patient trust and patient safety among low-priority ambulance patients referred to care at either the Community Health Centre (CHC) or the Emergency Department (ED).
Methods: This randomized controlled trial pilot study compared the level of patient trust and patient safety among low-priority ambulance patients who were randomized into two groups: CHC (n = 105) or ED (n = 83).
Results: There was a high level of trust in the care received, regardless of whether the patient received care at CHC or ED. Overall 31% fulfilled one or more of the given criteria for potentially jeopardizing patient safety.
Conclusion: Patient selection for the trial indicated a potential limit in patient safety. There was a high level of trust in the care received regardless of whether the patient received care. The accuracy of patient selection for the new care model needs to be further improved with the intention to enhance patient safety even further.

1. Introduction

Patients contacting the ambulance dispatch centre do not always get their needs met in the best way at the Emergency Department (ED). Primary Healthcare, usually the Community Health Centre (CHC), may on many occasions meet their needs better [1]. In Sweden, the CHC is intended to be the peoples' first contact of care in connection with injuries and diseases that are not in need of immediate or more extensive treatment. The CHC system is well developed and available country-wide. A recent study suggested that 16 percent of ambulance patients could have been treated at an CHC [2]. Other studies suggest that an even larger proportion of patients can benefit from healthcare at another level than that offered by the ED [1]. The starting point in this study is that patients should be assigned to a level of care as basic as possible, while maintaining high levels of patient trust and patient safety. We use the term an appropriate delivery of health care to label high-quality care with efficient resource utilization. The new care model evaluated in this study is expected to provide low-priority patients with care at another level other than the ED.

2. Background

The most critical aspect in the prehospital care of patients who call for an ambulance is the encounter between the patient and the prehospital health care provider. The challenge for the ambulance nurse is to make an initial decision that results in an appropriate delivery of health care (1) while a simultaneously maintaining the patients' trust (2), and without jeopardizing patient safety (3). These three keynotes will form the background to this work.

2.1. The initial decision is based on priority assessment

The priority assessment made by the dispatch centre is based on a medical index, categorizing patients into one of three priority-levels:

Abbreviations: ED, Emergency Department; CI, confidence interval; ESS, Emergency Signs and Symptoms; CHC, Community Health Centre; ICD, International Statistical Classification of Diseases; PTQ, Patient Trust Questionnaire; OR, the odds ratio; RETTS, the Rapid Emergency Triage and Treatment System

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(1) Life-threatening conditions, (2) acute but not life-threatening conditions, and (3) other conditions requiring care or monitoring where a reasonable waiting time is not deemed to negatively affect the patient's condition [3]. The dispatcher has a complex function, making assessments and decisions without visual contact. The process is even more complex since patients themselves make the calls in only 11–13% of cases [11]. This automatically leads to over-triage because of the need for a safety-margin [3].

When the ambulance personnel arrives on scene the ambulance nurse examining the patient, considering time on scene and transportation into the receiving unit, the ambulance nurse assigns a secondary priority. This priority is based on the same priority-levels as those used by the dispatcher, but without the medical index. Another triage, the Rapid Emergency Triage and Treatment System (RETTS) is used to identify patients in need of immediate medical interventions [4]. The RETTS-assessment is made in two steps: (1) patients' vital signs, and (2) a given algorithm, Emergency Signs and Symptoms (ESS). Together, the vital signs and the ESS-code result in one of five triage levels (red, orange, yellow, green or blue). Red indicates life-threatening conditions and orange indicates that patients may run a risk of deterioration. Yellow and green are non-life-threatening conditions. The blue level is not used in the emergency setting. Despite not being evidence-based [5], the RETTS is used in most of the acute settings in Sweden.

Because of the dispatchers' lack of visual contact and the need for safety-margin, one of the consequences may be that the ambulance nurse on scene makes a different assessment than the dispatcher [3]. Furthermore, Koarram-Manesh et al. [3] emphasize the need to assess patients already at the scene to an appropriate delivery of health care.

All patients receiving medical attention from a physician, in this case at a CHC or ED, are diagnosed according to the World Health Organization's (WHO's) International statistical Classification of Diseases (ICD-10).

2.2. Patient trust in the prehospital chain of care

Patients' trust in healthcare is considered important. Patients' experiences of trust in nursing depend especially on nurses' knowledge and level of commitment in the dialogue creating and developing the relationship [6]. Patients' trust in healthcare personnel depends largely upon staff behaviour, of which vital components are competence, compassion, integrity, confidentiality, reliability and communication [7]. Furthermore, patients' trust in the nursing profession cannot be taken for granted simply because patients actually need care and are therefore seeking care [8].

2.3. Patient safety in the prehospital care

According to Hagiwara et al. [9] there are no reports on patient safety issues in Swedish prehospital care and there are only very few in a global perspective [10]. The Swedish Nursing Association has agreed on six core competencies for nursing work. The goal is to improve the quality and safety in healthcare, so one of these core competences is patient safety.

Ambulance personnel have to deal with unfamiliar settings without any cognitive support [12]; establish trust while making advanced assessments [13]; and be able to make an accurate assessment of an appropriate delivery of health care [14]. All these aspects together increase the risk of human error in assessment and decision-making [15]. Thus referring patients to an appropriate delivery of health care [14] may include the risk of human error [15].

3. Aim of the study

In order to assess a new model for taking care of patients who call for ambulance due to primary care needs, the aim of this study has been to evaluate patient trust (primary endpoint) and patient safety (secondary endpoint) among low-priority ambulance patients participating in a study where they were referred to care at either an CHC or the ED.

4. Methods

4.1. Design

A Randomized Controlled Trial (RCT) pilot design was employed to compare the level of patient trust and patient safety among low-priority ambulance patients. Patients were randomized into two groups: 1) CHC and 2) ED. Patients admitted to a CHC received care according to a new care model and patients admitted to the ED received traditional care.

4.2. Setting

The study was conducted in eighteen CHCs and one hospital, covering 190,500 inhabitants in the southwest of Sweden, comprising urban and rural environments. The Emergency Medical Services in this district have seven 24-h ambulances on duty seven days a week and three daytime ambulances on weekday duty only. These ambulances collectively carried out 49,000 missions during the study period March 2013–May 2016.

The prehospital chain included the dispatch centre, the ambulances, and CHCs or the ED. In Sweden, ambulance personnel include at least one registered nurse who is responsible for the assessment, according to the requirements of the National Board of Health and Welfare (SOSFS 1999:17).

4.3. Sample and randomization

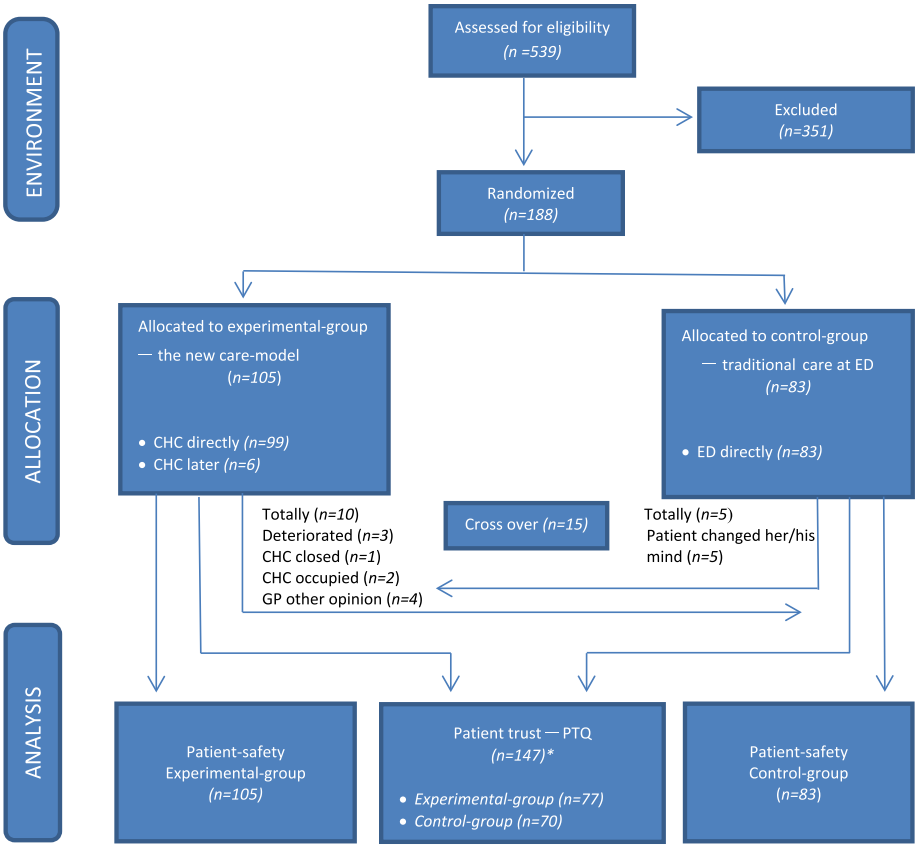
The criteria for inclusion were: (1) at least 18 years of age and (2) RETTS yellow or green. Patients incapable of filling in the questionnaire due to linguistic or intellectual reasons were excluded.

Patients were randomized using a computer-based random number generator in blocks of fifty. An envelope was prepared for each participating patient, containing a note stating where the patient should be referred. Half of the patients were randomized to a CHC (experiment) and the other half were randomized to traditional care at the ED (control). There were 15 crossovers: five from the control-group and ten from the experimental-group – patients who for different reasons landed in the opposite group to their randomized group (Fig. 1). Results are presented according to intention to treat (the randomization). However, data was also analyzed per protocol (excluding the crossovers from analysis). No major deviation in the results according to the intention to treat analysis, appeared when analyzing the data per protocol.

4.4. The procedure of the new care model

The new care model differs from traditional ambulance care in the following respects:

1) Identifying patients suitable for the intervention: patients were assessed as low-priority using the RETTS green or yellow by ambulance nurses already on scene.
2) A decision-support tool supported the ambulance nurse in the assessment. A written, paper-based decision-support tool (57 pages in Swedish) was developed uniquely for the study and based on the RETTS' ESS-codes. Physicians at the hospital had made recommendations regarding conditions suitable for healthcare at CHCs. For example, dizziness was one of these symptoms, but a case was only regarded as suitable for CHC if all the following criteria were fulfilled: (1) normal vital signs, (2) no new neurological symptoms, (3) no nausea/vomiting, (4) no headache (5) a previous history of dizziness and current similar symptoms, and finally (6)



* The reason for exclusion from this group is not known, except for those who in the phone call (reminder) did not want a new PTQ

Fig. 1. Flow diagram (CONSORT 2010) of patient enrolment, randomization, allocation, and analysis.

the ability to stand up without support (if previously capable). The decision-support tool had an advisory function for ambulance nurses in assessment and decision-making, and was not compulsory.

3) For patients randomized to an CHC (experiment), ambulance nurses had phone contact with a General Practitioner (GP) who confirmed patients' suitability for the CHC. Decisions were taken jointly. The following three alternatives were used: 1) CHC directly, 2) referred to CHC later (within 24 h), or 3) the ED if this was clearly the most appropriate delivery of health care as judged by the GP.

4.5. Outcome measures

Patient trust (primary endpoint) was assessed using the Patient Trust Questionnaire (PTQ) developed especially for use in this context [16]. It covers four items capturing the patient's perception of credibility and four items capturing the patient's perception of accessibility.

All eight items appear in three identical sets, where each set applies for each of the three frontline service providers in the prehospital chain (dispatch centre, ambulance care and ED/CHC), in total 24 items. The PTQ uses a five-point Likert scale ranging from 1 (disagree) to 5 (strongly agree). The concept validity of the concepts of credibility and accessibility was supported by separate factor analyses run with all eight items for each frontline service provider. On each occasion, the items were distributed as expected with all loadings >0.50. The outcome variables were dichotomized, i.e. the scales were split at 3.5 so that patients who scored below the split were judged to have lower trust in the healthcare provided and those who scored above the split were judged to have higher trust in the healthcare provided. This dichotomizing procedure was implemented on both the credibility and accessibility of the respective frontline service providers.

Patient safety (secondary endpoint) was assessed by a retrospective patient record review focusing on the following data: (1) secondary transports within 72 h, (2) critical conditions according to the final diagnosis (ICD-10), (3) requirement of hospitalization, (4) and death within 30 days. The records were also carefully studied to understand the underlying causes of the interventions recorded.

4.6. Data collection

Patients who gave their written consent to participation were included and given the PTQ. They were asked to fill in the questionnaire and respond to an invitation to participate in a follow-up call and send this back to the first author by post within three days. The PTQ was sent back to the first author in 147 cases, a response rate of 78%. The patient record review was a retrospective data collection to evaluate patient safety and patient characteristics, such as age, gender, medical history, priorities, ESS code and vital signs, examinations, activities and interventions.

4.7. Data analyses

Statistical analyses of patient trust (as operationalized by the PTQ) were carried out using SPSS (IBM SPSS Statistics, version 23). Total scores for each subscale of the PTQ were calculated by adding the scores of each of the four items and then dividing by the number of items (i.e. by four), so the total score for each subscale could vary

between 1 (low level of trust) and 5 (high level of trust). To illustrate differences between the two groups in terms of patient trust the results are expressed as the odds ratio (OR) and a 95% confidence interval (CI). For patient trust (primary endpoint), the experimental-group was compared with the control-group, and chi-square (χ^2) analysis was used to measure statistical significance.

For the retrospective record review, to determine patient characteristics and the outcome of patient safety, SAS (version 9.3) was used. Fisher's Exact Test was used for evaluation of dichotomous variables and Wilcoxon's Two-Sample Test was used for evaluation of ordered and continuous variables. For all analyses, a $P < 0.05$ was regarded as significant and when applicable the analyses were performed as two-tailed tests.

5. Results

A total of 188 patients were included in the study (for a description of their distribution through the process of the study, see Fig. 1), while 351 patients were excluded from participation. Reasons for exclusion were: patient <18 years ($n = 23$), cognitive impairment/inability ($n = 8$), language difficulties/inability ($n = 23$), drugged/inability ($n = 1$), other reasons/inability ($n = 13$), insisted on the ED – unwillingness ($n = 28$), wanted to stay at home – unwillingness ($n = 8$), other reason – unwillingness ($n = 55$), ambulance nurse found it unethical to randomize ($n = 1$), CHC closed ($n = 105$), GP's/district nurse's decision ($n = 10$), and other reasons for exclusion ($n = 76$).

5.1. Patient characteristics

The two groups, receiving care at an CHC ($n = 105$) at the ED ($n = 83$), were compared. Overall, the mean age was 65.8 years and 54% were women. There was no difference between the two groups (Table 1).

5.2. Priority and vital signs

With regard to the priority given at the dispatch centre all priorities were represented, but the majority of patients were given priority 2. No difference between the two groups was found.

The priority given by the ambulance nurse was higher in the ED group as compared with the CHC group. The difference was found in terms of priority (1–3) as well as in the triage (RETTS, red – green). A few patients (nine) were triaged orange, which was a protocol violation (Table 2).

Table 1
Baseline characteristics.

	CHC ($n = 105$)	Control (ED) ($n = 83$)	p
Age (Years; mean ± SD) (0, 0)*	65.2 ± 20.7	66.4 ± 21.8	
Sex (women) n (%) (0, 0)*	60 (57.1)	45 (54.2)	0.77
Previous history n (%)			
Previous healthy (5, 0)*	31 (31.3)	22 (26.5)	0.52
Immunosuppression (5, 1)*	1 (1.0)	0 (0)	1.00
Bleeding (15, 5)	8 (9.2)	9 (11.4)	0.80
Cardiovascular disease (8, 1)*	4 (4.2)	6 (7.3)	0.52
Renal disease (5, 1)*	2 (2.0)	1 (1.2)	1.00
Cerebrovascular disease (7, 1)*	6 (6.2)	5 (6.1)	1.00
Pulmonary disease (5, 1)*	10 (10.1)	8 (9.8)	1.00
Heart failure (9, 1)*	1 (1.0)	5 (6.1)	0.10
Malignancy (5, 1)*	2 (2.0)	5 (6.1)	0.25
Diabetes (5, 1)*	9 (9.1)	7 (8.5)	1.00
Myocardial infarction (8, 1)*	9 (9.4)	5 (6.1)	0.58
Angina pectoris (8, 1)*	5 (5.2)	7 (8.5)	0.55
Hypertension (6, 0)*	28(28.6)	28 (33.7)	0.52
Atrial fibrillation (5, 0)*	7 (7.1)	11 (13.2)	0.21
Peripheral artery disease (5, 0)*	0 (0.0)	1 (1.2)	0.46

* Number of patients with missing data in the two groups.

Table 2
Priority and vital signs on admission.

	CHC ($n = 103$)	Control (ED) ($n = 85$)	p
Priority at dispatch centre, n (%) (0, 0)*			0.95
Priority 1	18 (17.1)	15 (18.1)	
Priority 2	76 (72.4)	58 (69.9)	
Priority 3	11 (10.5)	10 (12.0)	
Priority in ambulance, n (%) (11, 1)*			0.005
Priority 1	0	0	
Priority 2	16 (17.0)	29 (35.8)	
Priority 3	78 (83.0)	52 (64.2)	
RETTS, n (%) (1, 0)*			0.007
Red	0	0	
Orange	2 (1.9)	7 (8.4)	
Yellow	47 (45.2)	47 (56.6)	
Green	55 (52.9)	29 (34.9)	
Heart rate (beats/min) (3, 0)*			0.71
Median	79.5	78	
Range	50–130	56–114	
Systolic blood pressure (mmHg) (4, 0)*			0.66
Median	149	148	
Range	90–200	100–200	
Respiratory range (breaths/min) (4, 0)*			0.18
Median	17	18	
Range	12–25	12–24	

* Number of patients with missing data in the two groups.

Table 3
The most frequent ESS codes.

	CHC ($n = 105$)	Control (ED) ($n = 83$)	p
Dizziness, vertigo n (%)	21 (20.6)	12 (14.5)	0.98[a]
Chest pain	16 (15.7)	13 (15.7)	0.94[a]
Back pain	13 (12.8)	11 (13.2)	0.86[a]
Dyspnoea, resp. correlated chest pain	9 (8.8)	7 (8.4)	0.97[a]
Nausea, vomiting, diarrhea	3 (2.9)	8 (9.6)	0.063[b]
Abnormal heart rhythm	4 (3.9)	4 (4.8)	0.073[b]
Pain/swollen extremities	5 (4.9)	3 (3.6)	1.0[b]
Unspecified symptoms	6 (5.9)	2 (2.4)	0.47[b]
Fever/infection	4 (3.9)	3 (3.6)	1.0[b]

[a] Chi square test, 2 × 2 contingency table.
[b] Fisher exact test, 2 × 2 contingency table.

5.3. The most frequent ESS codes

The three most common ESS codes (i.e. symptoms) among low-priority patients were dizziness/vertigo, chest pain and back pain (Table 3). Thus 20.6% of the patients in the experimental-group had dizziness, compared to 14.5% in the control-group. However, there were no significant differences between the two groups in any of the chosen ESS codes.

5.4. Patient trust

There was a high level of trust regardless whether the patients received care at a CHC or ED. Patient trust in the healthcare received did not differ significantly between the two groups, with all p-values ≥ 0.190 (Table 4). The OR to experience trust in the care received at CHC compared to ED (according to randomization) ranged between 0.87 and 1.68. The confidence limits were wide.

Table 4
Patient trust (PTQ).

	n	Lower trust[a] *n* (%)	Higher trust[b] *n* (%)	OR (95% CI)	χ^2 (df)	*p*
Dispatch Centre: Credibility						
CHC	58	6 (10.3)	52 (89.7)			
Control (ED)	60	7 (11.7)	53 (88.3)			
				0.87 (0.28–2.77)	0.053 (1)	0.819
Dispatch Centre: Accessibility						
CHC	58	17 (29.3)	41 (70.7)			
Control (ED)	59	15 (24.4)	44 (74.6)			
				1.22 (0.54–2.75)	0.222 (1)	0.637
Ambulance: Credibility						
CHC	72	7 (9.7)	65 (90.3)			
Control (ED)	75	6 (8.0)	69 (92.0)			
				1.24 (0.40–3.88)	0.135 (1)	0.713
Ambulance: Accessibility						
CHC	72	14 (19.4)	58 (80.6)			
Control (ED)	75	14 (18.7)	61 (81.3)			
				1.05 (0.46–2.40)	0.014 (1)	0.904
HCC/ED: Credibility						
CHC	72	20 (27.8)	52 (72.2)			
Control (ED)	75	14 (18.7)	61 (81.3)			
				1.68 (0.77–3.64)	1.715 (1)	0.190
HCC/ED: Accessibility						
CHC	72	25 (34.7)	47 (65.3)			
Control (ED)	73	23 (31.5)	50 (68.5)			
				1.16 (0.58–2.31)	0.169 (1)	0.681

[a] Lower trust represents patients who scored 1.0–3.5 on the PTQ.
[b] Higher trust represents patients who scored 3.5–5.0 on the PTQ.

In the PTQ, reliability for the concepts of credibility and accessibility respectively was 0.847 and 0.829 for the dispatch centre; 0.858 and 0.853 for the ambulance; and 0.941 and 0.911 for the receiving unit (ED or CHC). There was, however, a low response rate for the dispatch centre.

5.5. Patient safety

Out of a total of 188 patients, nine had a potentially serious final diagnosis: three stroke, one myocardial infarction, one transitory ischemic attack, one ileus, one gastrointestinal bleeding, one interstitial nephritis and one lumbar vertebra fracture. There were 22 secondary transports, 43 patients were hospitalized and two patients died within 30 days. Thus, a total of 59 (31%) patients were exposed to risks in patient safety (potential for harm), since they were, despite fulfilling any of the above mentioned criteria, regarded as low-priority patients and thus randomized in the trial (Table 5). However, a causal relationship between the study design and the different events were not confirmed for the most part.

Seventeen patients in the experimental-group were hospitalized. However, the rate was lower compared to the control-group. Secondary transports were more frequent in the experimental-group ($n = 16$; 15.7%) than in the control-group ($n = 6$; 6.2%) ($p = 0.11$).

6. Discussion

In this study, patient trust and patient safety were evaluated among a randomized sample of low-priority ambulance patients and thereafter referred to either care at a CHC (experimental) or at the ED (control). There was no significant difference regarding patient trust between the two groups. The results suggest that patients exposed to the new care model did not experience lower levels of trust in healthcare compared with the traditional care model. However, due to the low sample size and therefore low statistical power, our results should be looked upon as hypothesis generating.

Table 5
Patient-safety.

	CHC ($n = 105$)	Control (ED) ($n = 83$)	*p*
Hospitalized, *n* (%) (2, 1)*	17(16.8)	26 (32)	0.02
If hospitalized, number of days			0.38
Median	2	5	
IQ range	1–12	1–12	
Secondary transport, *n* (%) (0, 0)*	16 (15.7)	6 (7.2)	0.11
Mortality (30 days), *n* (%) (0, 0)*	1 (1.0)	1 (1.2)	

* Number of patients with missing data in the two groups.

6.1. Patient trust

Our data suggest that the low-priority patients in this pilot study had a high level of trust regardless of whether they received care at CHC or ED. One possible mechanism behind such a finding has been discussed by Løgstrup [17] who argues that humans feel a natural trust in the meeting with others. Trust also includes the unspoken expectation that the other will respond to this trust, expressed in terms of both attitude and behaviour and/or in words and actions [17]. When patients cannot handle their situation on their own, they need to feel trust in the caregivers, provided that they show both professional knowledge and moral character [18]. Tarrant et al. [19], argue that patients seeking healthcare experience institutional trust deriving from medical expectations and the view of healthcare providers as professionals. This expectation is usually sufficient to estimate the healthcare as good, since the patient already has an expectation of good healthcare. Furthermore, they suggest that to ensure and deepen trust, continuity is a prerequisite.

Thus, continuity can develop interpersonal relationships in a favourable direction and also raise patients' expectations and trust. In ambulance care it has been found that the reason behind this is that patients receive full attention throughout the entire ambulance mission [20]. Patients with robust healthcare needs want greater continuity in care, in order to experience trust. Accessibility, in terms of opening hours and the opportunity to book a GP visit, thus plays a decisive role. In addition, smaller practices have higher continuity [21], thus giving patient's stronger feelings of trust. Finally, the low response rate for the dispatch centre is explained by the fact that relatively few patients made the call themselves [11] and were thereby unable to assess their trust for this provider.

6.2. Patient safety

The results showed that a high proportion of participants may not have been appropriate candidates for the new care model, i.e. they fulfilled one or more of the given criteria for potentially reduced patient safety due to high risk. The proportion of potentially serious conditions was unexpected, as was the high proportion of hospitalizations. The fact that 22 patients received a secondary transport to the ED was expected since one previous study [22] states that there is no consensus in the assessment between nurses and GPs. However, the two deaths were in no way associated with the new care model. Overall, a causal relationship between the initial decision and the various events defined as "potential for harm" or "harm identified" were not confirmed for most of the part and therefore caution in the interpretation of these data is advised.

That said, the results are in line with previous research concerning

low patient safety in healthcare [9]. There is a knowledge gap of what can be considered as an acceptable level of lowest accuracy in terms of first assessment by the EMS crew. Berner and Graber [23] claim that the proportion of misdiagnoses made by medical practitioners is estimated to be 10–15%. The highest figure was found when the patient's symptoms were of recent onset. The most common diseases were the ones that were most frequently misdiagnosed [23]. According to Croskerry [24], 10–15% cannot be regarded as acceptable, particularly since physicians have more opportunities for examination and sampling as well as a higher medical education compared with nurses in the prehospital setting. However, ambulance nurses were only supposed to assess symptoms and to decide whether the conditions were serious enough to require care at the ED, which should make the assessment and decision easier. The reason for mistake in assessment is usually not lack of knowledge [25], but rather problems with cognitive thinking. Most errors in thinking arise when intuition takes over [24].

In order to become patient-safe, the new care model could be further developed and therefore the accuracy of the assessments could improve. We highlight that the RETTS should be evidence-based [26]. Sensitive decision-support tools specifically designed to identify low-priority patients are also required, which is in line with Sheffield et al. [27]. Furthermore, compliance with decision-support tools is high among ambulance nurses, especially if there is a relationship between the protocol and the patient's outcome [27]. They argue that failure to follow decision-support tools leads to increased mortality and other complications. Potentially serious conditions such as myocardial infarction, stroke, TIA and sepsis must be identified immediately at the prehospital scene. Education and clinical experience already exist [14], as well as the possibility to contact the GP. Three factors affecting ambulance personnel's decision-making have been reported concerning when low-priority patients should be referred to an alternative delivery of health other than the ED: (1) complexity, (2) the degree of support for diagnosis and treatment, and (3) the relationship of the protocol with patient outcomes [26].

7. Strengths and limitations

The major strength is that this is a RCT pilot study performed in a nonacademic milieu where such trials are uncommon. The major limitation is that the sample size is relatively small.

There was a crossover in 8% of the cases i.e. the patients received the alternative treatment than the one to which they were randomized. Therefore results have been analysed according to intention to treat as well as per protocol. No major deviation in the results appeared.

It is important to stress that this type of crossover reflects "the real situation" in prehospital praxis and should therefore not be looked upon as a limitation. Indeed, a number of patients who are brought by EMS to CHC will be sent directly to ED in the nearest hospital by the GP at the CHC. Thus, the randomization must reflect the EMS nurses judgement rather than the GPs judgement.

Only *539* of the participants were reported to be low-priority patients and candidates for the trial during the intervention period. Based on a calculation from a previous study [2], approximately 16% of all patients seen by EMS should have been potential candidates, which would correspond to about 7800 patients (16% of 49,000 patients) during the time of the survey. Thus, it is likely a majority of candidates for the trial escaped evaluation for inclusion.

A number of mechanisms may explain the low inclusion rate in the study:

1) It is possible that low-priority patients (green and yellow according to the RETTS) were identified by the ambulance nurse to a higher extent than reported, because of shortcomings in the data record system. Thus, the data record system does not compel anyone to document the causes of such exclusions.
2) The CHCs were mostly closed at night and during weekends.
3) The ambulance nurse may sometimes have hesitated to include patients for ethical reasons.
4) The ambulance nurse may sometimes have forgotten to evaluate the patient for inclusion in the trial.
5) Logistical reasons such as lack of time may sometimes have been an obstacle to randomization.
6) The decision-support tool unfortunately lacks validation. Furthermore, the tool only had an advisory function which must be regarded as a weakness in this study. The idea behind this was to limit the ambulance nurse's tasks, perhaps lowering the number of patients included. In retrospect, it is clearly important to have a decision-support tool that is compulsory and favours compliance from ambulance nurses.
7) This was the first RCT performed by EMS in this part of Sweden, and therefore the research experiences were limited. This may have led to hesitation among the EMS nurses to interview potential candidates for the trial.

In summary, the research climate in the prehospital setting at present does not favour RCT.

The consequences of the low inclusion rate are a narrowly selected study cohort. This is a well-known and more or less expected limitation in RCTs. This limitation creates difficulties in extrapolating the data to other environments.

There are two further limitations. Patients in the control-group were given a higher priority and a higher rate of hospitalization than patients in the experimental-group. The mechanisms behind these findings can only be speculated upon. However, since randomization was undertaken before prioritization, one may expect that the nurse unconsciously gave a higher priority to patients referred to the ED than to the CHC, to "justify" transport to the ED. The higher rate of hospitalization in the control-group may to some extent be explained by the fact that it was more convenient to hospitalize a patient from the ED within the same hospital than from an CHC at some distance from the hospital.

Finally, the experimental-group was larger than the control-group, which may partly be explained by the fact that there were many randomization envelopes per ambulance (50 each), and not all of them were used.

One may argue that when conditions for patients' safety are not met, then patients' trust in the intervention is of limited interest. We believe that patient safety and patient trust both represent aspects in healthcare of major and equal importance for the eventual success of a new intervention. Thus we need to consider both of them.

8. Conclusion and clinical implications

The new care model evaluated in this RCT pilot study did not appear to be completely patient-safe. This relatively small study showed a high level of trust regardless whether patients received care at a CHC or an ED. This new care model for low-priority patients' needs to be further developed in order to improve patient safety. Methods for evaluation of patient safety should be further strengthened. Suggestions for improvement include a sensitive, evidence-based decision-support tool with high compliance from ambulance nurses. With such a tool the model should be further evaluated in a larger RCT in order to confirm or reject the hypotheses that were raised in this pilot study.

Ethical statement

The Research Ethics Committee of the Medical Faculty at the University of Gothenburg (Registration number: 329-12). Participants were given written and oral information that participation was voluntary and could be interrupted whenever they wished. They were guaranteed complete confidentiality. Informed consent was obtained.

Founding

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Consent for publication

Not applicable.

Availability of data and material

Not applicable.

Trial registry

Clinical trial (ClinicalTrials.gov, registration number: NCT02524080, retrospectively registered 8 August 2015). The study was conducted in accordance with the CONSORT 2010 agreement.

Declaration of Competing Interest

None.

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