Safety of self-triage by patients using a symptom-checker: a prospective surveillance study

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Abstract

Background: Symptom-checker self-triage apps assist patients to determine the urgency of medical care. To be safe and effective, these tools must be validated, particularly to avoid potential hazardous undertriage.

Objective: To investigate the safety of patient's self-triage using a symptom-checker.

Methods: A single centre, prospective clinical trial comparing the individual outcomes of patients' self-triage with the assessment of the clinical urgency made by three successive interdisciplinary panels of physicians. Data collected between 25 November 2019 and 1 May 2020. Panel assessments and data analysis completed on 29 August 2022.
Setting: Walk-in-Clinic and Interdisciplinary Emergency Department (WIC/ED) of the cantonal hospital of Baden, Switzerland.
Partcipants: All patients ? 18 years attending the WIC/ED between 8:00 a.m. and 5:00 p.m. Exclusion criteria included ESI 1 and presence of symptoms not encompassed by the symptom-checker.
22 676 (12 655 ER, 10 021 WIC) used the facility during the enrollment period. 7550 patients attended WIC/ED within the recruitment window. 2550 gave informed consent, 7 patients withdrew.
Intervention: Participants assessed their symptoms using SMASSPathfinder, a web-based symptom-checker based on a computerized transparent neural network.
Main Outcome and Measure: The assessment by the panels encompassed the appropriate time-to-treat and the adequate point-of-care. If a case was adjudicated as undertriaged by the first two panels, the third panel assessed the patient's risk to health or life, making a decision on whether a potentially hazardous undertriage had been present. Using a Clopper-Pearson confidence interval, we assumed that in order to confirm the symptom-checkers safety, the upper confidence bound should lie below 1%.

Results: 2543 patients were included in the study, 1227 (48.25%) female, 1316 (51.75%) male, 1397 (54.94) 18-49 y, 668 (26.27%) 50.65y, 360 (14.16%) 66-80y, 118 (4.64%) >80y. Of the 2543 cases none reached the pre-specified criterion for a potentially hazardous undertriage. This resulted in an upper 95% confidence bound for the probability of a potentially hazardous undertriage of 0.1184%.

Conclusions: The symptom checker proved to be a safe triage tool, avoiding undertriage in a real-life clinical setting of emergency consultations at a WIC/ED. Our data suggest the symptom checker may be safely used in clinical routine. Clinical Trial: ClinicalTrials.gov (NCT04055298)

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Conclusion and Relevance: The symptom checker proved to be a safe triage tool, avoiding undertriage in a real-life clinical setting of emergency consultations at a WIC/ED. Our data suggest the symptom checker may be safely used in clinical routine.

Introduction

An increasing number of residents in Switzerland no longer have a primary care physician. This has resulted in increasing frequencies of visits to walk-in clinics and emergency departments, even for harmless complaints. Conversely, clinical warning signs may be considered too late due to lacking professional triage [1]. In this context, various initiatives have been launched to improve outpatient emergency care and the population's access to a low-threshold initial medical assessment [2]. Symptom-checkers, which enable medical self-triage, have recently been introduced for this purpose. In order to fulfil the regulatory requirements and to be used as a part of standard care, the appropriateness and safety of these instruments must be evaluated in concrete clinical settings with real patients.

An evaluation of 23 symptom checkers using 45 patient vignettes concluded that most symptom-checkers were deficient in both adequate triage and correct diagnosis [3]. However, the study did not comment on the safety of the tested devices. A review article cited only six studies that analysed the safety of symptom-checkers [4]. These studies were mostly short-term and included samples that were too small and heterogeneous to make reliable statements.

In view of the present shortage of data on self-triage, we aimed to investigate the safety of a newly developed symptom-checker (SMASS: Swiss Medical Assessment System), providing sufficient real patient data in the clinical setting of an interdisciplinary emergency department.

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Methods

The study was approved by the competent ethics committee and was conducted in accordance with the most recent version of the Declaration of Helsinki, complying with ICH-GCP and ISO EN 14155 (clinical investigation of medical devices for human subjects – good clinical practice) as well as with applying national legal and regulatory requirements. Prior to inclusion of the first patient, the study was registered (ClinicalTrials.gov identifier: NCT04055298).

Study population, setting and procedures. The study was performed between November 25, 2019 and May 1, 2020, at the Walk-in-Clinic and Interdisciplinary Emergency Department (WIC/ED) of the cantonal hospital of Baden, Switzerland. The WIC/ED is open 24 hours a day for 365 days a year and treats about 55 000 patients annually. Patients are routinely triaged by a nurse using the Emergency Severity Index (ESI)[5]. ESI 1-2 patients are treated in the Emergency Department, while ESI 3-5 patients are treated in the Walk-in-Clinic.

The symptom-checker SMASS in the Pathfinder version, Release 4.1.12, was used in the study. This symptom-checker is a Medical Device Class I under the Medical Device Directive (MDD) and Medical Device Class IIb under the Medical Device Regulation (MDR). The CE declaration of conformity to the Swiss Agency for Therapeutic Products (Swissmedic) was made on 4 June, 2018. The symptom-checker is a web-based software that aims to support health professionals and lay persons in the structured documentation and assessment of health problems and to advise users about possible medical assessment steps and treatment measures. This symptom checker is based on a computerized neural network that incorporates extensive data from scientific studies, guidelines, and expertise from various professional boards of specialists in the field of prehospital medical triage. The symptom-checker provides digitalised questionnaires of 85 frequent reasons for consultations (e.g. fever, cough, abdominal pain) and their associated red flags. Based on the triage result, a report including patient gender, age group, symptoms, medical history and recommendations as to the appropriate time-to-treat (T2T) and point-of-care (PoC) is provided. Depending on the presence of red flags, the symptom-checker assigns the clinical condition of the patient to a triage level (Tables 1 and 2). If five or more assessment questions are answered as "unclear," the user is notified that the software cannot provide targeted triage advice and that the patient should seek immediate consultation with a physician concerning his or her medical complaints.

All patients ≥ 18 years attending the WIC/ED between 8:00 a.m. and 5:00 p.m. were eligible. Exclusion criteria included age <18-years; ESI 1 patients requiring immediate, life-saving intervention; inability to use a tablet PC; inability to communicate in German, French, Italian or English; inability or unwillingness to give written informed consent and follow the procedures of the study; known or suspected non-compliance; known drug or alcohol abuse; presence of symptoms or complaints not encompassed by the symptom-checker data base (e.g. long-lasting hiccups, hair loss).

After instruction by the study staff and providing written informed consent, the participants independently assessed their health status and complaints as instructed by the symptom-checker on a tablet PC. They were subsequently evaluated and treated by routine medical staff.

E*valuation.* The assessment of the triage level was made by three external interdisciplinary panels of board-certified physicians not involved in the conduct of the study (Panel A, five experts; Panel B, two experts; Panel C, five experts). The assessment of the triage level encompassed the appropriate T2T and the adequate PoC.

Structured reports issued by the symptom-checker for all cases were initially evaluated by members of Panel A. The reports were prepared not to reveal the triage level recommendations (T2T and PoC). Each panellist defined a set of appropriate triage levels, and the range spanned by these triage levels was considered appropriate. Structured reports and panellist recommendations were then rated by an independent person. If the recommendation issued by the symptom-checker diverged from that by the panellist such that potential undertriage would have resulted, the case was passed on to Panel B. In 80 instances, panellists erroneously examined the same cases twice and concluded on diverse triage recommendations. In these cases, the first of the two recommendations were used for the analysis.

The same evaluation procedure was carried out by Panel B. If both rounds of evaluation resulted in an under-triage, i.e. the case was undertriaged according to all three experts (one expert from Panel A, two experts from Panel B), the case was analysed by Panel C.

Each member of Panel C individually assessed the clinical safety of the triage decision based on the complete structured reports generated by the symptom-checker as well as the WIC/ED's discharge reports. Both reports were redacted. Each of the five panellists decided individually on potentially hazardous

undertriage. In a modified Delphi process, the panellists first individually adjudicated potential undertriage on a 4-Point Likert-Scale. Possible ratings were “unlikely”, “rather unlikely”, “rather likely” and “likely” to be life-threatening or harmful. If the panellists subsequently reached a consensus that the triage of the symptom-checker was “rather likely” or “likely” life-threatening or harmful, the case was considered a potentially hazardous undertriage. As a complement to the original analysis plan, a modified criterion for potentially hazardous undertriage was evaluated, defined as a majority of Panel C members judging live threatening or harmful triage as “rather likely” or “likely”.

Statistical considerations. The primary analysis consisted of the calculation of a 95% upper Clopper-Pearson confidence bound for the probability of undertriage resulting in a risk to life or health (“potentially hazardous undertriage”). In order to confirm the safety of the symptom checker, this upper confidence bound should lie below 1%. For the sample size calculation, we assumed that a 20% probability of failure to meet this criterion is acceptable for a true probability of potentially hazardous under-triage of no more than 0.5%. (This is equivalent to requiring a one-sided test at level 5% to show that the probability of potentially hazardous under-triage is below 1% with a power of 80%, assuming that the true probability is 0.5%.) This resulted in a minimal sample size of 2185 patients; accounting for an estimated rate of “unclear” responses of 2%, at least 2230 patients were planned to be included, a total of 2550 cases were recruited. Secondary analyses included central 95% Clopper-Pearson confidence intervals for the further probabilities, based on corresponding empirical proportions. The software R version 4.2.0 (Windows, 64-bit) is used for the statistical evaluations.

Results

Baseline characteristics of the participants are shown in Table 3, and the recommendations obtained by the symptom checker in Table 4. Figure 1 shows the flow of analyses by Panels A – C. 210 (8.3%) of the 2543 patients included in the analysis were judged by Panel A to be undertriaged; 50 (1.9%) of these 210 patients were equally undertriaged according to Panel B. However, in none of these 50 patients did Panel C reach a consensus that the undertriage was potentially hazardous. This resulted in an upper 95% confidence bound for the probability of a potentially hazardous undertriage of 0.1184%. If the criterion for potentially hazardous undertriage was defined as a majority of Panel C members considering life-threatening or harmful self-triage “rather likely” or “likely”, four of the 50 cases fulfilled this criterion. This resulted in an upper 95% confidence bound for the probability of a potentially hazardous undertriage of 0.3616%.

Secondary Analyses. The central (two-sided) 95% Clopper-Pearson confidence interval for the probability of undertriage according to Panel A is [7.22%, 9.40%]. The central (two-sided) 95% Clopper-Pearson confidence interval for the probability of overtriage according to Panel A (450 cases, 17.7%) is [16.23%, 19.24%].

For the 50 out of 2543 cases that were undertriaged according to the judgments of Panels A and B, the central (two-sided) 95% Clopper-Pearson confidence interval for the corresponding probability is [1.539%, 2.688%].

The central (two-sided) 95% Clopper-Pearson confidence interval for the probability of a potentially hazardous undertriage is [0.0000%, 0.1458%] based on the original definition according to the protocol (zero out of 2543 cases), and [0.0431%, 0.4045%] according to the modified definition mentioned in the primary analysis (four out of 2543 cases).

Discussion

This study evaluated the safety of a symptom checker for medical self-assessment of acute complaints in a real-life clinical setting. In none of the 2543 consecutive participants, a consensus on potentially hazardous undertriage was reached in a stepwise evaluation process by three independent panels.

In a hitherto unpublished systematic literature search, we have found insufficient evidence from comparatively small studies for a safe use of symptom checkers in clinical routine [6]. One study with 825 patients showing “exactly matched” triage in 52.6% has been published in abstract form only [7]. Another study yielded correct triage in only 50-74% [8] . A third study from Germany evaluated the safety of urgency advice provided to 378 patients at an interdisciplinary emergency department by a symptom checker [9], showing undertriage in 34 (8.9%) and overtriage in 216 (57.1%) cases. A potentially hazardous situation was identified in 20 (5.3%) cases. This figure appears considerably higher than our finding, although an interrater variability was not taken into account in the German study.

In the absence of a broad study base, we cannot compare our results with previous, similarly designed studies for symptom checkers. In contrast, medical telephone triage has been extensively evaluated during the last 25 years [10,11,12,13,14,15] and has gained broad clinical support, despite ambivalent conclusions regarding safety.

A systematic review analysing 13 observational studies and 10 studies that simulated high-risk patients, safe triage was found in 46% to 97% [16]. Another systematic review involving computer-assisted telephone triage in urgent care [17] pointed out four studies that indicated potential undertriage errors [18,19,20,21]. Notably, hospitalisation rates of patients who were advised to seek non-urgent care ranged from 9.2% to 48%. Potentially life-threatening situations emerged in 0.84% of cases according to one study [20].

We have previously investigated the safety of computer-assisted telephone triage in 208 patients with non-life-threatening conditions consulting the emergency department at a university hospital [22]. We found poor agreement between the assessments by the call centre, the emergency physician, and the general practitioners who later cared for the patients. In one case, a risk to health or life was found. The Cochrane Collaboration in their 2004 systematic review on telephone triage concluded that insufficient

data existed regarding safety [23]. In light of the available information, the results of our study compare favourably to the published data on telephone triage.

Our study has several strengths and weaknesses. We included a large number of patients in a real-world clinical setting. In addition, the study design enabled us to eliminate the low inter-rater reliability of medical triage decisions by having three independent expert panels and an independent rater. This allows robust conclusions about the safety of the evaluated symptom-checker.

A potential weakness of our study is its single-centre design. However, the Cantonal hospital Baden serves a mixed urban and rural population of ~300 000 and offers all medical services with the exception of cardiac and neurosurgery. We therefore believe our findings can be extrapolated quite generally. The total number of patients frequenting the WIC and ED during the time of recruitment was 22 676; thus, only ~11% of them participated in the study. Due to limited resources, inclusions were possible only during the daytime, leaving ~8000 potential participants. Also, 1.5% of the 22 676 were ESI 1 patients, who were not eligible for the study.

In our study, we have focused on the safety of the symptom-checker. While maximum patient safety may theoretically be desirable, it should be weighed against the disadvantages of overtriage, notably inefficiency, unnecessary referrals and a higher risk of overmedicalisation, all of which increase costs. In our study, the overtriage rate after assessment by Panel A was 17.7% (450 cases). This figure is comparable to published rates of overtriage by teleconsultation and teletriage, which range from 12% to 57% (9)(24)(25)(26)(27)(28). In a further round of data analysis, we will also have the over-triaged cases assessed by Panel B in order to include interrater reliability in the analysis for these cases as well.

From the end of February, the COVID-19 pandemic required special hygiene measures for the tablet computers used, making patient recruitment more difficult as the first wave of the pandemic peaked in March 2020. The pandemic is also likely to have affected the case mix, which may have shifted slightly towards COVID 19-positive patients.

The urgency grading used in the two-dimensional matrix for the triage levels (Table 1) was defined at the discretion of the study team, implicating a certain degree of subjectiveness. While the range of appropriate triage levels was defined based on this order, the experts did not always explicitly mark all of the intermediate triage levels as appropriate.

Conclusion

The evaluated symptom checker proved to be a safe triage tool, avoiding undertriage in a real-life clinical setting of emergency consultations at a walk-in clinic and emergency department. Our data suggest the symptom checker may be safely used in clinical routine.

Other components

Table 1

	AMBULANCE	HOSPITAL	DOCTOR	CALLCENTER	PHARMACY	SELFCARE	UNCLEAR
EMERGENCY	16	15					
IMMEDIATELY	14	13	12				
TODAY		11	10	8	6	4	
LATER			9	7	5	3	1
UNCLEAR						2	0

Tab 1. Triage Level as defined by Time-to-treat (Emergency, Immediately, Today, Later, Unclear) and Point-of-Care (Ambulance, Hospital, Physician, Callcenter, Pharmacy, Selfcare, Unclear)

Table 2

Triage Level	Name	Recommended action
16	Emergency Ambulance	• **CPR/CPR readiness**. There is a **potentially life-threatening condition**. Medical treatment must be given **now.** • Alert the **emergency services** via the number 144.
15	Emergency Hospital	• **CPR/CPR readiness**. There is a **potentially life-threatening condition.** Medical treatment must be given **now.** Alert the **emergency services** via the number 144. • Medical treatment should be provided at a **hospital.**
14	Immediately Ambulance	• Medical treatment does not allow any delay. Treatment should be given **immediately.** • Alert the **emergency services** via the number 144.
13	ImmediatelyHospital	• Medical treatment does not allow any delay. Treatment should be given **immediately.** • Medical treatment should be provided at a **hospital.**
12	Immediately Doctor	• Medical treatment does not allow any delay. Treatment should be given **immediately.** • Medical treatment should be provided by a **registered doctor** [1]
11	Today Hospital	• Medical treatment does **not** have to take place **immediately**, but should not be delayed until tomorrow or over the weekend. Medical treatment should take place **within the next 24 hours.** • Medical treatment should be provided at a **hospital.**
10	Today Doctor	• Medical treatment does **not** have to take place **immediately**, but should not be delayed until tomorrow or over the weekend. Medical treatment should take place **within the next 24 hours.** • Medical treatment should be provided by a **registered doctor** [1]
9	Later Doctor	• Medical treatment is **not urgent**. If the symptoms do not subside in the next 2 days, treatment by a doctor is indicated. • Medical treatment should be provided by a **registered doctor** [1]
8	Today Call Centre	• Medical treatment does **not** have to take place **immediately**, but should not be delayed until tomorrow or over the weekend. Medical treatment should take place **within the next 24 hours.** • The affected person should be advised by a **telemedicine centre** on how to proceed.
7	Later call centre	• Medical treatment is **not urgent**. If the symptoms do not subside in the next 2 days, treatment by a doctor is indicated. • The affected person should be advised by a **telemedicine centre** on how to proceed.
6	Today Pharmacy	• Medical treatment does **not** have to take place **immediately**, but should not be delayed until tomorrow or over the weekend. Medical treatment should take place **within the next 24 hours.** • The affected person should be advised at a **pharmacy** on how to proceed.
5	Later Pharmacy	• Medical treatment is **not urgent**. If the symptoms do not subside in the next 2 days, treatment by a doctor is indicated. • The affected person should be advised at a **pharmacy** on how to proceed.
4	Today Selfcare	• Medical treatment does **not** have to take place **immediately**, but should not be delayed until tomorrow or over the weekend. Medical treatment should take place **within the next 24 hours.** • The complaints can be **treated independently** by simple measures.
3	Later Selfcare	• Medical treatment is **not urgent**. If the symptoms do not subside in the next 2 days, treatment by a doctor is indicated. • The complaints can be **treated independently** by simple measures.
0-2	Unclear	• The survey contains **too many ambiguities**. A targeted **initial assessment is not possible.**

Tab. 2. Recommended actions as defined by triage levels

1 e.g. family doctor, family doctor substitute, family doctor emergency service or suitable specialist

Table 3

Characteristics (n=2543)	Attribute	Value n (%)
Age	18-49 y	1397 (54.94)
	50-65 y	668 (26.27)
	66-80 y	360 (14.16)
	>80 y	118 (4.64)
Sex	Women	1227 (48.25)
	Men	1316 (51.75)
Reason for Encounter (15 most frequent)	Abdominal pain	287 (11.29)
	Chest pain	168 (6.61)
	Lumbar back pain	144 (5.66)
	Urinary tract problems	124 (4.88)
	Trauma/Fall	121 (4.76)
	Headache	90 (3.54)
	Dizziness	87 (3.42)
	Wound/skin injury	82 (3.22)
	Foot injury (caused by an accident)	81 (3.19)
	Leg problems	74 (2.91)
	Breathlessness	69 (2.71)
	Cold/influenza infection	64 (2.52)
	Finger injury (caused by an accident)	55 (2.16)
	Knee injury (caused by an accident)	51 (2.01)
	Hand injury (caused by an accident)	43 (1.69)

Tab. 3. Characteristics of the study population

Table 4

Triage Level	Value n (%)
Emergency Ambulance	57 (0.0224)
Emergency Hospital	142 (0.0558)
Immediately Ambulance	2 (0.0008)
Immediately Hospital	685 (0.2694)
Immediately Doctor	844 (0.3319)
Today Hospital	3 (0.0012)
Today Doctor	579 (0.2277)
Later Doctor	36 (0.0142)
Today Call Centre	26 (0.0102)
Later call centre	60 (0.0236)
Today Pharmacy	0 (0)
Later Pharmacy	30 (0.0118)
Today Selfcare	0 (0)
Later Selfcare	77 (0.0303)
Unclear	2 (0.0008)

Tab. 4. Cases in the various triage levels

Figure 1

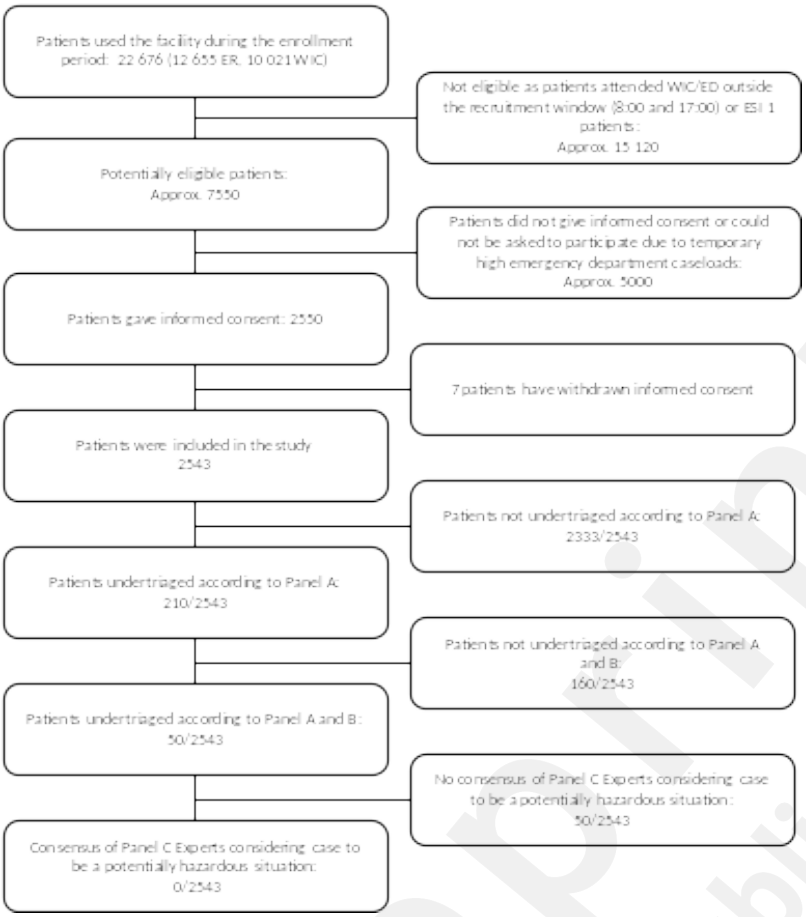

Fig 1. Flowchart patient recruiting and triage assessment Panel A, B and C

Authors Contributions

AM, JR, MS and MV were responsible for the concept and design. PR, MS and BG did the acquisition of the data. Which were analysed and interpreted by MV, AM, JD, JR. The first draft was written by AM, and then critically revised it in conjunction with JR, JD and MV. Data analysis was done by MV, with oversight by AM and JR.

Conflicts of interests

Andreas Meer is the owner and CEO of in4medicine. Bettina Grunder is a part-time employee of in4medicine, and Jacopo Demurtas received a scientific grant from in4medicine Inc. Michael Vock received a honorarium from in4medicine. The other authors report no conflicts of interest.

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