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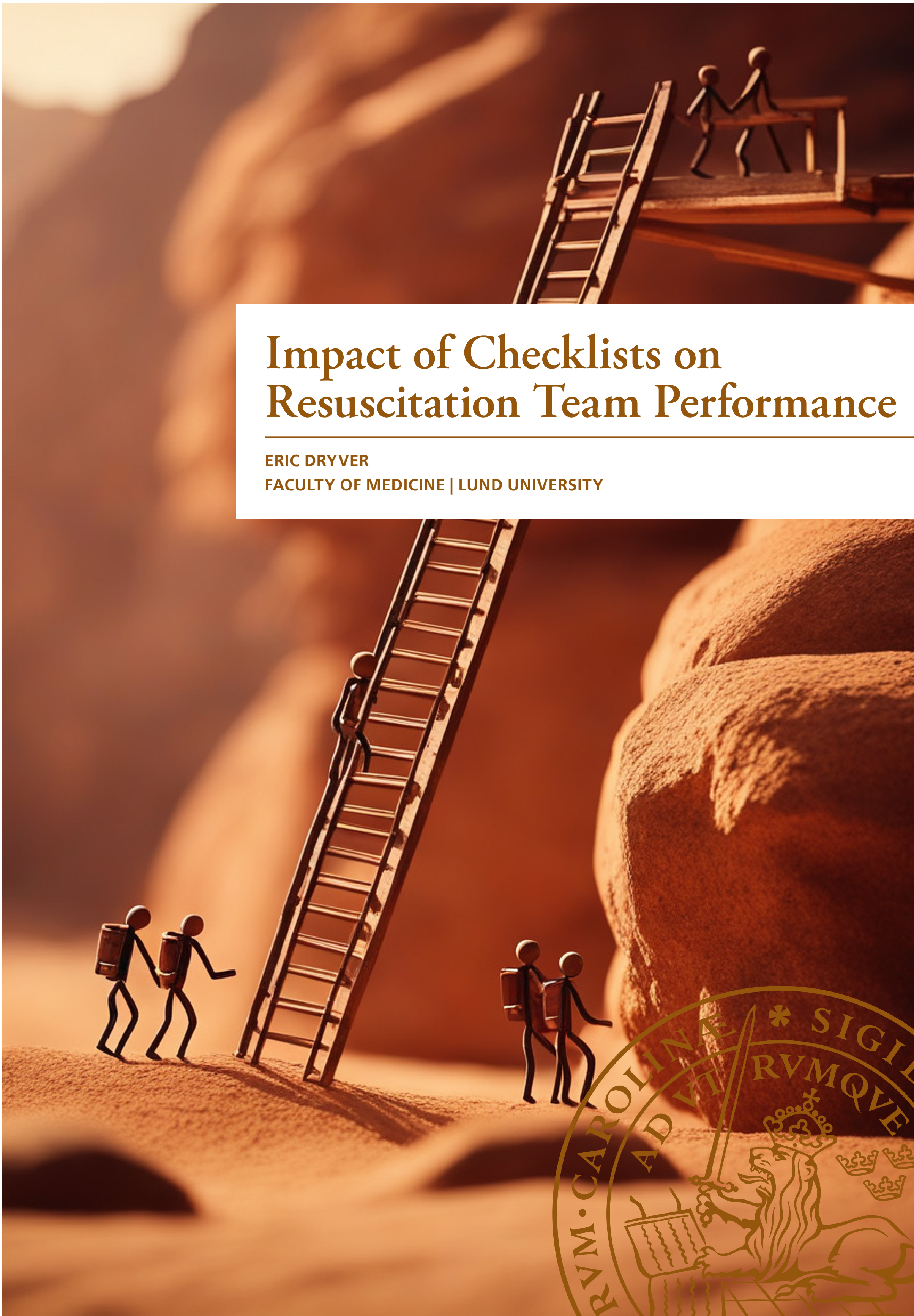

Impact of Checklists on Resuscitation Team Performance

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FACULTY OF MEDICINE | LUND UNIVERSITY

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ERIC DRYVER is a specialist in Emergency Medicine and Internal Medicine. He has been working in the Emergency Department of Skåne's University Hospital at Lund since 2002, long before Emergency Medicine became the thriving specialty that it now is in Sweden. He created the Emergency Medicine Core Competences course that is spreading throughout Europe. He has been struggling for years to master Chopin's Études.

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Eric Dryver

DOCTORAL DISSERTATION

Doctoral dissertation for the degree of Doctor of Philosophy (PhD) at the Faculty of Medicine at Lund University to be publicly defended on the 16th of May 2024 at 13:00 in Segerfalksalen, BMC, Lund

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Clinical Professor of Anesthesiology, Perioperative & Pain Medicine
Stanford University Anesthesia Department

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Abstract

Crisis checklists improve team performance during scenarios in a simulated operating theater and intensive care unit. Team performance is the product of interactions between personnel, tools, tasks and environment. The overarching goal of this thesis is to study the impact of checklists on the performance of resuscitation teams working in their usual workplace—the primary care center and the emergency department.

Paper I reports the impact of three checklists on the performance of 100 resuscitation teams in 22 primary care centers in Southern Sweden. Teams were randomized to checklist access and managed a simulated case of loss of consciousness due to hypoglycemia or a simulated case of anaphylaxis leading to cardiac arrest. Checklist access had no impact on the performance of key interventions.

Paper II reports the impact of eight checklists on the performance of 41 resuscitation teams in four emergency departments in Southern Sweden. Most teams managed two simulated crises—one with and one without checklist access. Eight critical conditions were simulated twice in each emergency department, once with and once without checklist access. The median percentage of indicated interventions performed was 38% for teams not using checklists and 86% for teams using checklists ($p < 0.001$).

Paper III describes the protocol for studying the impact of 63 checklists on the performance of resuscitation teams managing consecutive priority one patients during a six-month period in the resuscitation room of Skåne's University Hospital at Lund.

In conclusion, the impact of checklists on resuscitation team performance is highly dependent on the interactions between personnel, tools, tasks and environment. New tools should be evaluated by intended users in their usual workplace.

Key words:

Checklist; cognitive aid; emergencies; patient safety; simulation

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LUND UNIVERSITY

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Cover generated by Wowzer.ai from the prompt "team of five stick figures walking on a horizontal ladder over a gorge."

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MADE IN SWEDEN

To Maya and Elin

"This was passed on to me, and now I am passing it on to you: never stop working on yourself." Tijs Dryver

*"Don't just read with your mind,
listen with your heart." Louise Dryver*

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Dryver E, Knutsson J, Ekelund U, Bergenfelz A. Impediments to and impact of checklists on performance of emergency interventions in primary care: an in situ simulation-based randomized controlled trial. Scand J Prim Health Care. 2021;39(4):438-47

Paper II

Dryver E, Lundager Forberg J, Hård Af Segerstad C, Dupont WD, Bergenfelz A, Ekelund U. Medical crisis checklists in the emergency department: a simulation-based multi-institutional randomised controlled trial. BMJ quality & safety. 2021;30(9):697-705

Paper III

Dryver E, Olsson de Capretz P, Mohammad M, Armelin M, Dupont WD, Bergenfelz A, Ekelund U. Clinical use of an emergency manual by resuscitation teams and impact on performance in the emergency department: a prospective mixed-methods study protocol. BMJ open. 2023;13(10):e071545

Abbreviations

A	Airway
B	Breathing
BP	Blood Pressure (millimeters of mercury)
C	Circulation
CI	Confidence Interval
CRM	Crew Resource Management
CT	Computed Tomography
D	Disability
E	Exposure & Environment
ED	Emergency Department
EKG	Electrocardiogram
EM	Emergency Manual
Hb	Hemoglobin (grams per liter)
HR	Heart Rate (beats per minute)
IM	Intramuscular
IV	Intravenous
kPa	Kilopascal
L/min	Liters per minute
NaCl	Sodium chloride solution
NASEM	National Academies of Science, Engineering, and Medicine
NTSB	National Transport Safety Board
PVC	Peripheral Vein Catheter
RR	Respiratory Rate (breaths per minute)
SBP	Systolic Blood Pressure (millimeters of mercury)
SOP	Standard Operating Procedure
SpO2	Peripheral oxygen saturation measured by pulse oximetry
WHO	World Health Organization

Popular Science Summary

Checklists are lists of things to do or things to consider. They are meant to be carried out from top to bottom. The purpose of checklists is to help us perform tasks. Sometimes, we forget to do certain steps because we are distracted, tired, or stressed. Sometimes, we have trouble remembering how to do certain steps, because it has been a long time since we last did them or because we are very stressed. Checklists can help us perform tasks by drawing our attention to the steps that need to be carried out and by providing us with facts and instructions.

Checklists are routinely used by pilots ever since a plane crashed in 1935 because the pilot forgot to carry out a step prior to taking off. Checklists have become more common in medicine during the past two decades. In most of the world, medical personnel go through a checklist prior to operating on people. This checklist decreases the number of people who die after the operation from 10 in 1000 to 8 in 1000. Given that many thousands of people get operated on each year, using the checklist saves a lot of lives.

Checklists have also been written to help medical personnel deal with emergencies, for example patients who suddenly develop severe allergic reactions. Studying whether checklists help personnel deal with emergencies is difficult, because emergencies are rare events that occur unexpectedly. The main way these checklists have been studied is in simulation labs, with a manikin instead of a real patient. Studies in simulation labs show that personnel do a better job managing the emergency when they use checklists.

But that does not prove that personnel would do a better job with checklists when taking care of real patients in their usual workplace. Whether a tool works during the care of actual patients depends on who is using the tool, whether the user has experience using the tool, can find the tool in his or her usual workplace, whether he or she is allowed to use the tool, and whether using the tool disrupts the rest of the team. A drawback of many studies in the simulation lab is that the study is not done with actual teams used to working together and not done in the personnel's usual workplace.

We studied whether access to three checklists improved how personnel who work in primary care centers manage two emergencies in their usual workplace. We used a manikin to simulate, in 22 primary care centers in Southern Sweden, a patient who had become unconscious and had a seizure because her blood sugar was very low. The "patient" needed help to get oxygen into her lungs, and she needed fluid and sugar injected into her blood stream. We looked at whether putting on the wall of the room a checklist listing the steps that ought to be carried out improved how quickly personnel performed the required treatments. We simulated the case 51 times. Roughly half of the teams had access to the checklists and half did not. Access to the checklist did not improve team performance.

We used the same manikin to simulate another patient who develops a severe allergic reaction after having been stung by a wasp. We looked at whether putting on the wall of the room two checklists listing the steps that needed to be carried out improved how quickly personnel performed the required treatments. We simulated the case 49 times. Roughly half of the teams had access to the checklists and half did not. Again, access to the checklists did not improve team performance.

During this study, we also observed which aspects of emergency treatment the personnel had trouble performing. Some personnel had trouble finding and using equipment and medications that they only use during emergencies, and some personnel had trouble thinking about low blood sugar as a cause of unconsciousness.

What the study showed was that simply placing unfamiliar checklists on the wall does not improve a team's performance during simulated emergencies in the primary care center. During a crisis, people do not want to use unfamiliar tools. We think that checklists may be more beneficial if teams are familiar with them and when a team member has the specific task of reading out loud from the checklist.

We then studied whether access to checklists improved how personnel who work in the emergency department managed eight emergencies in their usual workplace. We used a manikin to simulate a patient with one of these eight emergencies in four emergency departments in Southern Sweden. The personnel involved were those who were ready at that time to take care of real patients with emergencies. In the study, most teams managed two emergencies, one with and one without access to the checklists. This time, we gave a nurse the task of reading out loud the steps in the checklist.

The study showed that teams without access to checklists did 4 of 10 indicated measures whereas teams using checklists did 8 to 9 of 10 indicated measures. Checklists improved team performance in all four emergency departments, for all eight scenarios, and for all teams. It did not matter whether the doctors or nurses where very experienced or not, everyone seemed to benefit from checklists. The personnel who used the checklists filled out a survey and indicated that they liked the checklists and would want to use them if they had a real patient with the emergency.

Why did checklists not have an effect in the primary care center and why did they have an effect in the emergency department? We believe there are several reasons for this difference:

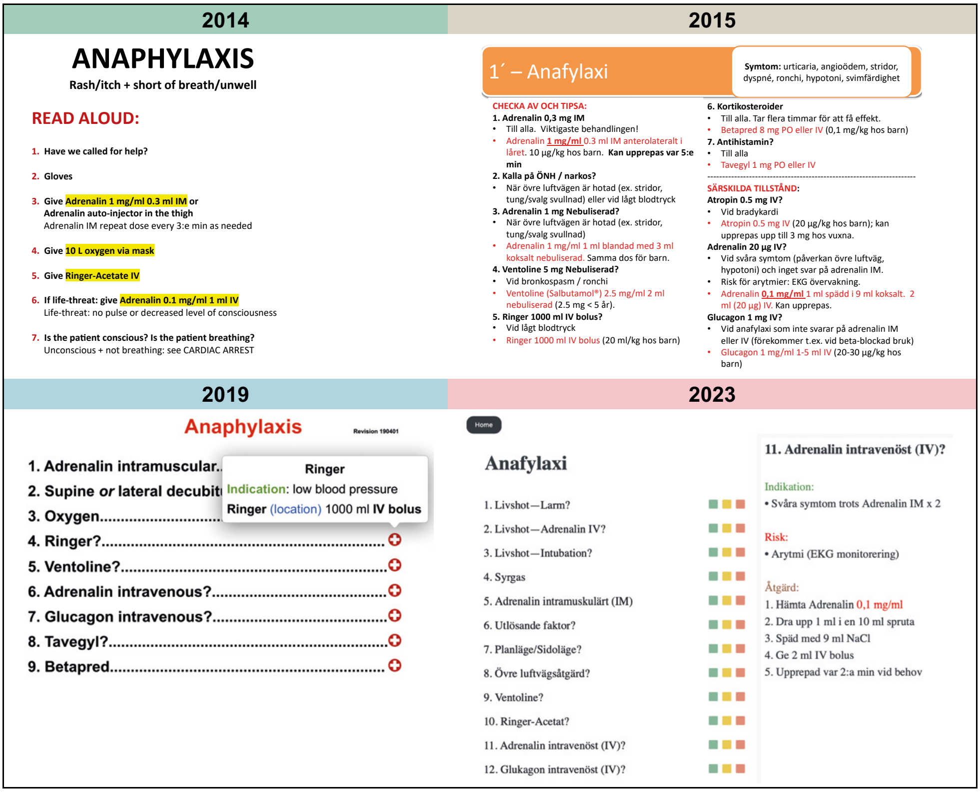
- In the emergency department, the personnel have more experience using emergency equipment.
- In the study in the emergency department, a nurse had the task of reading from the checklist.
- In the study in the emergency department, we included in the checklists where to find medications that are rarely used.

We are now going to study how teams use checklists when they take care of patients with real emergencies in one emergency department in Southern Sweden over a six-month period. We have written 63 checklists to help personnel manage patients with certain problems (for example, being found unconscious) or certain conditions (for example, heart attack). Teams will first manage patients as usual. Then the nurse will ask the physician which checklists to show on a large screen for the whole team to see. The nurse will read through each item on the checklist and if there are treatments that are indicated that have not yet been done, the nurse will note that these treatments are done thanks to the checklist. Specialists in Emergency Medicine will determine later whether they believe that these added treatments were of value for the patient or not.

In summary, checklists are a promising tool to help medical personnel take care of patients with emergencies. But simply putting a checklist on the wall does not help. The checklist may look simple, but how the checklist affects the way teams take care of patients is complex. Checklists need to be studied with real teams, in their usual workplaces, and with real patients to figure out how and when checklists can improve medical care.

Thesis at a Glance

	I	Pilot Study	II	III
Design	Randomized controlled trial	Randomized controlled trial	Randomized controlled trial	Non-randomized controlled trial
Data acquisition	January 2014 - June 2016	October-November 2015	June 2019 - February 2020	September 2024 - March 2025 (?)
Setting	22 primary care centers	1 resuscitation room	4 resuscitation rooms	1 resuscitation room
Personnel	347 local personnel	56 local personnel	138 local personnel	Local personnel
Tasks	100 simulations	16 simulations	76 simulations	Priority 1 patients
Checklists	3	8	8	63
Platform	Paper	Paper	Digital	Digital & website
Reader	None assigned	None assigned	Assigned	Assigned
Median % indicated interventions	Checklist access does not improve performance	44% without, 83% with checklists $p < 0.05$	39% without, 86% with checklists $p < 0.0001$	
Key observation	Finding and using crisis equipment is challenging	Having two checklist versions is problematic	Checklists do not impede initial management	



Preface

Being called "square" is not a compliment. Squareness connotes rigidity and lack of imagination. What could be squarer than a checklist? Checklists are columns of squares, and use of checklists in medicine is derogatorily referred to as "cookbook medicine."

Yet even professional cooks use checklists to ensure consistency of quality, as the surgeon Atul Gawande wrote in The Checklist Manifesto [1]. In the Manifesto, Gawande argues that checklists can help us cope with complexity in numerous fields—medicine, aviation, construction—and he concludes the penultimate chapter with the exhortation: "Try a checklist."

In January 2013, Alexander Arriaga, Atul Gawande, and colleagues published a study in the New England Journal of Medicine entitled Simulation-Based Trial of Surgical-Crisis Checklists [2]. The study reported that teams managed perioperative crises better when they had access to a collection of crisis checklists. In response to comments and questions concerning the study, Gawande and Arriaga wrote:

> "There is considerable opportunity for careful adaptation of these tools and concepts to improve crisis management in high-risk environments outside the surgical setting— whether in emergency rooms, labor and delivery wards, nonsurgical procedure areas, or elsewhere. We would enthusiastically support such efforts" [3].

At the time, I was running in-situ simulation-based training in the primary care setting. My colleague and I would drive out to a primary care center and run several simulations where the "patient" would suddenly deteriorate. Invariably, we would drive back wondering whether the training session would have a lasting impact on the personnel's ability to manage a true emergency. We had discussed whether checklists could play a role in boosting team performance.

I was also involved in developing the Swedish Specialist Examination in Emergency Medicine [4]. Checklists have been from the start a key ingredient in the specialist examination. For many of the processes being assessed, checklists have been developed based on current standards of care. These checklists are used during the examination to grade performance. By making the checklists available on-line, we also ensure that the examination has a degree of transparency.

I was also running monthly scenario-based training for residents in Emergency Medicine. The training is in accordance with the pedagogical model Constructive Alignment [5], namely that students learn best by being involved in learning activities, and that these activities should be aligned with the training goals.

Checklists are used to provide objective feedback after each simulation and to ensure that the training is aligned with the standard of care and with the specialist examination [6].

Last but not least, I was working in the emergency department of Skåne's University Hospital at Lund. The variety of clinical problems and the wide spectrum of patient acuity that we encounter in the emergency department is both exciting and anxiety-provoking. I was developing checklists to integrate new clinical information into streamlined approaches to problems and diagnoses, as a teaching tool but also to reduce my stress at work.

Arriaga et al's study, which blended checklists, simulations, and crisis management, hit a nerve. It lay in the zone common to several fields of interest. I told my wife that I wanted to design and conduct studies of checklists for the management of crises in the primary care center and the emergency department. She suggested that I carry out these studies within the framework of a doctoral dissertation. Anders Bergenfelz and Ulf Ekelund accepted me as PhD student. This dissertation is an account of the challenges we've faced, the solutions we've tested and what we've learnt during the past 10 years. The best is yet to come.

Context

Study I and Study II

The research proposals for Study I and Study II were submitted to the Ethics Review board in March and October 2013, respectively. Both studies are simulation-based randomized controlled trials of several crisis checklists. At the time, Arriaga et al's Simulation-Based Trial of Surgical-Crisis Checklists [2] and Ziewacz et al's preceding pilot study Crisis Checklists for the Operating Room: Development and Pilot Testing [7] were the only published trials of this nature. It was not clear whether crisis checklists would have the same benefit in the primary care center or emergency department.

Back then, there was little guidance in the medical literature about how to develop and implement crisis checklists. Goldhaber-Fiebert and Howard's article Implementing Emergency Manuals: Can Cognitive Aids Help Translate Best Practices for Patient Care During Acute Events? [8], Wu et al's article Supporting Crisis Response with Dynamic Procedure Aids [9], and Burian et al's article More Than a Tick Box: Medical Checklist Development, Design, and Use [10] had yet to be published. Finally, there were no studies analyzing impediments to crisis management in the primary care setting.

Study III

The research proposal for Study III was submitted to the Ethics Review Board in March 2022. This study will document how an emergency manual is used during the consecutive management of priority one patients in an emergency department over a six-month period.

At the time the research proposal was submitted, two studies of crisis checklists performed in simulated resuscitation rooms had been published [11, 12], both reporting improved team performance with checklist use. These studies strengthened the case for studying an emergency manual adapted to the resuscitation room during actual clinical practice. The only published study evaluating emergency manual use during actual clinical practice and supplying denominator data was Goldhaber-Fiebert et al's Clinical Uses and Impacts of Emergency Manuals During Perioperative Crises [13].

Background

The Tool, the Team, the Task and the Tapestry

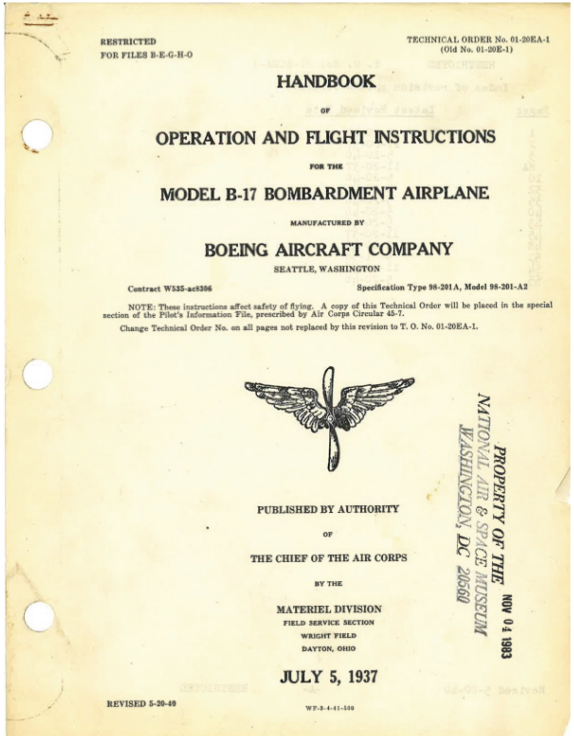
Tool

What is a Checklist?

A checklist is a cognitive aid. It consists of a list of items to do or consider (the "list") and it is intended to be used in a systematic way (the "check"). The most common checklist is the self-made "to-do list" such as a shopping list or packing list. The oldest known checklist, inscribed on a paperback-sized cuneiform tablet dating back to 1730 BC, is a Babylonian recipe for lamb stew [14]. The coolest checklists are the 9 x 6 cm (3.5 x 2.5 inch) cuff checklists that astronauts wore on their wrists on the lunar surface [15]. Despite the lack of text, the instructions provided to assemble IKEA furniture qualify as checklists.

The most influential checklist is arguably the B-17 pre-flight checklist. In 1935, the US Army Air Corps held a competition to determine which plane to purchase to replace its aging fleet of bombers [16]. The favorite was the Boeing prototype Model 299—the precursor to the B-17—nicknamed the "Flying Fortress". The plane had flown from Seattle, Washington to Dayton, Ohio where the competition was to be held in a record-breaking nine hours. On the day of the competition, October 30th, the plane crashed immediately after take-off, killing the test pilot, Major Ployer Peter Hill, and nearly bankrupting Boeing. The accident was caused by wind-gust locks on the elevators and rudder that Major Hill had forgotten to disengage. The gust locks were a new safety device designed to prevent the wind from damaging the plane's flaps when the plane was parked. It was as though Major Hill had forgotten to release the parking brake before taking off.

"Pete" Hill was a test-pilot extraordinaire [17]. He had test-flown 60 new Army aircraft and his prowess has been recognized by naming a US Air Force base in Utah after him. To prevent such tragedies from occurring again, more pilot training was not the solution. The root cause of the problem was deemed to lie in the increased complexity of the plane [18]. After a think-tank session, Boeing determined to design a pre-flight checklist for pilots (Figure 1).



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FOR FILES B-E-G-H-O

TECHNICAL ORDER No. 01-20EA-1
(Old No. 01-20E-1)

HANDBOOK

OF

OPERATION AND FLIGHT INSTRUCTIONS

FOR THE

MODEL B-17 BOMBARDMENT AIRPLANE

MANUFACTURED BY

BOEING AIRCRAFT COMPANY

SEATTLE, WASHINGTON

Contract W535-ac8306

Specification Type 98-201A, Model 98-201-A2

NOTE: These instructions affect safety of flying. A copy of this Technical Order will be placed in the special section of the Pilot's Information File, prescribed by Air Corps Circular 45-7.

Change Technical Order No. on all pages not replaced by this revision to T. O. No. 01-20EA-1.

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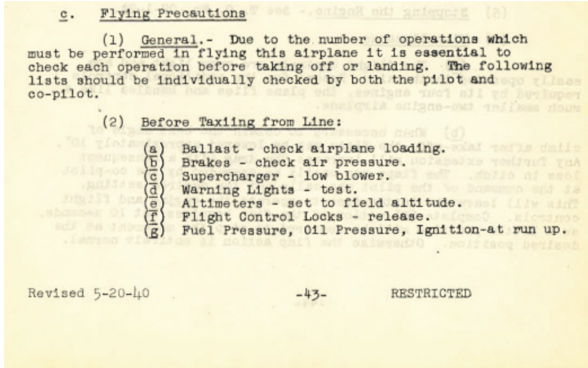

c. Flying Precautions

(1) General.- Due to the number of operations which must be performed in flying this airplane it is essential to check each operation before taking off or landing. The following lists should be individually checked by both the pilot and co-pilot.

(2) Before Taxiing from Line:

(a) Ballast - check airplane loading.
(b) Brakes - check air pressure.
(c) Supercharger - low blower.
(d) Warning Lights - test.
(e) Altimeters - set to field altitude.
(f) Flight Control Locks - release.
(g) Fuel Pressure, Oil Pressure, Ignition-at run up.

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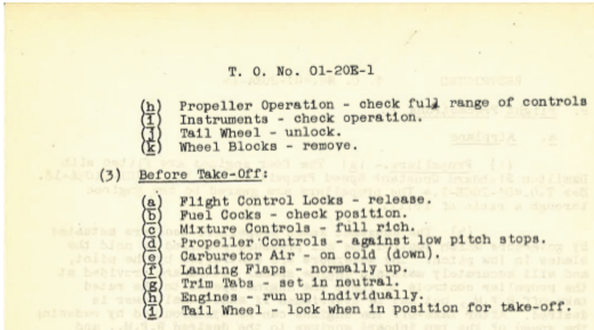


T. O. No. 01-20E-1

(h) Propeller Operation - check full range of controls
(i) Instruments - check operation.
(j) Tail Wheel - unlock.
(k) Wheel Blocks - remove.

(3) Before Take-Off:

(a) Flight Control Locks - release.
(b) Fuel Cocks - check position.
(c) Mixture Controls - full rich.
(d) Propeller Controls - against low pitch stops.
(e) Carburetor Air - on cold (down).
(f) Landing Flaps - normally up.
(g) Trim Tabs - set in neutral.
(h) Engines - run up individually.
(i) Tail Wheel - lock when in position for take-off.

Figure 1: Excerpt from the Handbook of Operation and Flight Instructions for the Model B-17 Bombardment Airplane
National Air and Space Museum (ref_2024-0247_B17_01-20EA-1_1940-05-20). Reproduced with permission.

Checklist use is now ingrained in aviation, even though it has not been subjected to a randomized-controlled trial. In the United States, "Checklist Day" is celebrated on October 30th.

What is the Checklist's Purpose?

The most basic purpose of using a checklist is to ensure completeness of task performance (e.g. placing all the items on the shopping list in the shopping cart). Checklists that are used more than once have the additional function of ensuring that a task is performed consistently according to a standard. A Standard Operation Procedure (SOP) is a detailed description of how a routine process ought to be performed to ensure reliability, quality and efficiency [19]. Checklists are cognitive tools that help the user carry out the SOP. Checklists can be thought of as highly distilled SOPs adapted to the user's knowledge (Figure 2). Knowledge-translation refers to knowledge synthesis to create tailored tools, followed by tool implementation and evaluation with the goal of improving health delivery [20]. Medical checklists are "knowledge-translation tools that promote completeness, consistency and alignment with best practice guidelines when carrying out a task" [8].

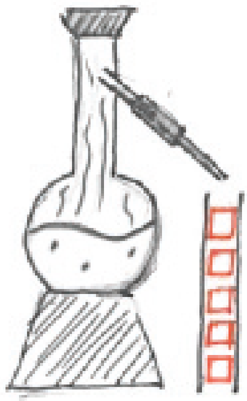


Figure 2: Checklists are distilled SOPs

How are Checklists Categorized?

Checklists used in aviation are categorized as "normal", "non-normal" and "emergency". A similar taxonomy is used for medical checklists [10, 21]. The checklists that are part of the World Health Organization (WHO) Surgical Safety Checklist can be categorized as "normal" or "routine" checklists. The checklist for dealing with a broken surgical instrument can be categorized as "non-normal" or "atypical" [10]. The checklist for malignant hyperthermia can be categorized as an "emergency" or "crisis" or "critical event" checklist [10]. In aviation, emergency and abnormal checklists are bundled into a Quick Reference Handbooks (QRH); in medicine, bundles of crisis checklists have been referred to as QRHs, Quick Reference Manuals (QRMs) [22] and Emergency Manuals (EMs) [8].

How are Checklists Carried Out?

The two main modalities for carrying out a checklist are Read-Do and Do-Confirm (Do-Verify)[10, 21]. As the term suggests, the Read-Do modality involves reading each item on the checklist and performing the task before progressing to the next item. The Do-Confirm modality refers to performing the task first and then using the checklist to ensure that all steps have been carried out. The user may switch between modalities. For example, one simulation-based study noted that teams usually did a least one measure (Do-Confirm) before accessing the checklist and using it to guide further management (Read-Do) [23].

Checklists may be used by a single user or by a team. Checklists may be used silently, or the item may be read out loud. When teams use a checklist, a team member may be assigned the role of reading out loud each item. This role is usually referred to as "the reader" [8, 24]. When teams use checklists in Read-Do mode with a reader and expect a verbal response from the team member carrying out the action, the modality of use is called Call-Response or Challenge-Response or Challenge-Do-Response [10, 21].

Some authors have suggested that checklists can be used in "sampling" mode where the user selectively retrieves information from the checklist or considers carrying out a selection of interventions [10, 25]. While this may be a useful way of using a checklist, a purist would argue that checklists are intended to be carried out systematically from start to finish (the "check") to ensure completeness of task performance, and that sampling is not an orthodox mode of checklist use.

Team

What is a Team?

A team can be defined as two or more people working together to achieve a common goal [26]. Communication and coordination between team members are implicit aspects of teamwork.

Crew-Resource Management

Following the crash of United Airlines Flight 173 in 1978, the US National Transportation Safety Board (NTSB) mandated that airline crew receive Cockpit Resource Management training to improve communication and coordination between crew members [27]. Investigation into the crash had led to the conclusion that poor communication between cockpit crew members and unhealthy team dynamics were important contributing factors to the crash. Cockpit Resource Management, renamed Crew Resource Management (CRM), highlights the impact on team-performance of "non-technical skills" such as communication, leadership skills and situation awareness.

One author defines CRM as:

> "a flexible, systemic method for optimizing human performance in general, and increasing safety in particular, by (1) recognizing the inherent human factors that cause errors and the reluctance to report them, (2) recognizing that in complex, high risk endeavors, teams rather than individuals are the most effective fundamental operating units and (3) cultivating and instilling customized, sustainable and team-based tools and practices that effectively use all available resources to reduce the adverse impacts of those human factors" [28].

Task

Medical Errors

The Institute of Medicine published in 1999 a report entitled To Err is Human: Building a Safer Health System [29]. The authors report that roughly 3% of patients admitted to hospital experience an adverse event, defined as an injury caused by medical management, and that 15% of adverse events result in death. Half of the adverse events are preventable adverse events, defined as adverse events attributable to error. Higher rates of error occur in highly technical surgical specialties, suggesting that complexity contributes to errors. Intensive care units, operating rooms, and emergency departments (EDs) are settings where high error rates with serious sequelae are more prone to occur.

The National Academies of Science, Engineering, and Medicine (NASEM) and the Institute of Medicine published in 2015 a report entitled Improving Diagnosis in Health Care [30]. The authors report that the impact of diagnostic errors has been largely unappreciated and that most people will experience at least one diagnostic error during their lives. Diagnostic errors are believed to affect 5-15% of patients [30-33].

Medical Errors in Emergency Medicine

In one study, only 4% of intrahospital adverse events occurred in the ED, yet half of these were deemed due to error (highest percentage of all intrahospital sites) [34]. The same study reported that only 2% of all adverse events were attributed to Emergency Medicine personnel, yet 95% of these were deemed due to error (highest percentage of all provider types). These errors consisted mainly of faulty diagnoses. The authors speculate that errors in Emergency Medicine result from task complexity and suggest that EDs "could cope with task complexity by improving teamwork and standardizing work procedures" [34].

Studying diagnostic errors in the ED is hampered by lack of consensus regarding what constitutes a diagnostic error [35, 36]. NASEM defines a diagnostic error as failure to "(a) establish an accurate and timely explanation of the patient's health problem(s) or (b) communicate that explanation to the patient" [30]. Another definition of a diagnostic error is a diagnosis that is “unintendedly delayed, wrong, or missed as judged from the eventual appreciation of more definitive information" [37].

Neither of these definitions are applicable to the ED. The primary task of personnel in the ED is not to establish an explanation of the patient's health problem, rather it is to evaluate the likelihood that a patient is suffering from a time-sensitive condition where appropriate therapy, administered within minutes to days, impacts on morbidity and mortality [38]. Failure to communicate an explanation of a problem to the patient is a failure in communication, not a failure in the diagnostic process. Neither definition takes into consideration over-investigation, which arguably is also a form of diagnostic error. Some argue that absolute certainty in diagnosis is unattainable and that the goal of the diagnostic process is to establish diagnostic likelihoods sufficient to guide decision-making [39]. This may be an extreme stance, but diagnostic uncertainty is common in the ED due to limitations in how much information can be acquired and how much time can be spent evaluating each patient. A definition of diagnostic error more suitable to the ED would be: failure to reasonably estimate the likelihoods of potential time-sensitive conditions based on available information.

Cognitive Causes of Diagnostic Errors

Daniel Kahneman, in his book Thinking Fast and Slow, popularized the concept that we think according to the two systems: System-1 and System-2 [40]. System-1 is essentially pattern-recognition. It is fast, unconscious, and effortless. It is unaware of the amount—or lack—of information available, rather it assumes that "what you see is all there is." System-1 jumps to conclusions without being aware of the size of the leap. System-2, on the other hand, is conscious, analytical, rule-based, and mentally taxing. Kahneman writes: "In the unlikely event that they would make a film about this, System-1 would be the central character." Kahneman is no trekkie. Films about System-1 and System-2 have been made, and they are called Star Trek. Captain Kirk is the spontaneous, emotional, intuitive System-1 while First Officer Spock is the hyperanalytical, always right but irritating System-2. The System-1 (heuristic, intuitive) and System-2 (systematic, analytical) dichotomy has been used to discuss diagnostic reasoning [41, 42].

Diagnostic errors have been categorized as system-related, no-fault (e.g. uncooperative patient) and cognitive, where cognitive errors are due to faulty data gathering, faulty knowledge and faulty synthesis [37]. According to one study, the most common phenomenon underlying diagnostic errors is premature closure, a type of faulty synthesis defined as "failure to consider other possibilities once an initial diagnosis has been reached" [37]. Yet teasing out whether diagnostic errors are due to faulty data gathering, faulty knowledge or faulty synthesis is not obvious.

One study reported an association between missing the diagnosis of stroke and not performing a thorough neurological examination [43]. One interpretation could be that missing the diagnosis resulted from faulty data acquisition. Yet it is inappropriate to carry out a detailed neurological examination on all patients in the ED. Another interpretation could be that the physician did not consider the possibility of stroke based on initial information, either because of faulty knowledge (e.g. that vertigo can result from stroke) or faulty data synthesis (e.g. prematurely closing in on the diagnosis vestibular neuritis), and therefore did not perform a detailed neurological examination.

As Geoffrey Norman and Kevin Eva have pointed out, the "root cause of diagnostic error is difficult to study as errors tend to be defined only in hindsight and the 'microscope' that can enable detection of mental processes in live time has yet to be invented" [42]. How the System-1 and System-2 dichotomy intersects with the faulty data, knowledge and synthesis trichotomy is unclear, but both provide a framework for tools and strategies meant to reduce the risk of diagnostic errors.

Tapestry

Tapestry?

"Tapestry" refers here to the physical, cultural, and emotional environment within which tasks are performed. "Fish don't know they're in water" [44], and medical personnel may be unaware of how the physical and socio-cultural environment they work in affects performance. As an example of the impact of environmental factors, one randomized controlled simulation-based study reported that rude comments from an "observer" significantly impaired the diagnostic and procedure-related performance of resuscitation teams [45].

Systems Engineering Initiative for Patient Safety and Actor Network Theory

The Systems Engineering Initiative for Patient Safety (SEIPS) model provides a framework for guiding research and initiatives designed to improve health-related outcomes [46, 47]. The "work system" in the model consists of people, tasks, tools, and environmental factors. The environmental factors consist of the physical environment, the socio-organization, and factors such as regulatory and economic contexts.

The SEIPS model emphasizes the impact of interactions between the elements in the work system (Figure 3A). Tools do not exist in a vacuum. Tools interact with people, other tools, and the environment to impact on task performance. A novel tool might boost performance when introduced into one work system but not another. Tools need to be tailored to the setting in which they are intended to be used. Given the complexity of all the interactions, it is difficult to predict how the introduction of a novel tool will affect performance.

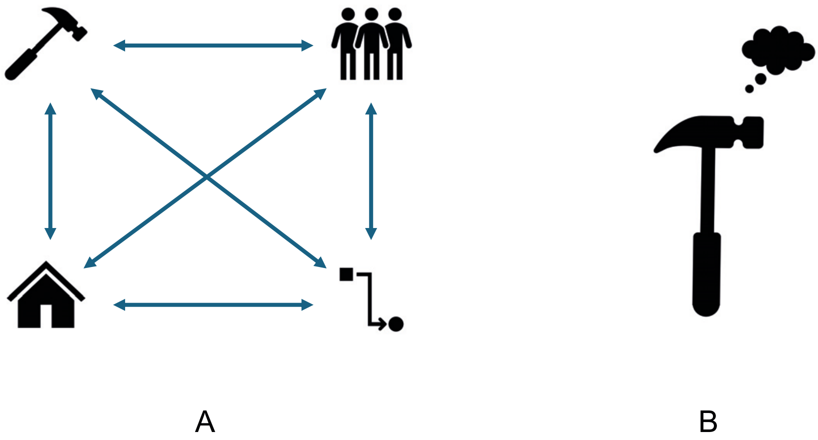


Figure 3: How a tool affects task performance
A: The work system in the Systems Engineering Initiative for Patient Safety model consists of the personnel, the tasks, the tools and the environment. The attributes of each component and how these components interact with each other affect task performance. B: According to Actor Network Theory, tools have agency.

Some frameworks such as Actor Network Theory (ANT) [48] even attribute agency to tools to emphasize the interactions between tools and their users. According to ANT, tools have a will (Figure 3B). Checklists were, according to the astronaut Michael Collins, the spacecraft's "fourth crewmember" and the real commander in flight [18]. According to an Apollo engineer, checklists were a "program" that ran not on machines but on people [18]. Grigg attributes agency to medical checklists when he writes: "Checklists must become intelligent, adaptable companions" [49].

How and When Might Checklists Work?

How Might Checklists Work?

Checklists don't "work" by themselves. They are cognitive aids designed to improve the performance of individuals or teams carrying out a task within a given physical and cultural environment. The following section provides putative mechanisms for how medical checklists may improve the performance of health-care teams.

1. Focus

Checklists direct attention to criteria of consideration and can prevent therapeutic omissions during the performance of routine tasks [9, 50] or during the management of a critical patient (Figure 4). Checklists may also prevent diagnostic errors by ensuring that key information is gathered in a certain context, and by prompting personnel to consciously consider certain diagnoses, thus guarding against premature closure.

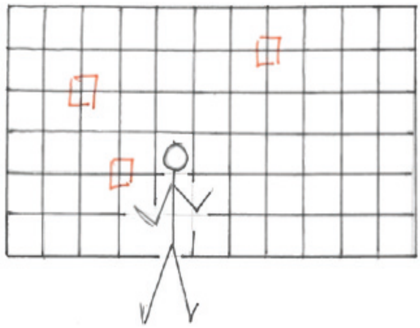


Figure 4: Checklists may work by directing focus

2. Facts

Checklists may help team members deliver interventions by providing facts that are unknown or difficult to recall (Figure 5). For example, checklists may provide a list of second- and third-line emergency interventions and the doses of medications that are seldom used.

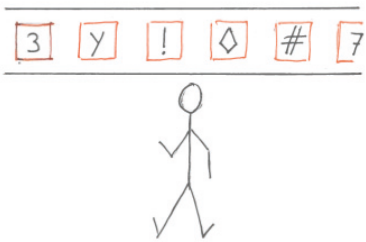


Figure 5: Checklists may work by providing facts

3. Forcing Function

Checklists are meant to ensure that processes are carried out in a systematic, reproducible, and complete way. Seen from the perspective of ANT, the checklist has a will: it wants to dictate, while it is being implemented, where users focus their attention and what they do (Figure 6). Checklists cannot "work" as intended unless the users temporarily subject themselves to the constraints of the checklist and actively engage with the checklist, as opposed to regarding checklist use as a tick-box exercise to be sped through in a perfunctory manner.

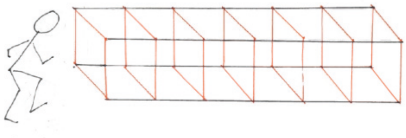


Figure 6: Checklists may work as a forcing function

4. aFFirmation

Checklists may provide the required impetus for team members to perform unusual, risky, invasive interventions that are indicated according to the checklist. For example, a patient with angioedema who is rapidly desaturating because of a swollen upper airway and who cannot be intubated requires an emergency cricothyrotomy [51]. It is physiologically indicated to perform such an intervention before the patient develops cardiac arrest from hypoxia, yet a daunting decision to make. A checklist that has been developed and approved by the local organization may provide teams with the necessary affirmation to perform the intervention (Figure 7).

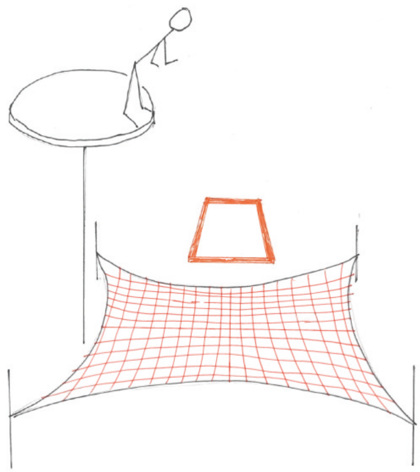


Figure 7: Checklists may work by affirming that the intervention is indicated, appropriate and approved

5. Fewer

Health care personnel using checklists do not need to allocate mental energy to recall the steps in the process. Checklist use frees up cognitive bandwidth [49]. Checklists may make carrying out a process more efficient by excluding unnecessary steps (Figure 8). Checklists may create an environment with fewer distractions, allowing for better performance [52].

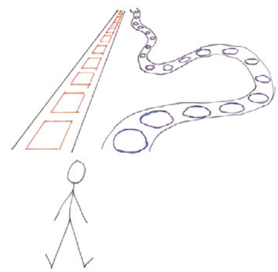


Figure 8: Checklists may improve efficiency by excluding unnecessary steps

6. Flow

Medical crises are complex situations where several interventions (treatments and investigations) are required. Deciding in which order interventions should be performed, and avoiding inefficiencies stemming from an order that violates engineering coherence (see below), is mentally taxing. Checklists may improve workflow by providing a carefully considered sequence and allowing teams to focus on carrying out steps one at a time [53]. Severe stress may paralyze personnel like a deer in the headlights. The checklist may reduce cognitive overload [50] and can provide a lifeline for personnel to latch onto and step-by-step pull themselves out of the stress cone (Figure 9).

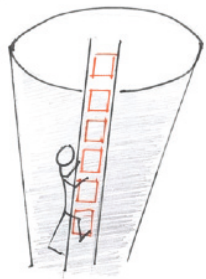


Figure 9: Checklists may improve performance by structuring the workflow

7. Forum

Checklists may improve teamwork by promoting communication between team members, resulting in a shared mental model [9, 50] associated with better performance [54]. Checklist use may allow for efficient task delegation among team members [53]. The checklist may also provide a concrete starting point for process-development through crowdsourcing [55] (Figure 10).

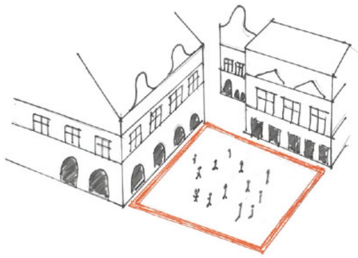


Figure 10: Checklists may improve perforamcne by creating a forum

8. Flat

Checklists can be viewed as team-based tools that flatten the traditional hierarchy where the physician is "on top"[50]. Checklists may empower all team members to voice their concerns [13]. In effect, the checklist improves performance by promoting the team, which according to CRM is the most resilient operating unit during high-risk endeavors [28] (Figure 11).

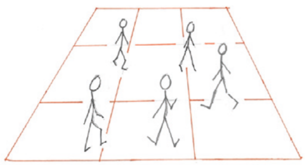


Figure 11: Checklists may improve performance by flattening the hierarchy within the team

The putative mechanisms for how checklists improve performance are summarized in Table 1.

Table 1. How checklists may work
This table provides an overview of the mechanisms through which checklists may improve performance.

Mechanism		Explanation
CONSCIOUS	Focus	Checklists direct attention towards criteria of consideration (e.g. blood glucose level for the unconscious patient)
	Facts	Checklists provide facts (e.g. the weight-based dose of tranexamic acid for pediatric hemorrhagic shock)
COMPULSION	Forcing-Function	Checklists approved by the organization make it harder to NOT do a step that is indicated according to the checklist
	aFFirmation	Checklists approved by the organization make it easier to DO a step that is indicated according to the checklist
COGNITIVE	Fewer	Checklists improve efficiency by excluding steps that do not add value and reducing cognitive workload
	Flow	Checklists improve workflow by providing a sequence in which items can be performed
CULTURAL	Forum	Checklists used by teams promote communication and a shared mental model
	Flat	Checklists used by teams flatten the hierarchy within the team

The Case for Crisis Checklists

What is a Crisis?

A crisis can be defined as a low-frequency, unexpected situation where appropriate, urgent management improves outcome. Borrowing from the taxonomy of aviation checklists, medical checklists are categorized as normal, atypical or crisis/emergency checklists. While the normal-atypical-crisis/emergency categorization may suit the airline industry and the operating room, the concepts of crisis, critical event and emergency are ambiguous in the ED. The management of a patient with cardiac arrest is arguably not a crisis, given that several patients in cardiac arrest are managed every week in a large ED. Whether a situation *feels* like a crisis depends not simply on the problem (e.g. hypoxemia) or the diagnosis (anaphylaxis) but rather on the degree of acuity, the patient's response to first-line treatments, and the experience and competence of the providers. The management of a patient with sympathetic crashing acute pulmonary edema may be a crisis for a young resident working without support and a routine occurrence for a seasoned specialist seconded by an experienced team.

In this manuscript, "medical crisis" refers to a situation where a patient requires immediate management by a health care team. Patients with medical crises are priority one patients and vice-versa. Health care teams tasked with the initial management of priority one patients are referred to as resuscitation teams.

The Case for Crisis Checklists

Crises are often stressful situations. Stress impairs focus, memory, and cognition [56-58]. Given that checklists may work by providing facts, directing focus, and reducing cognitive workload, crisis checklists may improve management and outcome. Crisis checklists may assist with the diagnostic process by providing a list of key information to acquire and time-sensitive conditions to consider. Crisis checklists may guide the treatment of presumed diagnoses by providing a list of interventions, with specific indications, contraindications, and details regarding administration. Priority one patients are usually managed by resuscitation teams, and checklists may improve teamwork by promoting communication, a shared mental model, and a flatter hierarchy.

Concerns about Checklists

Patients are not Planes

"Have you ever tried to land a septic 90-year-old?", ask McGowan in Why "Just Be Like Pilots" Just Doesn't Fly in Emergency Medicine [59]. The gist of McGowan's argument is that the context of medicine differs so much from that of aviation—where missions are pre-planned, can be aborted, and where pilots only fly one plane at a time—that tool transplantation is absurd.

Some argue specifically that checklists are not suitable for non-linear processes such as the management of a patient with sepsis [60]. A linear process is one where steps are undertaken in the same order every time, e.g. preparing a plane for take-off, or inserting a central venous catheter. For a non-linear process, the appropriate order of steps may vary, and steps may need to be revisited. As Goldhaber-Fiebert and Howard point out, "'check list' implies a linear flow to check off items, without subsequent reconsideration that may be needed in some medical situations" [8]. Burian et al report that rigid aviation-oriented checklist designs may be ineffective or disruptive in a crisis [10]. A variant of this argument is that good cooks use their flair to produce good food, and that since each patient is unique, using one-size-fits-all linear checklists—cookbook medicine—results in subpar health care.

Yet professional cooks use checklists to ensure reproducible food quality [1]. Restaurant-goers expect consistent food quality and patients expect consistent health care quality [61]. Gawande acknowledges that "Sick people are phenomenally more various than airplanes" [62]. The argument for standardization is not that all patients should be treated the same, but rather that health care personnel should strive to identify and implement optimal management pathways for patients with the same profile of relevant variables. Non-linear checklists could help physicians implement the relevant pathway. The simplest type of non-linear checklist is a branched checklist or flow-chart. Digital checklists allow for increased versatility.

Checklists are for Dummies

According to this argument, good physicians should be large repositories of accessible medical information: "our culture in medicine glorifies physicians who complete the critical task of diagnosis using their memories and disparages those who cheat by referring to a list" [63]. Yet memory is fallible, and health care personnel should not focus on displaying mental prowess but rather on getting diagnosis [63] and treatment right.

A variant of the argument is that physicians who use checklists lack the intelligence or expertise required for sound clinical judgement [10], and that checklist use erodes clinical judgement [64]. Some practitioners feel insulted by the term "cognitive aid", which they believe implies they suffer from cognitive impairment [8]. Yet a checklist is not a "how to do list for dummies" [64] designed to replace clinical judgement. Rather, checklists free up cognitive bandwidth to focus on complicated clinical decision-making [49].

Checklists as a Quick Fix

Prielipp and Birnbach argue that "the 'simplicity' of the checklist is one of its greatest strengths and weaknesses" [65]. They caution that checklists can be misused as inexpensive and verifiable solutions to adverse events and introduced into the workplace without thoughtful consideration. Too many checklists can lead to checklist fatigue, and Grigg warns that we might soon be "swimming in a sea of checklists" [49].

Checklists Can Harm

Kavanagh and Nurok point out that protocols with proven benefit in a certain context can lead to increased mortality when applied in another, a phenomenon known as protocol misalignment [66]. Delaney et al caution that physicians may feel obliged to provide unbeneficial protocol-driven interventions for fear of litigation [60]. One simulation-based study reported that teams that selected the wrong checklist underperformed teams that did not use checklists [67]. Checklists introduce another step in the delivery of health care and may disrupt the workflow [9] or be distracting when patients require immediate actions [8].

Some authors caution that poorly designed checklists may cause harm by delaying urgent initial management [50]. On January 15th 2009, United flight 1549 took off from LaGuardia Airport, New York City [68]. Two minutes after take-off, at an altitude of 2800 feet (850 meters) above ground level, both engines were disabled by a bird strike. The pilot took over control of the aircraft and started the auxiliary power unit (APU). The first officer selected the Engine Dual Failure checklist from the QRH but was unable to complete more than a third of the checklist due to the accident happening at low altitude. The NTSB noted that activation of the APU was a critical item that improved survivability while ditching in the Hudson. The NTSB pointed out that this item would not have been performed had the flight crew simply followed the checklist, and it recommended the development of a checklist for dual engine failure at low altitude [68].

These concerns highlight the importance of carefully considering the anatomical features of checklists and going through the phases of the checklist lifecycle when implementing checklists.

Checklist Anatomy & Lifecycle

In 2009, Winters et al wrote: "The science of developing checklists in health care is new. In an informal review of the literature, we did not find any standardized methodology to develop and design checklists in medicine" [69]. Ten years later, Burian et al wrote: "there is currently no comprehensive, integrated framework to guide the development and design of robust, effective medical checklists" [10]. In between, Goldhaber-Fiebert and Howard highlighted key phases in the implementation of EMs [8].

This section provides an overview of the guidance provided in the literature regarding the development and implementation of medical checklists. Burian's "lifecycle" analogy [10] suggests a rigid one-way progression from one stage to the next, whereas in reality, the stages are interconnected and can influence each other [8]. The checklist lifecycle is illustrated in Figure 12.

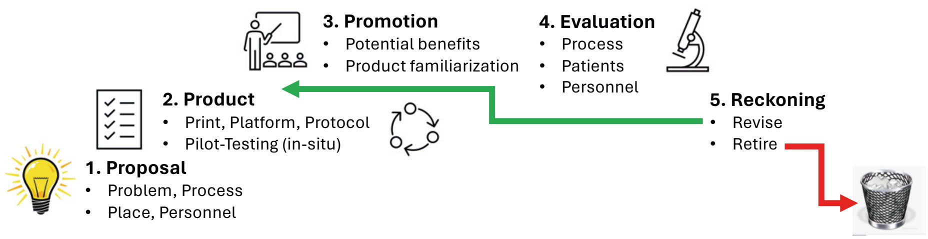


Figure 12: The checklist lifecycle

1. Proposal

Problem

The impetus to introduce a checklist into the medical workflow is usually a problem such as an adverse event. The hypothesis is that introducing a checklist will prevent the problem from reoccurring. Ideally, there should be data on the incidence of the adverse event that can be used when evaluating whether the checklist has the intended effect. For example, Pronovost et al requested data on the rates of bacteremia secondary to central venous catheter insertion prior to implementing the Keystone ICU project [1].

Process

The next step is to identify the process or processes that lead to the problem. Burian cautions against rushing to the conclusion that a checklist will prevent future adverse events [10]. Should the initiative to develop and implement a checklist remain, this step involves writing or revising a SOP for how the process should optimally be carried out.

Place

The checklist proposal should consider the physical and cultural environment in which the checklist is intended to be used [70], including the pre-existing guideline ecosystem [71].

Personnel

Checklists are distilled SOPs adapted to the user's knowledge. The proposal should specify who the intended user of the checklist is.

2. Product

Features that need to be addressed during the creation of medical checklists can be organized according to four headings: print, platform, protocol and pathways. These features are interrelated—font size will depend on type of display, checklist length will depend on ease of navigation between checklists. The checklists then need iterative improvement through pilot testing.

Print

"Print" refers here to the text and symbols featuring on the checklist.

Title: the title of checklist should be simple, memorable [64] and describe the process.

Items: each item should be actionable and specific. Long, open-ended questions may increase cognitive burden [72].

Order: the order in which items are presented should respect "engineering coherence", e.g. the checklist for obstructed tracheostomy tube should not feature oral bag-valve-mask ventilation prior to confirming that the tracheostomy cuff is deflated. The order of items in crisis checklists should take into consideration time to perform the item, time for the intervention to have an effect, and risk of deterioration if the intervention is delayed. Burian provides the example of including emergency landing instructions early on in the checklist for in-flight fire since smoke could lead to crew incapacitation and loss of control of the aircraft [73].

Structure: checklists may be linear or branched. One study reported that teams performed better using linear as opposed to branched cognitive aids [74], and one study reported that two-thirds of participants preferred linear over branched aids [11].

Layout: Wu et al recommended a design that allows for taking in all steps in one glance [9].

Text: the amount of text should be kept to a minimum. Cluttering reduces the user's ability to find required information. Yet a checklist lacking required instructions is not helpful. Paper checklists can suffer from providing both too little and too much information simultaneously [9].

Typography: sans-serif typefaces (i.e. a typeface lacking the small strokes at the ends of long strokes) are recommended. Font size should be sufficient to ensure legibility and will depend on how the checklist is displayed. Bold face and italics should be used judiciously. Font and background colors should contrast. Using capital letters only is not recommended.

Language: language should be simple and unambiguous [72]. The language should be familiar ("every day" as opposed to "per diem" [75]). Abbreviations should be clear and consistent.

Symbology: using symbols may shorten the amount of text and improve readability [9]. Symbol use should be consistent.

Length: checklists should be short [70, 76]. Bloating the checklist with items to prevent any conceivable error detracts from the usability to the product [64, 73]. Checklists are not comprehensive "how to do" lists [64].

Pathways

"Pathways" refers here to the internal organization of bundles of checklists—e.g. EMs—and the ability to access a specific checklist and navigate between checklists. Accessing checklists and navigating between them should be easy and quick. The number of required "jumps" between checklists should be limited.

Platform

"Platform" refers here to the physical aspects of checklist storage, access and display. Checklists should be easy to find and access when needed [9]. Crisis checklists should be visible, accessible and usable without impeding workflow in a crisis [8]. They may be displayed on paper, on a tablet computer, or on a large screen visible to a whole team of personnel. Checklists displayed on a screen for a team need to take into consideration the "wall-scale form factor" [9] which refers to legibility at a distance. Displaying the same checklist to the whole team promotes a shared-mental model [9]. Checklists in paper format that lack a fixed place of use can be put down and covered by other material, reducing their potential for use [9].

Protocol

"Protocol" refers here to determining when the checklist is to be used, by whom and how. Checklists may be used as Do-Confirm, Read-Do, silently or read out loud. Simulation-studies show that providing a checklist does not guaranty its use. In one study, the checklists were not used in roughly a third of cases where they were available [67]. One simulation-based study observed 28 resident physicians managing a crisis (malignant hyperthermia or obstetric cardiac arrest) [24]. Crisis checklists were available. A medical student was assigned the task of reading the steps in the checklist for the team if the team did not perform all steps. Before the reader intervened, none of the residents performed all the critical steps. After the reader intervened, all critical steps were performed. Physicians commented that it was difficult to switch back and forth between reading, managing the patient, thinking, and communicating with the team. In a study of clinical EM use, anesthesia residents reported that a barrier to EM use was "balancing your focus on the patient and trying to read the pages" and they commented on the need for "someone dedicated to just reading" the EM [77]. Yet even when a reader is assigned, checklists may not be used. In one study, teams assigned the reader function to a team member, yet 25% of these teams did not use the checklists [22].

Pilot Testing

The checklist needs to be pilot tested by intended users in the intended workplace and during the intended setting [8, 50, 71]. Problems that appear need to be corrected and the process reiterated. Involving intended users in checklist development increases buy-in. Simulations are recommended for testing cognitive aids [78, 79]. Studies that focus on whether a tool improves performance in a simulated environment can be categorized as T1-translational research [80].

3. Promotion

Potential

Introducing a new tool will affects the workflow. It is an additional step that medical personnel, already burdened with many tasks, need to shoulder. Checklists will not be used as intended unless there is a degree of buy-in. Prior to implementation, the users should be presented with the rationale for checklist use.

Product

The intended users should have the opportunity to familiarize themselves with the checklists [71]. Checklists that are not familiar are unlikely to be used properly if at all [8]. Simulations are a method to familiarize user with checklists [78, 79]. The protocol for use should be clearly presented.

4. Evaluation

Process

The first step in evaluating the implementation of a new tool is determining whether it is being used, and if so whether it is used as intended. Studies that focus on whether a tool is used in the clinical setting can be categorized as T2-translational research [80].

Patients

The purpose of checklist use is not that the checklist be used, but rather that its use improves clinically relevant outcomes. Studies that focus on whether a tool improves patient outcomes can be categorized as T3-translational research [80]. Evaluation should also seek evidence of unintended negative consequences resulting from the use of the tool.

Personnel

How use of the tool impacts on personnel's job satisfaction should also be evaluated [46].

5. Reckoning

Revision or Retirement

Based on the results, the checklist should either be improved and re-evaluated or discarded.

Evidence for Checklists

Reducing Catheter-Related Blood Stream Infections

Introduction

In 2006, the New England Journal of Medicine published an article by Pronovost et al reporting that an intervention reduced catheter-related blood stream infections by up to two-thirds 18 months after its implementation [81]. A checklist was used to ensure adherence to five evidence-based infection-control procedures: hand washing, use of full-barrier precautions during catheter insertion, skin cleaning with chlorhexidine, avoidance of the femoral site and removal of unnecessary catheters.

Discussion

Checklist-use was only one of several interventions that were part of the Keystone ICU project. Other aspects included interventions to improve communication and promote safety culture, the identification of local team-leaders partnered with local infection-control practitioners, educational campaigns, and monthly feedback about the rates of blood stream infections. The checklist was given credit for the intervention's success, yet the word "checklist" appeared only once in the article and the checklist itself was hidden in the Supplementary Appendix.

The complexity of interactions between tools, teams, tasks and tapestry makes it impossible to ascertain how much the checklist itself deserves credit for the reduction in blood stream infections. Arguably, the credit for the reduction in blood stream infections is mainly due to the implementation of a change in work culture. As Bosk, Pronovost and colleagues write, "How support was mobilized for coordinating work around infection control is the real story of the Keystone ICU project" [82].

It is noteworthy that nurses were empowered to stop physicians from inserting catheters if the physicians had not washed their hands first [82]. Nurses were essentially empowered to be forcing functions: you can't get your cash from the automated teller machine unless you retrieve your debit card first.

WHO Surgical Safety Checklist

Introduction

The WHO Surgical Safety Checklist (WHO SSC) is the poster child for the potential of medical checklists. The checklist was initially trialed in eight hospitals in different cities (New Delhi, India; Toronto, Canada; Amman, Jordan; Manila, Philippines; Auckland, New Zealand; London, England; Ifakara, Tanzania; Seattle, United States). Mortality and complication rates were documented prior to WHO SSC implementation and within one year after implementation. Both were reduced by roughly 40% following introduction of the WHO SSC [83]. The WHO SSC has since been implemented in 70% of countries [84]. A meta-meta-analysis including a third of a million patients reported that WHO SSC implementation was associated with decreased mortality from 1.0% to 0.8% [84].

Discussion

Detractors of the WHO SSC point to the absence of correlation between compliance with the WHO SCC and reductions in mortality and complications in the original study [52]. A study reported that the introduction of the WHO SSC in 133 surgical hospitals in Ontario, Canada did not result in reductions in mortality or complications [85]. Yet this study focused only on the first three months after the implementation of the checklist and mortality rates were low given that operations included outpatient surgeries [86].

Some conclude that adoption of the WHO SCC selects for hospitals or teams that are prone to improvement: the "public success of surgical safety checklists is a triumph of selection bias over rigorous implementation science" [86]. The authors of the original study acknowledge that many factors may account for the results found in the study, including changes in systems (e.g. location of antibiotics) and changes in practices (e.g. preoperative briefings and postoperative debriefings) [83]. They point out, for example, that the checklist was intentionally designed to improve team-communication. They argue that, regardless of the mechanism, introduction of the checklist along with implementation support "is among the most powerful tools for improving the safety of surgical care introduced in recent years" [86].

Reader and Conflict

In the first edition of the WHO SCC implementation manual, it states that a single person—the checklist coordinator—should be assigned the function of filling out the checklist [87]. This person has essentially a reader function. The checklist coordinator is as a rule the circulating nurse.

Furthermore, it states that the checklist coordinator "can and should prevent the team from progressing to the next phase of the operation until each step is satisfactorily addressed." As for the Keystone ICU project, the circulating nurse is empowered to be a forcing function (Figure 13). The operating surgeon no longer has full control over the workflow in the operating room. The implementation manual warns that the flattening of the hierarchy can be disruptive: "The coordinator . . . may alienate or irritate other team members. Therefore, hospitals must carefully consider which staff member is most suitable for this role" [87].

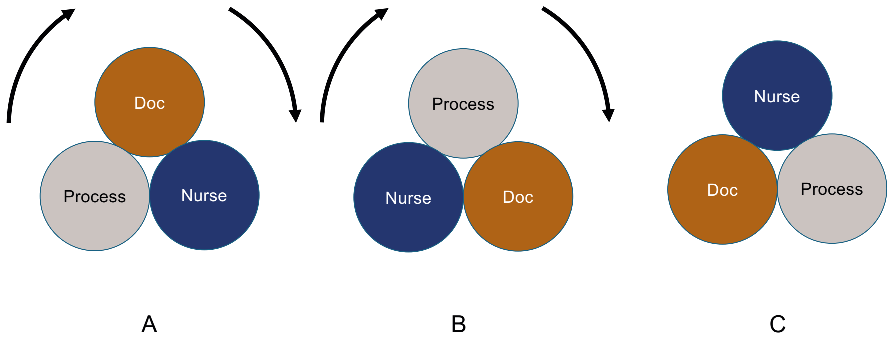


Figure 13: Revolutions in work culture
The Keystone ICU project and the WHO SSC empower a nurse to prevent a physician from proceeding with the procedure unless items in the checklist have been completed. The physician is no longer in full control over the workflow (A). When the change in work culture has been successfully implemented, physicians and nurses are partners in carrying out the process according to the SOP (B). One type of unsuccessful implementation results in the perception that the nurse is throttling the workflow (C).

Crisis Checklist Studies in the Simulation Center

Clinical simulation has emerged as a valuable modality to study processes and interventions in health care [88]. Given that crises are low-frequency, high-stakes events that occur at unpredictable times, simulations have been the main modality to study whether crisis checklists improve team performance. This section summarizes and discusses the findings from five simulation-based trials where teams were randomized to manage several medical crises with or without checklist access [2, 11, 12, 22, 67].

Setting & Participants

All five studies were performed in simulation centers. Participants for three of the studies were recruited on a voluntary basis [11, 12, 22]. In one study, participants had enrolled in a critical care course. In the fifth study, some of the participants were recruited randomly among personnel scheduled to work that day [2]. In one study, participants were relatively inexperienced (medical students with ≥ 2 years' experience) [12]. Some of the teams were composed exclusively of physicians [11, 67].

Processes and Checklists

The processes targeted in the studies consisted of the management of cardiac syndromes (e.g. cardiac arrest with non-shockable rhythm), suspected diagnoses (e.g. anaphylaxis, pulmonary embolism), and general resuscitation (e.g. of a newborn infant). The checklists for managing these processes were based on the medical literature, current guidelines, and expert opinion. The checklists were displayed on paper. In three of the studies, a team member was assigned to be checklist reader [12, 22, 67]; in the other two studies, there was no assigned reader [2, 11]. In three studies, the checklists had been pilot tested [7, 11, 22]; in the two other studies, there was no mention of pilot testing [12, 67].

Scenarios

Scenarios were written to test the management of the selected processes. There was no explicit mention that the scenarios were based on real cases.

Interventions and Simulations

In four of the studies, teams performed half of the stimulations with and half without checklist access [2, 11, 12, 22]. In one study, teams performed three scenarios, either all with or all without checklist access [67].

Outcomes and Observations

Most studies equated performance quality with the number of key interventions performed. One study weighted interventions on a score of 1-15 based on their perceived value [12]. In one study, the order in which interventions were performed mattered [11]. In all studies, on average, teams using checklists outperformed teams not using them. In two studies, every team performed better when they had access to checklists [2, 11].

Checklists—though available—were not used in one third of cases in one study [67] and in one fourth of cases in another [22]. When reported, there was no evidence that checklist access impeded the workflow [22].

All five studies included a questionnaire evaluating user satisfaction with checklist use (whether the checklist was deemed user-friendly, whether the participant would want to use the checklist during an actual emergency, whether the participant would want the checklist used if he or she were the patient). In all studies, participants felt that the checklists were helpful and were in favor of checklist use during clinical care.

Validity

Neither the participants, the investigators nor the assessors could be blinded to the intervention (checklist access or not). The risk that the investigators may have biased the results through co-interventions provided to groups randomized to checklist access was likely low, given that the degree of interaction between investigators and study participants during the simulations was limited. One study mentions the use of scripted verbal prompts in response to participant actions [11].

Relevance

The main outcome measure in T1 simulation-based studies is none other than adherence to the checklist itself. This is unavoidable given that the checklist is derived from a gold-standard, that the goal of the study is to determine whether checklist use improves adherence to the gold-standard, and that there is no real patient. The value of these studies is critically dependent on the clinical relevance of the scenario and the degree of evidence underpinning the items in the checklist. Let us imagine a study where the scenario involves vampires attacking an ED, that the key intervention consists of putting a pendant with cloves of garlic around the vampire's neck, and that this intervention features on the Vampire Attack checklist. The study would likely report that teams using the checklist performed better.

While the scenarios in the five studies were clinically relevant, the clinical relevance of some of the interventions for which points were allocated is debatable. For example, in one study, announcing who the team-leader was within 25 seconds earned 2 points [12]. In a scenario where the patient presents with agitation and an empty bottle of tricyclic antidepressant medications, teams earn one point each for ordering glucose and paracetamol levels and one point each for noting that the QRS is > 100 msec and that there is an R′> 3 mm in lead aVR [11].

Generalizability

Simulated environments may deprive participants of the usual cognitive aids they employ in clinical practice, thereby biasing the study results toward checklist-benefit. In simulated environments, participants are informed of the location of emergency equipment and medications and the study does not factor in difficulty finding and using equipment and medications that are seldom used. Furthermore, it is unclear whether personnel perform in the same way in the clinical setting—with or without checklist access—as they do in the simulated setting [2].

In the study by Arriaga et al, some of the study participants were randomly selected among personnel scheduled to work on the study day [2]. In the remaining four studies, the participants were volunteers. Volunteers for trials tend to differ from the average member of the target population [89]. Volunteers for simulation-based trials of checklists may be more predisposed to use and benefit from checklists. In addition, none of these studies recruited preexisting teams used to working together. Teams in some studies were composed according to a strict formula (e.g. one resident in intensive care, one nurse in intensive care, one additional nurse [22]). Teams in other studies were composed of a variable number of personnel with various professions (e.g. teams of 3-6 members, a mixture of nurses and physicians, on occasion all physicians [11]).

Finally, in each of these studies, the checklist was a novel tool for the participants. All of these factors impact on the generalizability of the results. Table 2 summarizes the salient features of the five studies.

Table 2. Simulation-based studies of crisis checklists
This table presents aspects of five simulation-based randomized controlled trials of crisis checklists.

	Arriaga et al 2013	Just et al 2015	Hall et al 2020	Knoche et al 2021	Sellman et al 2022
Simulated setting	Operating room	Intensive care unit	ED Resuscitation room	ED Resuscitation room	ED Resuscitation room
Number of teams	17	16	21	6	80
Team composition	Anesthesia staff (attending physicians, residents, and certified registered nurse anesthetists), operating-room nurses, surgical technologists	1 intensive care resident and 2 nurses	3-6 members, nurses or physicians	4 medical students in year ≥ 2	3-6 physicians (most 2nd-4th year of residency)
Processes	1. Anaphylaxis 2. Unstable tachycardia 3. Unexplained hypotension and hypoxemia followed by unstable bradycardia 4. Malignant hyperthermia 5. Asystolic cardiac arrest 6. Hemorrhage followed by ventricular fibrillation	1. Unstable bradycardia 2. Obstructed tracheostomy 3. Pulmonary embolism 4. Status epilepticus	1. Infant resuscitation 2. Status epilepticus child 3. Adult cardiac arrest ventricular tachycardia 4. Adult tricyclic antidepressant poisoning	1. Cardiac arrest shockable 2. Cardiac arrest non-shockable 3. Unstable tachycardia 4. Unstable bradycardia	1. Myocardial infarction deteriorating into ventricular fibrillation 2. Hemodynamic unstable ventricular tachycardia 3. Bradycardia deteriorating into asystole caused by hyperkalemia
Checklist platform	Booklet with 12 checklists	Manual with 22 checklists	Handbook with 27 checklists	Folder with 4 checklists	Folder with 10 checklists
Scenarios per team	3 with checklists AND 3 without	2 with checklists AND 2 without	2 with checklists AND 2 without	2 with checklists AND 2 without	3 with checklists OR 3 without
Interventions performed without vs with checklist	77% vs 94% $p < 0.001$	7 vs 9 $p < 0.05$	61% vs 82% $p < 0.001$	56% vs 82% $p < 0.01$	40% vs 57% $p < 0.05$

Crisis Checklist Studies in the Clinical Setting

The number of studies evaluating the use of EMs in the clinical setting is so far limited. In one study, a survey was electronically distributed to 74 anesthesia residents at one institution (Stanford Hospital) 15 months after clinical implementation of an EM [77]. Forty-two residents answered the survey questions. Roughly half of the respondents reported using the EM since its implementation and 80% of those reported that EM use had improved team-management of the patient (20% reported that the EM had a neutral effect on performance).

An adapted version of the survey was used in another study of EM use in the clinical setting [90]. The survey was sent to nine hospitals with anesthesia departments where EM simulation training had been carried out within the past six months. Two hundred and thirty anesthesiologists (40% residents, 43% attending physicians) responded to the survey. The average number of EM uses per respondent over a six-month period was two.

An interview-based study was carried out at two large academic medical centers (Stanford Hospital and Massachusetts General Hospital) where the EM had been implemented [13]. Clinical crises that had occurred over an 18-month period were identified using criterion-based sampling. Fifty-three anesthesia professionals involved in these crises were interviewed. The EM was used in roughly half the cases. Errors of omission were identified in 60% of cases thanks to EM use. EM use was credited for decreasing stress and improving teamwork. In roughly 60% of the cases where the EM was not used, personnel self-identified errors of omissions or delays. In a third of the cases where the EM was not used, the crisis was too brief for EM use.

A survey-based study investigated whether EM use was sustained six-years following EM implementation at a large academic center (Massachusetts General Hospital) [91]. The EM was used in 0.17% of surgeries one-year post implementation and in 0.21% of surgeries six-years post implementation. The EM was used in roughly 50% of cardiac arrests one year and six years post implementation. These results suggest sustained use.

These studies report EM use in two large academic centers in the United States and nine Chinese hospitals following an implementation program. While the generalizability of the findings to other centers and to EM use in settings other than the operating theater is unclear, the studies suggest that EM use can be successfully implemented and sustained, and that it improves team performance during actual crises. While the first two studies did not provide the proportion of crises where EMs were used, the results from the other two studies suggest that the EM was used during only half of the crises despite a rigorous implementation program.

Rationale

Studies I and II

At the time the research proposals for Studies I and II were submitted, there had only been one published simulation-based study of crisis checklists. The personnel involved in the study were anesthesia staff and operating room personnel, and the study was set in a simulated operating room. The degree of generalizability of the findings to other settings was unknown. In addition, the frequency and nature of impediments to emergency intervention performance that personnel in the primary care center encounter were unknown.

Study III

At the time the research proposal for Study III was submitted, there was no study reporting detailed, prospectively acquired data on EM use. In addition, there was no published T2 translational study on the use of an EM tailored to the ED.

Aims

Overall Aim

The overall aim of the thesis is to study how access to crisis checklists impacts on the performance of resuscitation teams in their actual workplace.

Study I: Specific Aims

I Determine the nature and frequency of impediments to the performance of emergency interventions in primary care centers.

II Determine whether access to crisis checklists impacts on the performance of resuscitation teams in primary care centers.

Study II: Specific Aims

I Determine whether use of crisis checklists impacts on the performance of resuscitation teams in the resuscitation rooms of EDs.

Study III: Specific Aims

I Systematically study how an EM is used by resuscitation teams during the management of unselected, consecutive priority one patients in one ED during a six-month period.

II Evaluate the clinical value of interventions performed thanks to EM use during the management of priority one patients in one ED.

Crisis Checklists in the Primary Care Center: Multicenter Simulation-Based Randomized Controlled Trial (Paper I)

Methods

Setting & Participants

Setting

The study was performed in primary care centers in Southern Sweden that had requested in-situ simulation-based training in medical crisis management.

Participants

Study participants consisted of nurses, nursing assistants, physicians and other personnel working at the primary care centers where the study was performed.

Processes & Checklists

Processes

The first target process was the generic initial management of a patient whose condition has suddenly deteriorated. The goals of this process are to identify serious physiological abnormalities where acute interventions may impact on morbidity and mortality and carry out these interventions.

The second target process was the initial management of a patient with anaphylaxis. In severe cases, patients with anaphylaxis can rapidly deteriorate and urgent administration of adrenalin can reduce the risk of fatal outcome [92, 93].

The third target process was the initial management of a patient with cardiac arrest in the primary care setting. Time to chest compressions and defibrillation impacts on survival [94].

Print

Three checklists were developed—one for each of the above processes. The first checklist—ABCD—was a generic resuscitation algorithm adapted to the primary care setting and organized to identify cardiac arrest, open the airway, supply supplemental oxygen, ventilate, provide bronchodilators, deliver an intravenous bolus of crystalloid and administer glucose according to specific indications (Checklist 1-1). The algorithm was based on the generic resuscitation algorithm developed by the Swedish Society for Emergency Medicine and used during the Swedish specialist examination in Emergency Medicine [95].

The second checklist—Anaphylaxis—consisted of specific measures for managing this condition (Checklist 1-2). The checklist includes first-line therapy (adrenalin intramuscular), push-dose intravenous adrenalin if the patient fails to respond, and it refers to the Cardiac Arrest checklist if the patient becomes unresponsive and stops breathing. The content of the checklist was based on European Resuscitation Council guidelines [96].

ABCD

Unstable patient

READ ALOUD:

1. **Have we called for help?**
2. **Gloves**
3. **Is the patient unconscious? Is the patient breathing?**
   Unconscious + not breathing: see CARDIAC ARREST
4. **Limit neck movements if trauma to the head**
5. **Move the jaw foreword if snoring breathing sounds**
6. **Give 10 L oxygen via mask if oxygen saturation < 95%**
7. **Ventilate (pocket mask) if respiratory rate < 8**
8. **Give bronchodilators if obstructive airway sounds**
9. **Give Ringer-Acetate IV if weak pulse, blood pressure < 100**
10. **Give Glucose 300 mg/ml at least 20 ml IV if glucose < 4**

ANAPHYLAXIS

Rash/itch + short of breath/unwell

READ ALOUD:

1. **Have we called for help?**
2. **Gloves**
3. **Give Adrenalin 1 mg/ml 0.3 ml IM or**
   Adrenalin auto-injector in the thigh
   Adrenalin IM repeat dose every 3:e min as needed
4. **Give 10 L oxygen via mask**
5. **Give Ringer-Acetate IV**
6. **If life-threat: give Adrenalin 0.1 mg/ml 1 ml IV**
   Life-threat: no pulse or decreased level of consciousness
7. **Is the patient conscious? Is the patient breathing?**
   Unconscious + not breathing: see CARDIAC ARREST

Checklists 1-1 and 1-2: Generic resuscitation checklist (ABCD) and Anaphylaxis checklist for the primary care setting

The third checklist—Cardiac Arrest—dealt with the initial management of cardiac arrest and included chest compressions, ventilation, rhythm analysis, and either defibrillation or the administration of 1 mg of adrenalin intravenously (Checklist 1-3). The checklist focused on the first few minutes of management and was based on European Resuscitation Council guidelines [97]. The checklist did not feature the administration of amiodarone given that this medication is not routinely available in the primary care setting.

Linear checklists were used. Each item was actionable and in boldface. Text was kept to a minimum. A sans sérif font (Frutiger) was used. Medication doses were highlighted with a yellow background. The item numbers were in red font.

CARDIAC ARREST

Unconscious + not breathing

READ ALOUD:

1. **Call 112**
2. **Gloves**
3. **Give chest compressions**
   Rate: 100/min. Depth: 5 cm
4. **Ventilate with pocket mask**
   30 compressions : 2 ventilations
5. **Start the defibrillator and apply electrodes**
6. → **If defibrillation recommended: push on the button**
   → **If defibrillation NOT recommended & patient pulseless: give Adrenalin 0.1 mg/ml 10 ml IV bolus**
   Adrenalin ordered by physician, repeat every 4th
7. **Continue chest compressions / ventilations for 2 min**

Checklist 1-3: Cardiac arrest checklist for the primary care setting

Platform

The ABCD checklist was printed on a 105 x 70 cm (41 x 28 inch) poster in portrait format. The Anaphylaxis and Cardiac Arrest checklists were printed side by side on a 70 x 105 cm (28 x 41 inch) poster in landscape format. The checklists were also printed back-to-back on a 28 x 42 cm (11 x 17 inch) rigid board.

Pathways

The ABCD checklist and the Anaphylaxis checklist directed to the Cardiac Arrest checklist should the patient become unconscious and stop breathing.

Protocol

The condition for implementing the checklist was specified under the checklist's title, namely "Unstable patient" for the ABCD checklist, "Rash/itch + short of breath/unwell" for the Anaphylaxis checklist, and "Unconscious + not breathing" for the Cardiac Arrest checklist. The checklists were intended to be read out loud for the whole team, and this message was conveyed through the words READ ALOUD highlighted in extra-large red font at the top of each checklist. An assigned reader was not specified. Whether the checklist was intended to be used as Read-Do or Do-Confirm was not specified.

Pilot Testing

The checklists were developed iteratively by a group of nurses and physicians who had experience with emergency simulation training in the primary care setting. No pilot testing of the checklists was performed.

Scenarios

The first scenario focused on the generic initial management of a patient whose condition has suddenly deteriorated (Scenario 1-1). The second scenario focused on the initial management of a patient with anaphylaxis who deteriorates and develops cardiac arrest due to a combination of hypoxemia and hypotension (Scenario 1-2).

Scenario 1-1: Hypoglycemia scenario

Team members receive the following introduction: "The patient is an unidentified woman in her 50s who has become unconscious. You have no background information about the patient. The patient came into the primary care center and registered. She was in the waiting room and reportedly appeared increasingly drowsy. Suddenly she had a seizure and fell to the floor. You and the secretary have placed her on a gurney and brought her into this room. She has stopped convulsing."

Clinical Information	Emergency Interventions
• A: snoring airway sounds • B: SpO2 89%, RR 6, normal breath sounds on lung auscultation • C: weak radial pulse, SBP 85, HR 110 • D: unconscious, pupils equal and normal size, withdraws extremities to pain • E: pale, diaphoretic, 36.2°C (97.2°F) • Bedside tests: capillary glucose 0.9 mmol/L (16 mg/dl)	• Chin-lift or jaw-thrust • Supplemental oxygen • Mask ventilation • Crystalloid 500 ml IV bolus • Glucose 300 mg/ml ≥ 20 ml IV or Glucagon 1 mg IM

Scenario 1-2: Anaphylaxis-arrest scenario

Team members receive the following introduction: "You are here in the room with a 25-year-old woman, Anna, who has just been stung by a wasp. The patient was stung by a wasp a year ago in the arm. Back then, she developed a large local reaction. She suffers from panic attacks but is otherwise healthy. The patient was eating an ice cream outside the health center. She was stung by a wasp on the outside of her neck. She feels worried and has rushed into the health center." Despite therapy, the patient becomes unconscious, stops breathing and is pulseless. The EKG reveals a regular tachycardia with HR 130 and narrow QRS-complexes.

Clinical Information	Emergency Interventions
Initial state: • A: swollen tongue, develops stridor, vomits • B: SpO2 93%, RR 40, inspiratory ronchi on lung auscultation • C: no radial pulse, SBP 70, HR 130	• Adrenalin 0.3-0.5 mg IM • Supplemental oxygen ≥ 10 L/min via mask • Crystalloid IV bolus • Chest compressions upon cardiac arrest • Adrenalin 1 mg IV push upon cardiac arrest

Interventions & Simulations

Introductory Lecture

The study was carried out within the context of in-situ simulation-based training in medical crisis management. All personnel listened to a one-hour lecture that covered the generic management of a critically ill patient in the primary care setting, the initial management of anaphylaxis and cardiac arrest, the recommended doses of glucose and adrenalin, and non-technical skills such as the importance of an assigned team-leader and closed-loop communication. The lecture concluded with a couple of slides presenting the study's purpose and methods.

Enrolment and Randomization

The participants were enjoined to enroll in the study and sign a written consent form. If all or all but one of the personnel consented to participate in the study, the group was randomized to checklist access versus no checklist access according to a previously generated random sequence. Simple randomization was used. If two or more personnel did not consent to enroll in the study, participants received simulation-based training without being included in the study.

Simulations

Simulations were performed in the room in the primary care center dedicated to the resuscitation of critical patients. If the participants had been randomized to checklist access, the checklists were mounted on the wall and the checklist board was placed on the crash cart that was to be used. Participants were divided up into two teams, ensuring the presence of at least one physician and one nurse in each team and striving for equal participant numbers in each team. The first team carried out the hypoglycemia scenario while the second team observed. Debriefing followed, including discussing medical management, teamwork, and hands-on training regarding equipment use. The second team then carried out the anaphylaxis-arrest scenario followed by additional debriefing. Both teams managed their cases either with or without checklist access. The scenario-leaders followed a predetermined script and were prohibited from enjoining teams randomized to checklist access to use the checklists.

Performance was recorded using two videos arranged at right angles to each other. Given that identifying and managing each of the five key interventions was an important learning objective, we did not interrupt simulations after a fixed time had elapsed. Instead, simulations were terminated after all five interventions had been carried out or under two circumstances: when the team had "jumped" over one intervention and the "patient" had responded to the final intervention and recovered; or when the team had been "stuck" for several minutes and appeared to have given up on further progression.

Exclusions

If the number of team members had dwindled to three or less by the time the second scenario was performed, the team was excluded from the study and one investigator played the role of a nurse.

Questionnaire

Following the second debriefing, personnel randomized to checklist access filled out a questionnaire regarding the value of the checklists. The questions were based on those used in the simulation-based trial of surgical crisis checklists [2].

Observations, Outcomes & Statistics

Impediments to Performance of Emergency Interventions

Impediments to performance of emergency interventions were categorized according to whether the personnel did not consider the intervention at all or whether consideration of the intervention was delayed; whether the personnel had difficulty finding the equipment or medication; whether the personnel had difficulty using the equipment; and whether the wrong dose of medication was administered. Audio video footage was used to note when interventions were suggested by personnel, when personnel demonstrated or voiced difficulty in finding or using the equipment, and when wrong medication doses were administered. Descriptive statistics were used for the analysis.

Number of Interventions Performed

The emergency interventions to be performed during the simulations (Scenario 1-1 and Scenario 1-2) derive from application of the checklists to the clinical information provided. We used as one outcome measure of checklist impact the total number of interventions performed during the simulation. Sample size calculation was based on the results of simulations performed without checklist access in the simulation-based trial of surgical crisis checklists [2]. We assumed that the mean percentage of key interventions performed without checklist access would be 70% and that the standard deviations in groups with ($\sigma1$) and without ($\sigma0$) checklist access would be 30%. To detect a clinically significant increase in the performance of key interventions ($\mu1 - \mu0$) of 20% with a type 1 error risk of 0.05 ($v = 1.96$) and a power of 80% ($u = 0.84$), we calculated that a minimum of 35 simulations with and 35 simulations without checklist access were required using the following equation [98]:

$$\text{Minimal sample size in each group} = (u + v)^2\,(\sigma1^2 + \sigma0^2) / (\mu1 - \mu0)^2$$

Given the uncertainty in being able to fully carry out each simulation, we aimed for 50 simulations with and 50 simulations without checklist access. Since the input variable was binary (checklist access), the output variable was ordinal (number of interventions) and the observations were independent (separate teams), we analyzed the data using the Chi-square test for trend.

Time to Performance of Emergency Interventions

Since we strove to have teams perform every intervention for educational purposes, we also used time to performance of key interventions as an outcome measure. If the intervention was not performed, we replaced the missing value by the time at which the simulation was terminated or, for the first three interventions in the anaphylaxis-arrest scenario, the time at which cardiac arrest occurred. Given a binary input variable (checklist access) and a quantitative output variable (time to performance) with an assumed non-normal distribution from separate teams (independent observations), we analyzed the association between checklist access and time to performance with the Mann-Whitney *U*-test. No adjustment was made for multiple testing.

Interrater Reliability

One investigator analyzed all simulations. A second investigator analyzed time to performance of emergency interventions from a random sample of 10 hypoglycemia simulations and 10 anaphylaxis-arrest simulations (total of 100 emergency interventions). Interrater reliability for whether the intervention was performed or not was assessed using a kappa statistic [98] and disagreements resolved by re-reviewing the videos. Discrepancies in recorded times upon intervention performance were also noted.

Questionnaire

Descriptive statistics were used to analyze the answers to the questionnaire.

Ethical Considerations

Enrolment

Subjecting personnel to simulations with an unusual degree of acuity in their own workplace while video recording them can be experienced as intrusive at the least, and harmful at the worst. We surmised that many personnel would not consent to participate in the study without a clear understanding of its purpose and methods and guaranties that personal data would be safeguarded. Our enrolment strategy took this assumption into consideration.

Each primary care center was informed that we would seek to combine the educational session with a study of crisis checklists pending personnel consent on the day of the educational session. The purpose of the study was presented at the end of introductory lecture, where we highlighted the challenges of resuscitation in the primary care center, the promise of the checklists and the need for objective data to justify promoting its use. We informed potential participants that the simulations would be videotaped, that the recordings and signed consent forms would be stored in a locked facility at Practicum Clinical Skills Centre, and that the recordings would be destroyed after 10 years. Potential participants were informed that analysis would be carried out at the team-level without reference to the identity of the primary care center and that individual names would not be recorded.

Potential participants then had the option to refuse to participate in the study. We recognize that participants did not have much reflection time, but we believe that our enrolment strategy is ethically justifiable.

Exclusion

The study was "piggybacked" on simulation-based training that had been requested by the primary care center. We sought to strike a balance between our educational assignment and the potential value—for patients and medical personnel—of being able to carry out the study. We decided that:

- should one team member refuse to participate, he or she would be an observer for both scenarios.
- should two or more personnel opt out from participation, all personnel would carry out the simulations outside of the scope of the study.

We recognize that lone participants who refused to enroll were deprived of active involvement in simulation-training, but we believe that our exclusion strategy is ethically justifiable.

Ethics Approval

The study was approved by the Regional Ethics Review Board of Lund (Dnr 2013/289).

Results

Settings, Participants & Simulations

Primary Care Centers

The study was carried out in 22 primary care centers from across Skåne between January 2014 and June 2016: Vårdcentralen Rosengården, Malmö; Vårdcentralen Lomma; Vårdcentralen Kärråkra, Eslöv; Vårdcentralen Påarp-Mörarp; Vårdcentralen Centrum, Landskrona; Vårdcentralen Bokskogen; Vårdcentralen

Staffanstorp; Vårdcentralen Löddeköpinge; Läkarhuset Roslunda, Ängelholm; Vårdcentralen Tåbelund, Eslöv; Vårdcentralen Linero Östra Torn, Lund; Vårdcentralen Sjöcrona, Höganäs; Helsa Vårdcentral, Bromölla; Vårdcentralen Dalby; Vårdcentralen Gullviksborg, Malmö; Vårdcentralen Lunden, Malmö; Vårdcentralen Råå, Helsingborg; Läkargruppen Munka-Ljungby; Helsa Vårdcentral, Lönsboda; Vårdcentralen Osby; Brahehälsan, Eslöv; Vårdcentralen Södertull, Lund.

Participants

A total of 347 personnel took part in the study. Professions and years of experience are presented in Table 3. There were no significant differences in team characteristics between those randomized to checklist access versus no access.

Table 3. Professional characteristics of participants in Study I

This table presents the professions and years of experience of the personnel that participated in Study I.

Profession	Participants (n=347)	Years of experience				
		<1	1-5	6-10	11-15	> 15
Nurse or nursing student	162	8	11	27	19	97
Nursing assistant	55	2	3	4	5	41
Specialist physician	92	1	16	16	20	39
Resident	36	5	27	4	0	0
Medical student	1	1	0	0	0	0
Social worker	1	1	0	0	0	0

Simulations

Enrolment in the study was offered during fifty-three educational sessions, i.e. to one hundred and six potential teams. In one instance, more than one personnel declined to participate, resulting in the exclusion of two teams. The remaining 104 teams were randomized to checklist access (48) versus no checklist access (56). In two instances, the number of participants had dwindled to three by the time the anaphylaxis-arrest scenario was performed, resulting in the exclusion the two simulations. In one instance, one video camera malfunctioned, and the video footage from the other was insufficient to assess when the emergency interventions were performed, resulting in the exclusion of two additional simulations. The final analysis focused on one hundred simulations: 51 hypoglycemia simulations (23 with and 28 without checklist access) and 49 anaphylaxis-arrest simulations (22 with and 27 without checklist access) (Figure 14). The total duration of analyzed video footage was 18.5 hours.

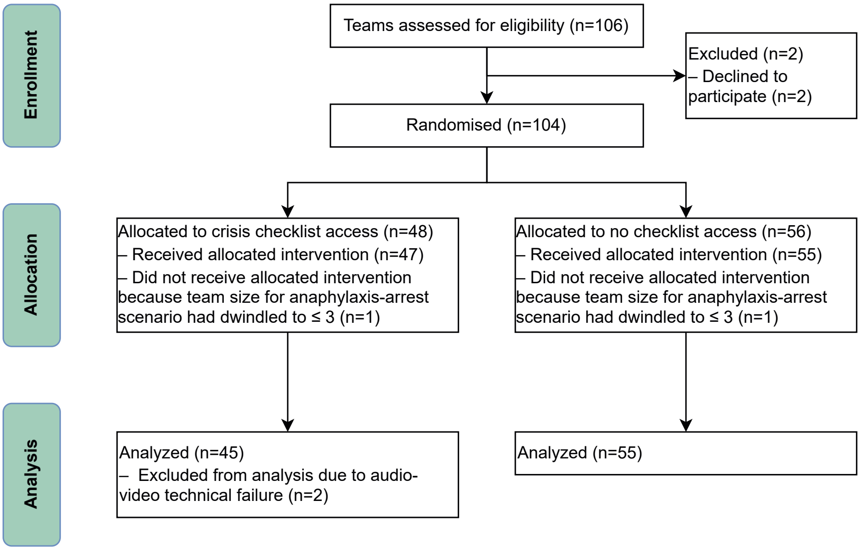


Figure 14: CONSORT flow diagram for Study I

Observations & Outcomes

Impediments to Performance of Emergency Interventions

Eight separate emergency interventions were to be performed during the combined simulations. The frequencies of impediments to performance are listed in Table 4. The noteworthy observations were the following:

- personnel had trouble connecting the tubing of an oxygen mask to the oxygen regulator and opening the oxygen flow during 10% of the hypoglycemia simulations.
- ventilation was not performed in the setting of bradypnea and hypoxemia in 20% of simulations.
- a crystalloid bolus was not administered in the setting of hypotension in 25% of simulations.
- hypoglycemia was not considered during the first 10 minutes of the management of a patient with unclear altered consciousness in 20% of simulations.

- personnel had trouble or were unable to find a glucose solution in 20% of simulations, and an insufficient dose was administered in 30% of simulations.
- intramuscular adrenalin could not be properly administered in two-thirds of simulations of a patient with anaphylaxis.

How the adrenalin auto-injector was used during the anaphylaxis-arrest simulation is illustrated in Figure 15.

Impact of Checklist Access on Team Performance

Fewer than five interventions were performed in roughly a third of simulations, regardless of whether the teams had checklist access. Given the absence of association between checklist access and number of interventions, no ordinal logistic regression was performed. Figure 16 illustrates the timing of intervention performance during the simulations of the hypoglycemia scenario. Figure 17 illustrates the timing of intervention performance during the simulations of the anaphylaxis/arrest scenario. When comparing times to performance of individual interventions between teams with and without checklist access, median time to adequate delivery of glucose or glucagon was shorter in the group randomized to checklist access (632 sec) as opposed to without (756 sec) and associated with a p-value of 0.03.

Table 4. Impediments to performance of emergency interventions

This table provides the frequencies of impediments to the performance of emergency interventions according to whether the personnel did not consider the intervention, had difficulty finding or were unable to find the equipment/medicaton, had technical problems using the equipment, or administered the wrong dose. A denominator of 51 refers to the hypoglycemia simulations, 49 to the anaphylaxis-arrest simulations, and 100 to all simulations.

Intervention	Not considered	Difficulty or inability to find equipment or medication	Wrong technique or wrong administered dose
Jaw thrust	0% (0/51)	Not applicable	None noted
Supplemental oxygen	5% (5/100)	None noted	10% (5/51)
Ventilation	20% (10/51)	None noted	Technique not assessible
Crystalloid bolus	24% (24/100)	None noted	None noted
Chest compressions	22% (11/49) within 1 min of arrest	Not applicable	None noted
Glucose/glucagon	70% (36/51) within 5 min of simulation start 20% (10/51) within 10 min of simulation start	18% (9/49)	30% (14/49)
Adrenalin IM	4% (2/49)	2% (1/49) (unable to locate both auto-injector and adrenalin vial)	76% (28/37) with the auto-injector 2% (1/9) with the adrenalin vial
Adrenalin IV	8% (4/49)	2% (1/49)	24% (12/49)

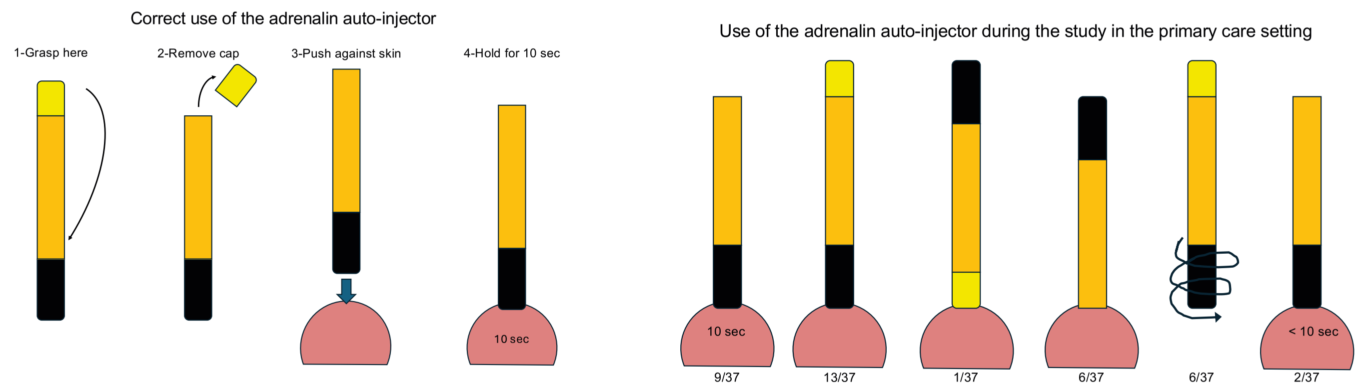


Figure 15. Use of the adrenalin auto-injector
The figure on the left demonstrates proper use of the adrenalin auto-injector. The figure on the right depicts the ways the auto-injector was used during Study I. The auto-injector was used correctly in 9 of 37 instances. In 13 instances, the cap was not removed. In one instance, the cap was not removed and the injector was used upside down. In six instances, the cap was removed and the injector used upside down, which could have led to the user injecting adrenalin into his or her thumb. In six instances, the user tried to unscrew the needle end of the injector. In two instances, the injector was not applied to the skin for 10 seconds.

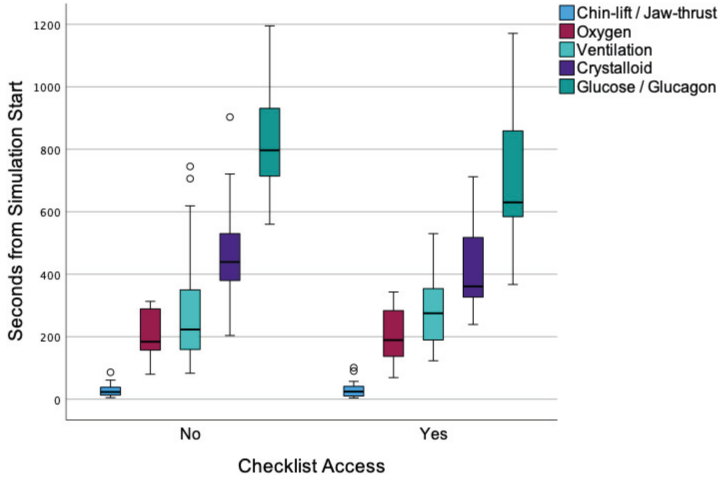


Figure 16: Timing of performance of measures during the simulations of the hypoglycemia scenario
This box plot illustrates the times in seconds from simulation start when the five indicated interventions were performed, for teams with and teams without checklist access.

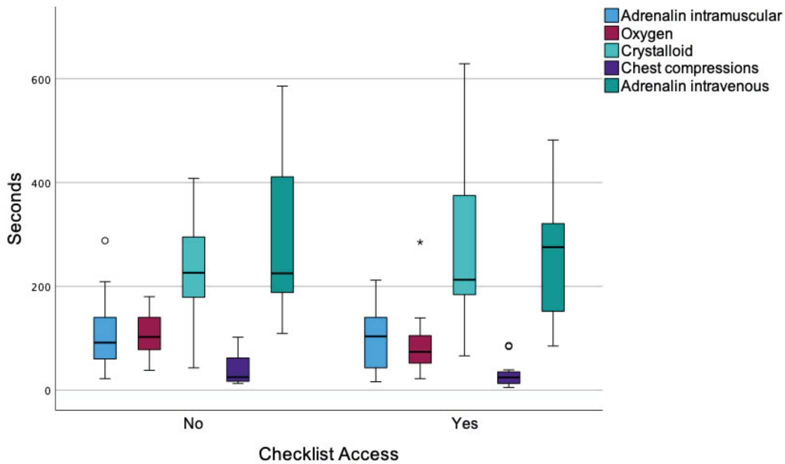


Figure 17: Timing of performance of measures during the simulations of the anaphylaxis/arrest scenario
This box plot illustrates the times in seconds from simulation start (for the administration of intramuscular adrenalin, oxygen and crystalloid) and from cardiac arrest (for chest compressions and the administration of intravenous adrenalin) when the indicated interventions were performed, for teams with and teams without checklist access.

Interrater Reliability

The kappa statistic relating to whether one hundred emergency interventions were performed or not was 0.81. Discrepancies were confined to whether ventilation was performed or not and whether oxygen and ventilation were adequately performed or not. Recorded times for intervention performed differed by less than 5 seconds in 96% of paired observations.

Subjective Checklist Evaluation

One hundred and fifty-five personnel responded to the questionnaire regarding the checklists. The results are presented in Table 5.

Table 5. Subjective evaluation of crisis checklists during Study I

One hundred and fifty-five participants were ask to grade, on a Likert scale of 1 (strongly disagree) to 6 (strongly agree), the degree to which they agreed with the statements provided in the table. Results are reported as means +/- standard deviation.

Statement	Degree of Agreement
The checklists helped me manage the scenario	4.87 ± 1.06
The checklists were user-friendly	5.24 ± 0.93
I would use the checklists if I had a similar case in real life	5.45 ± 0.77
Checklists did not hinder the acute management of the case	5.51 ± 0.80
If I were the patient, I would want the team to use the checklists	5.62 ± 0.64

Discussion

Validity

Confounders?

Teams were allocated to checklist access through randomization, the process used to ensure that proportions of known and unknown confounders are balanced between the groups [89]. Simple randomization was used, and fewer simulations were allocated to checklist access (48) than to no access (56). Permuted block randomization would have allowed for more equal numbers. However, Schulz and Grimes argue that an obsession with equal group size is cosmetic and not scientific [89].

Participants were blinded to the allocation sequence. The investigators were not blinded to the allocation sequence, but on all but one occasion did all or all but one of the participants consent to enroll in the study.

Co-Interventions or Contamination?

Neither participants nor investigators could be blinded to the intervention—checklist access. The investigators delivered the same introductory lecture to all participants. To minimize the risk of co-intervention, the investigators followed a script during the simulations and were specifically forbidden from enjoining teams randomized to checklist access to use the checklists. Teams were allocated to run both scenarios with or both without access to the checklists to prevent contamination.

For some of the centers, the study was carried out over the course of several days and it is possible that personnel participating at a later study date could have learned from their colleagues about the nature of the scenarios and the expected emergency interventions. It is unlikely, though, that they reproduced the checklists which were not handed out during the study period.

Ascertainment Bias?

The primary investigator was also the primary data assessor and analyst and was not blinded to checklist allocation. Yet data was captured and analyzed in the same manner for all groups. A random data sample was assessed independently by another study author and the kappa statistic of 0.81 suggests excellent inter-rater reliability for categorical variables [98].

Relevance

Relevant Scenarios and Interventions?

Severe hypoglycemia [99] and cardiac arrest do occur in the primary care setting [100-102]. While the incidence of anaphylaxis ranges from 0.04 to 0.5% of visits to the ED [103], the incidence of anaphylaxis requiring acute management in the primary care setting is unknown. Nevertheless, the large number of studies evaluating knowledge and competence for recognizing and managing anaphylaxis in the primary care setting suggests a broad consensus that these tasks are relevant to the setting [103]. The emergency interventions that were assessed are performable within the primary care setting.

Relevant Outcomes for Patients?

The emergency interventions studied during both scenarios are current standard of care, can be performed within the primary care center setting, and rapidly address critical physiological disorders where timely care likely impacts on patient outcome. Interventions that did not directly address physiological disorders—such as calling for help or putting on gloves—were not examined. The study focused not simply on stating that a measure was to be performed but on finding the medication/equipment and using it properly/administering the correct dose, e.g. delivering IV glucose or

IM glucagon in the setting of severe hypoglycemia. In other words, the study looked at the performance of the whole chain of steps required from identifying the need for an intervention, through finding the local equipment, and using it/performing the measure on the manikin. These aspects argue that the study outcomes were clinically relevant for potential patients.

There is a lack of data regarding the nature of the impediments to emergency care in the primary care setting, and this study provides valuable observational data in this regard. Whereas personnel performed jaw-thrust and chest compressions adequately and without delay, and had no trouble starting a crystalloid infusion, personnel wrestled with oxygen administration in 10% of cases and used the adrenalin auto-injector incorrectly in three of four cases. These observations highlight the risk of improper use of unfamiliar equipment during a crisis and suggest that a lack of technical skills is an important impediment to crisis care.

In 20% of cases, personnel had trouble or were unable to find a glucose solution, suggesting that unfamiliarity with the location of medications seldom used is an impediment to crisis care. Despite an introductory lecture highlighting the importance of checking glucose in the patient with decreased level of consciousness and covering the dose, hypoglycemia had not been considered within 10 minutes of simulation start in 20% of simulations, and an insufficient amount of glucose was administered in 30% of cases.

In theory, point-of-care checklists ought to help personnel remember to check the glucose and administer correct medication dosages. Median time to adequate delivery of glucose or glucagon was shorter in the group randomized to checklist access (632 sec) as opposed to without (756 sec). This difference was associated with a p value of 0.03 and may suggest that checklists improve the delivery of correct medication doses. However, the median times in both groups exceed 10 minutes and the difference between the times is of unclear clinical significance. In addition, no adjustment was made for multiple testing, and it is possible that the difference obtained was due to chance alone.

The lack of impact of checklist access on time to administration of glucose and correct dosage of glucose and IV adrenalin suggests that the checklists were not used as intended. Other simulation-based studies have reported that provision of a checklist immediately prior to simulation of a crisis does not guaranty its use [22, 67]. Having an assigned reader might have improved the study results. The study suggests that personnel are disinclined to use an unfamiliar tool during a crisis, and that the simple provision of a checklist on a wall is not sufficient to improve acute care. There was no evidence that checklist access impeded performance and personnel responded that they would want to use the checklists if they had to management of critical patient.

Relevant Outcomes for Personnel?

It is valuable for personnel in primary care centers to know that their colleagues have wrestled with certain technical skills such as the use of the adrenalin auto-injector. The study also suggests that primary care personnel are positively inclined to crisis checklist access.

Generalizability

Setting

A strength of the study was that it was performed in 22 actual primary care centers, where personnel used their own equipment and had access to their usual cognitive aids. These aspects increase the generalizability of the study results to other primary care settings, at least in Sweden.

Personnel

Personnel involved in the study were local primary care personnel used to working with each other. Only on one occasion (two teams) did participants opt out from participating. Personnel did not volunteer individually to participate in the study and were not allocated to ad hoc teams. These study aspects increase the generalizability of the findings to other primary care personnel.

Lecture and Planned Simulation Training

All participants attended a lecture immediately prior to simulations. This lecture covered the steps included in a generic resuscitation algorithm as well as the doses of adrenalin and glucose. Participants knew that they would practice the management of critically ill patients and may have refreshed their knowledge of emergency algorithms prior to the simulations. It is dubious that a study of this magnitude—22 centers, 346 personnel—could have been conducted without a clear educational component, yet "piggybacking" the study on planned teaching and training detracts from the generalizability of the study findings to actual patient care. The lecture and planned simulation-training may well have improved the performance in all groups and biased the results towards the null hypothesis that checklist access has no impact on resuscitation team performance. Yet, one or more of the five emergency interventions were not performed in a third of all simulations. Such results underscore the limitations of lectures as a knowledge-translation tool.

Tasks

The ABCD resuscitation checklist was designed to be of generic value and applicable to all patient with sudden deterioration (e.g. obtundation from intracranial hemorrhage or poisoning) and not exclusively for patients with hypoglycemia. The initial management of non-traumatic cardiac arrest follows the same algorithm regardless of etiology. As such, the checklists studied were generalizable to medical crises other than the ones studied.

Tool

The lack of assigned reader likely hampered checklist use, yet readership assignation does not guaranty checklist used [22]. Readership assignation would arguably have detracted from the generalizability of the study results. Had the simple provision of checklists on a wall shown an impact on crisis management, a simple intervention could have been recommended. Instead, the study results suggest that simply providing checklists is not sufficient to improve crisis management, and that the threshold for using a new tool in a stressful situation should not be underestimated. As Goldhaber-Fiebert and Howard pointed out, "the mere presence of cognitive aids does not ensure that they will be used or used appropriately" [8].

Crisis Checklists in the Resuscitation Room: Pilot Study

Methods

Setting & Participants

Setting
Study II was designed to be performed in the resuscitation rooms of actual EDs.

Participants
The participants in study II were those composing actual resuscitation teams working during actual clinical shifts.

Processes & Checklists

Processes
The general process of interest was the initial management of a critical patient with a non-traumatic diagnosis not responding to first-line medical therapy. The diagnoses selected were anaphylaxis, hemorrhagic shock from an upper gastrointestinal bleed, inferior ST-elevation myocardial infarction, calcium-channel blocker poisoning, sodium-channel blocker poisoning, status epilepticus, severe sepsis and increased intracranial pressure. The focus was on the treatment of a specific diagnosis and not on the diagnostic process.

Print
Checklists were developed for each of the eight diagnoses listed above. The actions and investigations in the checklist were based on a review of the medical literature and input from specialists in Emergency Medicine and nurses with experience working in the resuscitation room. The order of the items followed as a rule the ABCD sequence and whether the diagnosis-specific intervention was first-line, second-line or third line. All checklists were linear. The checklists were written in the sans sérif typeface Calibri. More advanced treatments can be given in the ED

than in the primary care setting, resulting in longer checklists than those used during Study I.

Many of the interventions had specific indications, contraindications, and risks, which led to cluttered checklists. To resolve the dilemma of having either checklists with too little information or checklists with too much clutter, two checklists were generated for each condition:

- a team-checklist, with larger font and limited specific information, designed to be displayed for the whole team (Figure 18)
- a pulpit-checklist designed to provide details regarding each treatment (Figure 19).

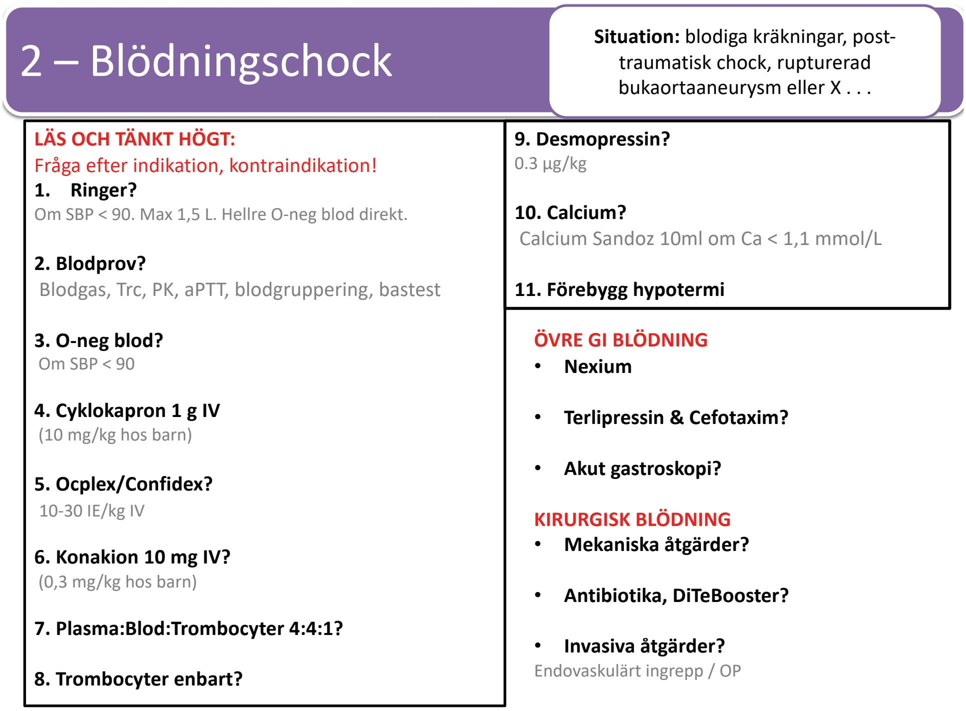


Figure 18: Team-checklist used during the pilot study
The team-checklist was designed to be displayed to the whole team.

2´ – Blödningschock

Situation: blodiga kräkningar, post-traumatisk chock, rupturerad bukaortaaneurysm eller X . . .

CHECKA AV OCH TIPSA:

1. Ringer?
- Om systoliskt blodtryck < 90 mm Hg (< 110 mm Hg vid skalltrauma). Hellre O-neg blod direkt.
- Ringer 500 ml IV (10 mg/kg hos barn), helst varm. Max 1,5 Liter.

2. Blodprov?
- Beställ "blodgas", trombocyter, PK, blodgruppering & bastest.

3. O negativ blod?
- Om systoliskt blodtryck < 90 mm Hg (< 110 mm Hg vid skalltrauma) eller Hb < 80 g/L .
- O negativ blod IV (10 mg/kg hos barn), helst varm.

4. Cyklokapron 1 g IV
- Hos alla patienter med blödningschock.
- Kontraindicerad om trauma inträffade > 3 timmar sedan.
- Cyklokapron® (Tranexamsyra) 1 g IV över 10 min (10 mg/kg hos barn).

5. Ocplex/Confidex?
- Om patienten tar Waran, Rivaroxaban (Xarelto®) eller Apixaban (Eliquis®)
- Ocplex® eller Confidex® 10-30 IE/kg IV

6. Konakion?
- Om patienten tar Waran.
- Vitamin K1 (Konakion®) 10 mg IV (0,3 mg/kg hos barn)

7. Plasma:Blod:Trombocyter 4:4:1?
- Vid kritisk blödning (> 4 enheter blod inom 1 timme) eller ≥ 2 av: SBP < 90, HF > 120, penetrerande skada, frivätska enligt ultraljud
- Prioritera trombocytinfusion. Två infarter. Helst varm.

8. Trombocyter enbart?
- Vid trombocytopeni (< 50) eller vid Trombyl, Plavix, Prasugrel, Ticagrelor. 1 påse IV

9. Desmopressin?
- Vid Trombyl eller NSAID bruk, svår leversvikt, svår njursvikt.
- Desmopressin (Octostim®) 0,3 µg/kg späd i 50 ml koksalt IV

10. Calcium?
- Vid ioniserad Calcium < 1.1 mmol/L. Calcium sjunker vid blodtransfusion.
- Calcium Sandoz® 9 mg/ml 10 ml IV över 5 min (0,3-0,5 ml/kg hos barn)

11. Förebygg hypotermi
- Hos alla med blödningschock (försämrar koagulopatin)
- Varma filtar, Bair Hugger

ÖVRE GI BLÖDNING

Nexium
- Esomeprozal (Nexium®) 80 mg IV

Terlipressin & Cefotaxim ((Claforan®)
- Vid blödande esofagusvaricer.
- Terlipressin (Glypressin®) 2 mg IV & Cefotaxim (Claforan®) 1 g IV.

Akut gastroskopi?

KIRUGISK BLÖDNING

Mekaniska åtgärder?
- Direkt tryck med kompress på blödande sår
- Tourniquet vid extremitetsblödning som inte svarar på direkt tryck
- Bäckengördel vid bäckenfraktur; kontraindicerad vid lateral / lågenergi (t ex fall) våld
- Hare-splint vid femurfraktur; kontraindicerad vid bäcken / fot fraktur.

Antibiotika, DiTeBooster?
- Ekvacillin 2 g IV vid öppen extremitetsfraktur
- Claforan 1 g vid skallfaktur
- Claforan 1 g + Flagyl 1,5 g IV vid penetrerande buktrauma
- DiTeBooster 0,5 ml IM vid sår utomhus

Invasiva åtgärder?
- Vid bäckenfraktur: angiografi/coiling eller OP (bäckenpackning)
- Vid intraabdominell / intrathorakal blödning: OP / akut thorakostomi
- Vid rupturerat bukaortaaneurysm: OP eller CT/EVAR

Figure 19: Pulpit-checklist used during the pilot study
The pulpit-checklist was designed to provide detailed information regarding the indications, contraindications and modes of administration of each treatment. The pulpit-checklist presented more information than the team-checklist but suffered from clutter.

Platform

The checklists for the team-leader were printed on A4 (21x 30 cm; 17 x 23 inches) paper and placed in a folder on the documentation pulpit and a folder on the crash cart. The checklists for the team were printed on A2 (59 x 42 cm; 16.5 x 23.4 inches) sized posters and the selected checklist hung on a movable screen placed at the foot of the bed (Figure 20).

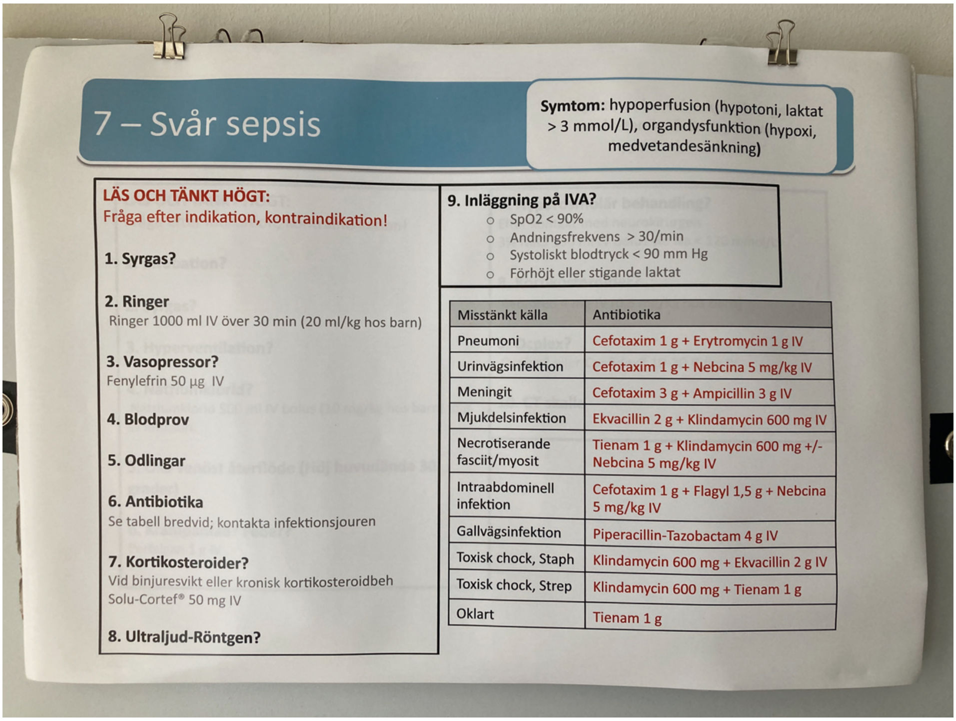


Figure 20: Team-checklist used during the pilot study in the resuscitation room
Team-checklists were printed on A2 (59 x 42 cm; 16.5 x 23.4 inches) sized posters and hung up on a movable screen. Photo by Eric Dryver.

Pathways

A menu featuring the titles of all eight checklists was printing on A2 paper and hung on a movable screen placed at the foot of the bed when teams were randomized to checklist access. Each checklist had a different background title color to aid navigation from the menu to the checklist.

Protocol

Teams were not enjoined to assign checklist readership to a specific team member.

Scenarios

Eight scenarios—one corresponding to each of the eight diagnoses—were written based on actual patient cases. Details regarding the scenarios that ended up in the actual study (Study II) are provided in another section of this manuscript.

Interventions & Simulations

Introduction

When the ED personnel in charge of patient flow deemed that the time was suitable, a resuscitation team was summoned to the resuscitation room. The team was informed of the study's goal and methodology, and that the simulation would be followed by debriefing and feedback. Teams were instructed to treat the manikin as though it were a real patient, including fetching medications to be replaced with placebo and administering the placebo to the manikin. Teams were explicitly allowed to use their usual cognitive aids.

Randomization

The randomization process is described in the Study II section of this manuscript. Participants were not asked to provide written informed consent to participate in the pilot study.

Interventions & Simulations

The introduction to the randomly chosen scenario was read to the whole team. When teams were randomized to checklist access, the checklist menu in A2 format was hung on the screen at the foot of the bed and the folders with the pulpit-checklists were placed on the pulpit and emergency cart at the start of the simulation. The investigator asked teams randomized to checklist access which checklist among the menu they wished to see and hung up the request team-checklist. Investigators were then allowed to provide clinical information upon request but not to enjoin the teams randomized to checklist access to use them. Simulations were terminated after 12 minutes or when all indicated interventions had been performed.

Debriefing

Following the simulations, all personnel took part in a debriefing focusing on medical management, teamwork and communication. The checklists were used to discuss medical management for all teams, including those not randomized to checklist access.

Questionnaire

Personnel randomized to checklist use were then asked to fill out a questionnaire regarding the checklist's perceived value and grade their agreement with statements using a 1-5 Likert scale. The statements in the questionnaire were based on the questionnaire used by Arriaga et al in their simulation-based study of surgical-crisis checklists [2].

Observations, Outcomes & Statistics

Outcomes

For each scenario, there were 7 to 11 indicated interventions in accordance with the checklist content. The outcome measures were whether and when the indicated interventions were performed. Time of performance was recorded independently by two observers. Discrepancies were resolved directly after each scenario through consensus.

Statistics

Since the input variable was binary (checklist access), the output variable was ordinal (number of interventions) and the observations were paired (each scenario with and without checklist access), we analyzed the data using the Related-Samples Wilcoxon Signed Rank Test.

Questionnaire

Descriptive statistics were used to analyze the answers to the questionnaire.

Ethical Considerations

Enrolment

Participants were informed that their names would not be recorded, and that team performance would be the main outcome measure of interest. Performance was not recorded with audio-video. Given that this was a pilot study combined with an educational debriefing, signed informed consent was deemed unnecessary.

Clinical Care

The ED personnel in charge of patient flow chose when the timing was suitable to perform the simulations and were explicitly allowed to interrupt the simulations if required.

Ethics Approval

The pilot study was carried out within the framework of Study II which had been approved by the heads of ED of Lund and by Lund's Regional Ethics Committee (Dnr 2013/858).

Results

Settings, Participants & Simulations

Emergency Department

The pilot study was carried out in the ED of Skåne's University Hospital at Lund during the months of October and November 2015.

Participants

A total of 56 personnel took part in the study. Teams consisted of three to five personnel: at least one physician (usually two, one senior and one junior), one nurse and one nursing assistant. The professions and years of experience are presented in Table 6.

Table 6. Professional characteristics of the participants in the pilot study
All three specialist physicians were specialists in Emergency Medicine. Six of the 17 residents were residents in Emergency Medicine.

Profession	Participants (n=56)	Years of experience					
		<1	1-5	6-10	11-15	> 15	Unknown
Specialist physician	3	0	1	0	1	1	0
Resident	17	3	13	1	0	0	0
Nurse	26	1	5	4	5	9	2
Nursing assistant	10	1	1	5	1	2	0

Simulations

Sixteen simulations were run between 08 AM and 12 PM. None of the participants performed the same scenario more than once.

Observations & Outcomes

The median percentage of interventions performed was 44% when teams were randomized to no checklist access and 83% when teams were randomized to checklist access ($p = 0.018$) (Figure 21). For each scenario, teams using the checklist performed as well or better than teams without checklist access.

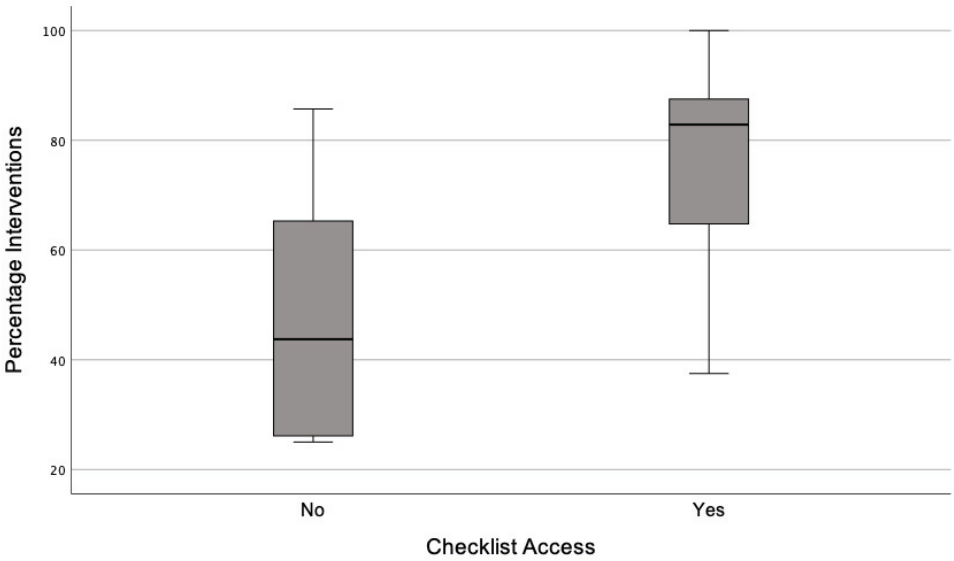


Figure 21: Percentage of interventions performed with and without checklist use
Median percentage of interventions performed was 44% when checklists were not used, and 83% when checklists were used (p = 0.018).

One simulation had to be interrupted due to the arrival of a priority one patient and it was subsequently repeated with a team composed of different personnel. In one simulation allocated to checklist access, the correct team checklist was chosen by the team, yet the physician selected the wrong pulpit-checklist and ordered treatments that were inappropriate. In several instances, the teams only used the team-checklists and did not open the folder where the pulpit-checklists were provided. Nurses had trouble locating medications that are seldom used. The results of the questionnaire are presented in Table 7.

Table 7. Subjective evaluation of crisis checklists during the pilot study
Seventy-six participants (30 physicians, 33 nurses and 13 nursing assistants) graded their agreement wtih statements in a questionnaire using a 1 (strongly disagree) to 5 (strongly agree) Likert Scale. Results are reported as means +/- standard deviation.

Statement	Degree of Agreement
The checklists helped me manage the scenario	4.08 ± 0.87
The checklists were user-friendly	4.33 ± 0.76
I would use the checklists if I had a similar case in real life	4.56 ± 0.63
Checklists did not hinder the acute management of the case	4.40 ± 0.91
If I were the patient, I would want the team to use the checklists	4.65 ± 0.59

Discussion

Validity

Confounders?

Teams were randomly allocated to scenarios with or without checklist access. The investigator was not blinded to the allocation sequence. Given that this was a pilot study, no analysis for potential confounders was carried out.

Co-Interventions or Contamination?

In theory, teams allocated to checklist access benefitted from knowing that the diagnosis was one of the eight featuring on the checklist menu. Yet the diagnosis was arguably obvious from the introduction provided for each scenario. The introductory text is provided for each scenario in the section describing the actual study (Study II).

Ascertainment Bias?

The independent observers were not blinded to the pilot study's purpose and intervention performance was not recorded with audio video footage. Audio video recording and independent outcome assessment was planned for the actual study.

Relevance

Reflections regarding the relevance of the study scenarios and interventions are provided in the section describing the actual study (Study II).

Generalizability

The pilot study showed that performing the study in-situ in a busy ED with actual resuscitation teams was feasible. The results also suggested that checklists may improve resuscitation team performance. Pilot study results were presented during a platform presentation at the European Congress in Emergency Medicine [104].

The main issue of concern that surfaced during the pilot study pertained to the use of two versions of each checklist. According to CRM, the team is the most resilient unit in a crisis [28]. In one instance, the team chose the correct team-checklist while the physician chose the wrong pulpit-checklist and ordered inappropriate interventions. We also observed that teams sometimes did not use the pulpit-checklist at all. We resolved to find a solution whereby a single checklist for each diagnosis provided all necessary information without clutter.

Crisis Checklists in the Resuscitation Room: Multicenter Simulation-Based Randomized Controlled Trial (Paper II)

Methods

Setting & Participants

Setting
The study was designed to be performed in the resuscitation rooms of several EDs.

Participants
Study participants were those composing actual resuscitation teams working during actual clinical shifts.

Processes & Checklists

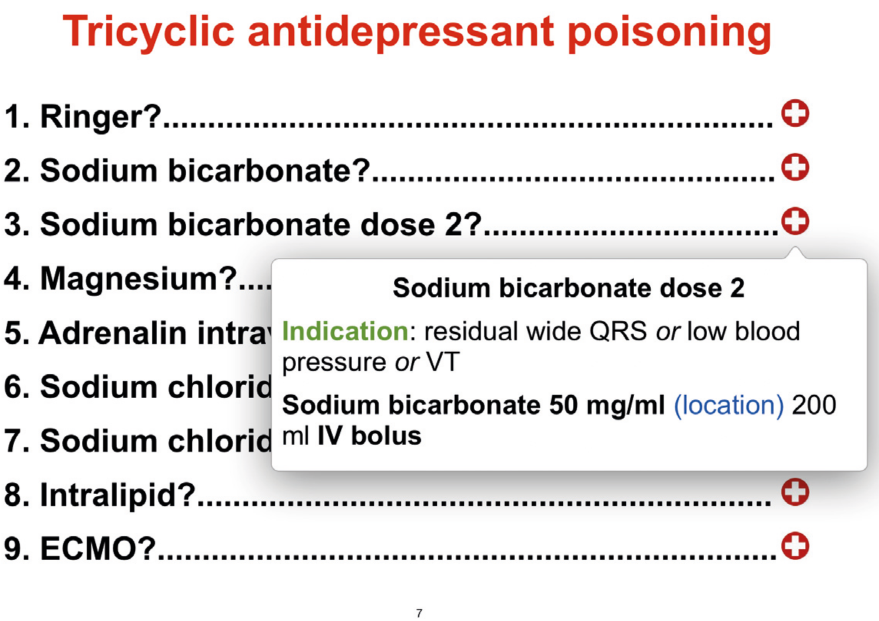
Processes
The study focused on the initial management of non-traumatic crises where several emergency interventions that can be provided in the resuscitation room of an ED are indicated. The following diagnoses were selected: anaphylaxis, status asthmaticus, upper gastrointestinal bleed, sepsis, poisoning with a calcium channel blocker, poisoning with a tricyclic antidepressant, status epilepticus, and increased intracranial pressure. We replaced the inferior ST-elevation myocardial infarction scenario used in the pilot study with a case of status asthmaticus, which had a larger number of indicated emergency interventions and centered on a breathing (B) problem.

Print
A checklist was written for the management of each of the eight conditions. Each item was actionable and based on at least two authoritative sources. Interventions

were ordered as a rule according to the ABCD sequence. First-line measures preceded second-line measures and so forth.

Patients that respond to first-line measures do not require more intensive therapy, and depending on the circumstances, some measures may be indicated for some patients and contraindicated for others. We therefore felt it necessary to provide information regarding the circumstances when each measure was indicated or contraindicated and details regarding how each measure was to be carried out. The challenge was to figure out how to provide detailed information without cluttering the checklist. The pilot study demonstrated that providing two versions of each checklist with different degrees of detail was problematic.

We stumbled across a solution in the form of the iBook Authors software. This software made it possible to display the forest of potential interventions on the left of the screen, and provide the trees of indications, contraindications and administration details for each intervention on the right of the screen using pop-over windows. A generic Study II checklist format is presented in Checklist 2-0.



Checklist 2-0: Generic checklist format used during Study II
This checklist demonstrates how the pop-over window function allows for the provision of details regarding each intervention without cluttering the checklist.

The checklists were written in the sans sérif typeface Helvetica. Text was kept to a minimum. Measures were followed by a question mark if their performance was contingent on specific circumstances. A white cross on a red circle background featured on the same line as each measure in the right margin; pressing on this icon brought forth the relevant pop-over window. Pressing on the screen outside of the pop-over window hid the window. Green font was used for the word Indication(s) and red font for the words Contraindication(s) and Risk(s). Red font was also use to highly specific items, e.g. whether adrenalin was to be administered intravenously or intramuscularly. The content of each checklist and the sources the interventions were based on is presented in Checklists 2-1 to Checklists 2-8.

Checklist 2-1: Anaphylaxis

The interventions in this checklist were based on several sources in the medical literature [105-109].

Items	Pop-Over Window Content
1. Adrenalin intramuscular	Indication: all patients Adrenalin 1 mg/ml (location) 0.5 ml intramuscular anterolateral thigh Can repeat every 5 min
2. Supine *or* lateral decubitus?	Indication: low blood pressure/feeling faint (prevents severe hypotension) Contraindication: if the patient wants to remain upright due to dyspnea Supine, lateral decubitus if nausea, left lateral decubitus if advanced pregnancy
3. Oxygen	Indication: all patients Oxygen ≥ 10 L/min via mask with reservoir
4. Ringer's acetate?	Indication: low blood pressure Ringer (location) 1000 ml IV bolus
5. Ventoline?	Indication: bronchospasm/ronchi Risk: hypokalemia Ventoline (Salbutamol, Airomir) (location) 2 mg/ml 2.5 ml (1 ampule) nebulised (can be given with patient in lateral decubitus)
6. Adrenalin intravenous?	Indication: severe symptoms despite adrenalin IM Risk: arrhythmia (EKG monitoring) Take a 10 ml syringe Draw up 1 ml of Adrenalin 0.1 mg/ml (location) Dilute with 9 ml NaCl Give 5 ml of the solution (50 microg) IV over 1 min Repeat after 3 min as needed
7. Glucagon intravenous?	Indication: severe symptoms unresponsive to adrenalin (e.g. use of beta-blocker) Risk: vomiting Glucagon 1 mg/ml (location) Inject the fluid into the vial and mix with the powder Draw up the solution using a separate syringe Inject the solution (1 ml) IV over 1 min Repeat as needed
8. Tavegyl?	Indication: itch/hives Tavegyl (Klemastin) (location) 1 mg/ml 2 ml IV
9. Betapred	Indication: all patients Betapred 4 mg/ml (location) 2 ml IV

Medications have a generic name (e.g. Tranexamsya) and one or several brand names (e.g. Cyclokapron, Statraxen). Medications are stored alphabetically in medication closets, and finding medications that are seldom used is complicated by the different names in use. The checklists featured the medication names most used and sometimes other names between parentheses. The checklists also included ED-tailored information about where to find each medication.

Checklist 2-2: Asthma exacerbation

The interventions in this checklist were based on several sources in the medical literature [110-113].

Items	Pop-Over Window Content
1. Oxygen?	Indication: SpO2 < 93% Oxygen via nasal prongs *or* oxygen mask *or* nebulizer mask with target SpO2 94-98%
2. Ventoline + Atrovent?	Indication: all Risk: hypokalemia Ventoline (Salbutamol, Airomir) 2 mg/ml (location) 2,5 ml (1 ampule) + Atrovent (Ipratropium) 0.25 mg/ml (location) 2 ml (1 ampule) nebulized Repeat immediately if no improvement
3. Adrenalin intramuscular?	Indication: severe exacerbation + can't inhale Ventoline Adrenalin 1 mg/ml (location) 0.5 ml intramuscular anterolateral thigh
4. Ketanest?	Indication: severe exacerbation + severe agitation which impairs treatment Has PVC: Ketanest (Esketamin) 5 mg/ml (location) 10 ml IV over 2 min No PVC: Ketanest (Esketamin) 25 mg/ml (location) 3 ml IM in each anterolateral thigh (total 6 ml)
5. Magnesium?	Indication: severe exacerbation unresponsive to above treatments Risks: vomiting, hypotension Magnesium (Addex) 1 mmol/ml (2.5 g/10 ml) (location) 8 ml in 100 ml NaCl IV over 20 min
6. Endotracheal intubation?	One or several of the following indicate life-threatening exacerbation: SpO2 < 92% *or* PaO2 < 8 pCO2 > 5.5 arterial *or* > 6.5 venous *or* rising Diminished breath sounds on lung auscultation Hypotension *or* arrhythmia Altered level of consciousness Call anesthesia *or* Call a Code
7. Betapred?	Indication: exacerbation that does not respond promptly to Ventoline Betapred 4 mg/ml (location) 2 ml IV

Checklist 2-3: Upper gastrointestinal bleeding

The interventions in this checklist were based on several sources in the medical literature [114-123] . Fluido is a device to warm fluids prior to intravenous administration. Konakion is vitamin K1.

Items	Pop-Over Window Content
1. Ringer's acetate?	Indication: blodtryck < 90 mm Hg Ringer (location) 500 ml IV bolus
2. Blood tests	Indication: all Bedside blood tests + Thrombocytes + INR + aPTT + Type and Cross-Match. If severe bleeding: + Fibrinogen
3. Prevent hypothermia	Indication: all Remove wet clothes Cover with blanket
4. Blood transfusion?	Indication: blood pressure < 90 mm Hg *or* Hb < 70 *or* Hb < 90 + [ongoing blood loss *or* ischemic heart disease] 0 negative blood (location) 1-2 SAG via Fluido
5. Confidex - Konakion - Praxbind?	Indication: severe bleeding in a patient taking Warfarin *or* NOAC If Warfarin, Eliquis, Xarelto, Lixiana: Ocplex *or* Confidex (location) 2000 E IV If Warfarin: Konakion (location) 10 mg IV If Pradaxa: Praxbind (location) 5 g IV over 5 min
6. Desmopressin?	Indication: severe bleeding in a patient taking Aspirin Desmopressin (Octostim) 15 mikrog/ml (location) 1 ml (50 kg) - 2 ml (100 kg) diluted in 10 ml NaCl IV over 10 min
7. Terlipressin?	Indication: liver cirrhosis + blood pressure < 100 mm Hg Terlipressin (Glypressin) (location) 2 mg IV
8. Antibiotics?	Indication: liver cirrhosis + blood pressure < 100 mm Hg Risk: allergy to antibiotic Cefotaxime (location) 1 g IV over 3 min
9. Nexium	Indication: all Nexium (Esomeprazol) (location) 80 mg IV
10. Cyklokapron?	Indication: severe bleeding Cyklokapron (Tranexamic acid, Statraxen) 100 mg/ml (location) 10 ml IV over 10 min
11. Calcium?	Ionised calcium < 1.0: Calcium gluconate 10% (location) 10 ml IV over 5 min Blood transfusion in liver disease: Calcium gluconate 10% 10 ml IV over 5 min for each SAG

Checklist 2-4: Sepsis

The interventions in this checklist were based on several sources in the medical literature [124-127].

Items	Pop-Over Window Content
1. Oxygen?	SpO2 ≤ 90%: Oxygen 10 L/min via oxygen mask SpO2 91-95%: Oxygen 3 L/min via nasal prongs
2. Ringer's acetate?	Indication: all Ringer 500 ml (location) IV bolus Repeat directly if remains hypotensive
3. Adrenalin intravenous?	Indication: SBT < 60 mm Hg Risk: arrhythmia (monitor EKG) Take a 10 ml syringe Draw up 1 ml Adrenalin 0.1 mg/ml (location) Dilute with 9 ml NaCl and mix Give 2 ml (20 mikrog) IV bolus Repeat after 3 min as needed
4. Cultures	Indication: all Blood cultures (aerobic + anaerobic) x 2 Urine culture + urine dipstick Consider cultures from suspected infectious foci (wound, nasopharynx); rapid strep-A test, urine antigen?
5. Foley Catheter?	Indication: low blood pressure *or* elevated lactate Foley for urine output (+ obtain urine for culture)
6. Antibiotics	Indication: give even if urine cannot be obtained for culture Risk: allergy to antibiotic See table (press on "Antibiotics")
7. Solu-Cortef?	Indication: known adrenal insufficiency *or* chronic corticosteroid treatment Solu-Cortef (Hydrocortisone) (location) 100 mg IV bolus
8. Targeted investigations?	Indication: suspected infectious focus where procedure is required Abscess, empyema, obstructive pyelonephritis, bowel perforation: X-ray *or* ultrasound Necrotising fasciitis: surgery- *or* orthopedic consult

Checklist 2-5: Calcium channel blocker poisoning

The interventions in this checklist were based on several sources in the medical literature [106, 128-130].

Items	Pop-Over Window Content
1. Ringer?	Indication: low blood pressure Ringer (location) 1000 ml IV bolus
2. Atropine?	Indication: bradycardia Atropine 0.5 mg/ml (location) 2 ml (1 mg) IV bolus Can repeat up to a max of 3 mg
3. Calcium?	Indication: low blood pressure Calcium gluconate 10% (location) 30 ml IV over 5 min
4. Adrenalin intravenous?	Indication: critical patient (severe hypotension *or* bradycardia) Risk: arrhythmia (monitor EKG) Take a 10 ml syringe Draw up 1 ml Adrenalin 0.1 mg/ml (location) Dilute with 9 ml NaCl and mix Give 2 ml (20 mikrog) IV bolus Repeat after 3 min as needed
5. Glucose?	Indication: critical patient (severe hypotension *or* bradycardia); given along with 6. Insulin Glucose 300 mg/ml (30%) (location) 50 ml IV bolus
6. Insulin?	Indication: critical patient (severe hypotension *or* bradycardia); given along with 5. Glucose Risk: hypokalemia Humalog *or* Actrapid *or* Novorapid (location) 1 E/kg IV bolus (70 E for a 70 kg patient)
7. Glucagon intravenous?	Indication: critical patient (severe hypotension *or* bradycardia) Risk: vomiting Glucagon 1 mg/ml (location) Inject the fluid into the vial and mix with the powder Draw up the solution using a separate syringe Give 5 ml IV bolus (i.e. 5 packs)
8. Intralipid?	Indication: cardiac arrest *or* critically low blood pressure Intralipid 200 mg/ml (location) 100 ml IV over 1 min Repeat every 5th minute x 2
9. ECMO?	Indication: cardiac arrest *or* critically low blood pressure Extracorporeal membrane oxygenation (ECMO) - contact thoracics #####

Checklist 2-6: Tricyclic antidepressant poisoning

The interventions in this checklist were based on several sources in the medical literature [126, 127, 131-134].

Items	Pop-Over Window Content
1. Ringer?	Indication: low blood pressure Ringer (location) 500 ml IV bolus
2. Sodium bicarbonate?	Indication: wide QRS-complex *or* low blood pressure *or* ventricular tachycardia Sodium bicarbonate 50 mg/ml (location) 200 ml IV bolus
3. Sodium bicarbonate dose 2?	Indication: remaining wide QRS-complex *or* low blood pressure *or* ventricular tachycardia Sodium bicarbonate 50 mg/ml (location) 200 ml IV bolus
4. Magnesium?	Indication: ventricular tachycardia despite Sodium bicarbonate bolus x 2 Magnesium (Addex) 1 mmol/ml (2.5 g/10 ml) (location) 10 ml IV over 2 min
5. Adrenalin intravenous?	Indication: remaining low blood pressure despite Sodium bicarbonate bolus x 2 Risk: arrhythmia (monitor EKG) Take a 10 ml syringe Draw up 1 ml Adrenalin 0.1 mg/ml (location) Dilute with 9 ml NaCl and mix Give 2 ml (20 mikrog) IV bolus Repeat after 3 min as needed
6. Sodium chloride 3%?	Indication: remaining low blood pressure despite above treatment Fetch Sodium chloride 9 mg/ml (isotonic NaCl) (location) 100 ml Add Addex-Sodium chloride 4 mmol/ml (location) 10 ml Give the whole solution (110 ml) as IV bolus
7. Sodium chloride 3% dose 2?	Indication: remaining low blood pressure 10 min after Sodium chloride 3% bolus Fetch Sodium chloride 9 mg/ml (isotonic NaCl) (location) 100 ml Add Addex-Sodium chloride 4 mmol/ml (location) 10 ml Give the whole solution (110 ml) as IV bolus
8. Intralipid?	Indication: cardiac arrest *or* critically low blood pressure Intralipid 200 mg/ml (location) 100 ml IV over 1 min Repeat every 5th minute x 2
9. ECMO?	Indication: cardiac arrest *or* critically low blood pressure Extracorporeal membrane oxygenation (ECMO) - contact thoracics #####

Checklist 2-7: Seizure

The interventions in this checklist were based on several sources in the medical literature [135-143].

Items	Pop-Over Window Content
1. Nasopharyngeal airway?	Indication: obstructive airway sounds Risk: high-energy facial trauma (basilar skull fracture) Nasal pharyngeal airway
2. Oxygen	Indication: all ≥ 10 L/min via oxygen mask
3. Bag-valve-mask ventilation?	Indication: low respiratory rate (< 10/min), reduced chest excursions Bag-valve-mask connected to oxygen 12 breaths/min
4. Ringer?	Indication: blood pressure < 120 mm Hg Ringer (location) 500 ml IV bolus
5. Benzodiazepine?	Indication: ≥ 5 minutes of continuous *or* intermittent seizure Stesolid (Diazepam) (location) 10 mg IV bolus *or* Midazolam (location) 10 mg IM
6. Glucose - Sodium - Calcium?	Hypoglycemia: Glucose 300 mg/ml (30%) (location) 30 ml IV bolus Hyponatremia: Fetch Sodium chloride 9 mg/ml (isotonic) (location) 250 ml Add Addex-Sodium chloride 4 mmol/ml 20 ml Give the whole solution (270 ml) as IV bolus Hypocalcemia: Calcium gluconate 10% (location) 10 ml IV over 5 min
7. Specific therapies?	Meningoencephalitis: Betapred (location) 10 mg + Cefotaxime (location) 3 g + Doktacillin (location) 3 g + Acyclovir (location) 10 mg/kg IV Eclampsia: Magnesium (Addex) 1 mmol/ml (2.5 g/10 ml) (location) 20 ml IV over 5 min Intoxication *and* wide QRS-complex: Sodium bicarbonate 50 mg/ml (location) 200 ml IV bolus
8. Benzodiazepine dose 2?	Indication: continuous *or* intermittent seizure despite Stesolid (Diazepam) *or* Lorazepam IV Stesolid (Diazepam) (location) 10 mg IV bolus
9. Keppra?	Indication: ≥ 5 minutes of continuous *or* intermittent seizure regardless of response to treatment with Stesolid (Diazepam) *or* Midazolam Keppra (Levetiracetam, Matever) 100 mg/ml (location) 60 mg/kg (max 6000 mg) IV over 10 min
10. Deep sedation + endotracheal intubation?	Indication: continuous *or* intermittent seizures persist despite above therapy Call anaesthesia for deep sedation and endotracheal intubation

Checklist 2-8: Increased intracranial pressure

The interventions in this checklist were based on several sources in the medical literature [144-150].

Items	Pop-Over Window Content
1. Oxygen?	Indication: SpO2 < 95% Oxygen 10 L/min via oxygen mask
2. Elevate head	Indication: all Elevate the head of the bed by 30° *or* tip the gurney (reverse Trendelenburg) in order to increase venous return from the brain
3. Ventilation	Indication: all Follow endtidal pCO2 (EtCO2) Ventilate with bag-valve-mask *or* via endotracheal tube as needed Aim for EtCO2 5 kPa If unconscious + fixed dilated pupil (imminent coning): aim for EtCO2 3.5 kPa
4. Sodium chloride 0.9%?	Indication: blood pressure < 110 mm Hg Sodium chloride 9 mg/ml (isotonic) (location) 500 ml IV bolus
5. Benzo + antiepileptic?	Indication: suspected seizure Treat seizures aggressively since they increase brain metabolism See checklist Seizure
6. Paracetamol?	Indication: temperature > 37.7°C Contraindication: allergy to paracetamol Paracetamol 10 mg/ml (location) 100 ml IV *and/or* physical measures Target normal body temperature
7. Sodium chloride 3%?	Indication: unconscious + fixed dilated pupil (imminent coning) Fetch Sodium chloride 9 mg/ml (isotonic) (location) 250 ml Add Addex-Sodium chloride 4 mmol/ml (location) 20 ml Give the whole solution (270 ml) as IV bolus
8. Betapred?	Indication: known brain tumor *or* CNS-infection Contraindication: traumatic brain injury, stroke Betapred 4 mg/ml (location) 4 ml IV
9. Endotracheal intubation?	Indication: unconscious *or* severely reduced level of consciousness Risk: drop in blood pressure impairs brain perfusion Summon anaesthesia
10. Head CT	Indication: all Head CT without contrast

Platform

The checklists were stored and displayed on a tablet computer. The tablet computer was connected wirelessly to a large screen (roughly 90 x 47 cm; 35 x 19 inch) that displayed the checklist for the whole team (Figure 22).

Pathways

A main menu page listed all eight medical conditions and featured hyperlinks to the individual checklists. The study did not focus on the personnel's ability to navigate between the main menu and the specific checklist nor between checklists. We were concerned that unfamiliarity with the navigation function would result in teams allocated to checklist access not being able to access the checklist.

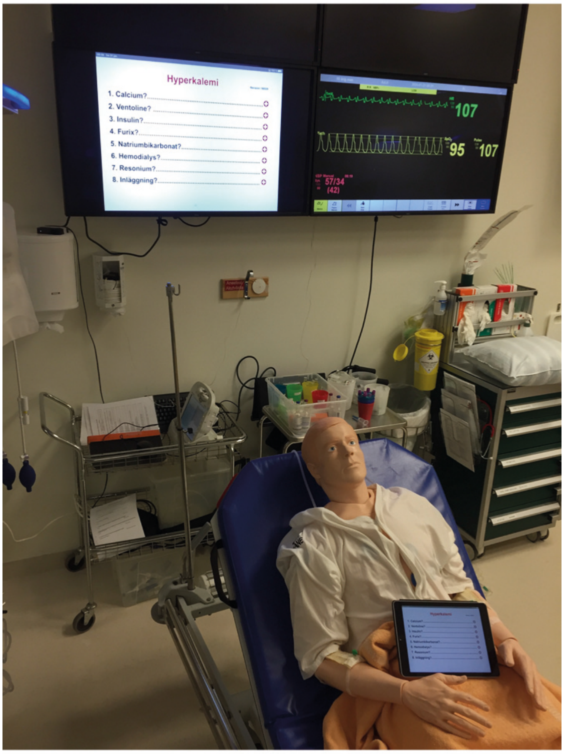


Figure 22: Checklist display, Study II
Checklists were stored on a tablet computer (resting on the manikin's lap in this photo). The tablet computer was connected wirelessly to a large screen that displayed the checklists for all team members. Photo by Eric Dryver.

Protocol

Study I showed that provision of a checklist did not guaranty its use. We therefore assigned to the documentation nurse the task of reading systematically through the checklist and opening/closing each pop-over window. We wanted to maximize the likelihood that the checklists would be used as intended, given that the aim of the study was to determine whether checklist use improves management.

Pilot Testing

Pilot testing of the checklists and scenarios is reported in the previous section.

Scenarios

Eight scenarios were developed based on real patient cases, using actual presenting vital signs, EKGs and bedside blood test results (Scenarios 2-1 to 2-8). The introduction to each scenario conveyed the diagnosis—the focus was on the management of specific conditions and not on the diagnostic process.

Scenario 2-1

Team members receive the following introduction: "A 50-year-old man has just presented to the ED after being stung by a wasp 5 minutes ago. The patient has previously had a heart attack and is taking Aspirin and Metoprolol. He is also severely allergic to wasps. The patient's arm was stung by a wasp 5 minutes ago outside the ED and the patient came here immediately." During the scenario, vital signs do not improve despite therapy. The scenario focuses on the management of anaphylactic shock.

Clinical Information	Emergency Interventions
• A: wheezing on expiration, swollen tongue • B: SpO2 90% on room air, RR 40, bilateral wheezing on expiration on lung auscultation • C: BP 60/30, HR 140, narrow QRS-complexes • D: drowsy • E: pale,diaphoretic, 37.2°C (99.0°F) • Bedside tests: pH 7.28, lactate 4.7 mmol/L (42 mg/dl)	• Adrenalin 0.3-0.5 mg IM • Supine position • Oxygen ≥ 10 L/min via mask • Crystalloid 1000 ml IV bolus • Salbutamol 5 mg nebulised • Adrenalin 50 microg IV • Glucagon 1 mg IV

Scenario 2-2

Team members receive the following introduction: "A 52-year-old man with shortness of breath will be arriving by ambulance in 1 minute. The patient suffers from asthma and anxiety. He takes Oxis (Formoterol), Bricanyl (Terbutaline), Betapred as needed and Oxascand as needed. He became short of breath 2 hours ago. He reports that it feels like the asthma attacks he has previously had, though worse this time. Ambulance personnel have been treating him for the last 15 minutes with 5 mg of Ventolin nebulized and have placed two PVCs." SpO2 drops from 93% to 85% at a rate of 1%/min, and 6 minutes into the scenario the patient becomes agitated and takes off his oxygen mask repeatedly. The scenario focuses on the management of status asthmaticus.

Clinical Information	Emergency Interventions
• A: wheezing on expiration • B: SpO2 93% dropping by 1%/min to 85%, RR 35, rather silent wheezing on expiration on lung auscultation • C: BP 190/110, HR 130, narrow QRS-complexes • D: alert, anxious, severely agitated 6 minutes into the scenario • E: pale,diaphoretic, 37.1°C (98.8°F) • Bedside tests: pH 7.17, pCO2 9.3 kPa (70 mm Hg)	• Supplemental oxygen • Ventoline 5 mg nebulized • Atrovent 0.5 mg nebulized • Adrenalin 0.5 mg IM • Esketamine 50 mg IV over 2 min • Magnesium 8 mmol IV over 20 min • Endotracheal intubation

Scenario 2-3
Team members receive the following introduction: "A 67-year-old man is brought to the emergency room because of hematemesis. The patient lives alone. He takes Aspirin because of a heart attack 10 years ago. He suffers from chronic alcohol abuse and has liver cirrhosis. Throughout the night, he has vomited a mixture of fresh blood and coffee grounds. He was found by home care, and the ambulance personnel have placed 2 PVCs." During the scenario, the blood pressure increases from 70/40 to 90/60 if the patient receives intravenous fluids (crystalloid or blood). The scenario focuses on the management of upper gastrointestinal bleeding.

Clinical Information	Emergency Interventions
• A: dried black coating on the tongue • B: SpO2 95% on 5L/min oxygen via mask, RR 35, normal breath sound on lung auscultation • C: BP 70/40, HR 130, narrow QRS-complexes • D: alert, pupils 3 mm, scleral icterus • E: pale, swollen abdomen, black foul-smelling faeces, 36.0°C (96.8°F) • Bedside tests: Hb 37 g/L, lactate 7.7 mmol/L (69 mg/dl)	• Crystalloid 500 ml IV bolus • Blood tests including fibrinogen • Blanket • 0 negative blood x 2 units • Octostim 15 mikrog over 10 min IV • Terlipressin 2 mg IV • Cefotaxime 1 g IV • Nexium 80 mg IV • Tranexamic acid 1 g IV over 10 min • Calcium gluconate 10% 10-20 ml IV

Scenario 2-4
Team members receive the following introduction: "A 42-year-old woman with a fever will be arriving in the emergency room in 1 minute via ambulance. The patient underwent a sectoral resection of the right breast six weeks ago because a mass was detected; the pathology showed no malignancy. She is otherwise healthy. For the past three days, the patient has had a high fever and a dry cough. During the last day, she has developed increasing pain in the right axilla and abdomen. Today, she became confused, and her husband called for an ambulance." During the scenario, vital signs do not improve despite therapy. The scenario focuses on the management of septic shock from toxic shock syndrome.

Clinical Information	Emergency Interventions
• A: normal airway sounds • B: SpO2 92% on room air, RR 32, normal breath sounds on lung auscultation • C: BP 55/30, HR 145, narrow QRS-complexes • D: drowsy • E: salmon-colored/sunburn-like rash over the chest, no petechiae. Right axilla: significantly warm, red, somewhat swollen, 40.0°C (104.0°F) • Bedside tests: lactate 11.4 mmol/L (103 mg/dl), Creatinine 564 micromol/L (6.34 mg/dl)	• Oxygen 3L/min via nasal prongs/oxymask • Crystalloid 500 ml IV bolus • Adrenalin 20 microg IV bolus • Blood cultures x 2 and urine culture • Bladder catheter • Antibiotics including Clindamycin • X-ray or ultrasound ("axillary abscess?") or surgical consult

Scenario 2-5

Team members receive the following introduction: "A 45-year-old woman has been found with decreased level of consciousness in her apartment. The patient has high blood pressure and is on Cardizem Retard. She also suffers from depression. The patient was found by her daughter. The patient has written a suicide note. Thirty tablets of 180 mg Cardizem Retard are missing. It is unclear when the patient took the tablets. The ambulance personnel have placed two PVCs and inserted a nasopharyngeal airway, and the patient is receiving 10 L/min of oxygen via mask. The personnel state that they have not been able to palpate the radial pulse. They connected 1 L of Ringer just before arrival in the ED." During the scenario, vital signs do not improve despite therapy. The scenario focuses on the management of calcium channel blocker poisoning.

Clinical Information	Emergency Interventions
• A: nasopharyngeal airway in place, normal airway sounds • B: SpO2 96% on 10 L/min oxygen via mask, RR 20, normal breath sounds on lung auscultation • C: BP 70/50, HR 31, wide QRS-complexes • D: drowsy • E: 36.8°C (98.2°F) • Bedside tests: lactate 6.2 mmol/L (56 mg/dl), EKG shows a ventricular espace rhythm	• Crystalloid bolus • Atropine ≥ 1 mg IV bolus • Calcium gluconate 10% 30 ml IV • Adrenalin 20 microg IV bolus • Glucose 300 mg/ml 50 mg IV • Humalog or Actrapid or Novorapid 70 E IV bolus • Glucagon ≥ 1 mg IV bolus • Intralipid 100 ml IV • ECMO

Scenario 2-6

Team members receive the following introduction: "A 54-year-old man has been found unconscious at his home by his relatives. The patient will be arriving by ambulance in 1 minute. The patient suffers from depression and takes Saroten (Amitriptyline), a tricyclic antidepressant. The patient was found unconscious. His relatives suspect that the patient took an overdose of Amitriptyline. The time of ingestion is unclear. The ambulance personnel have place a nasal pharyngeal airway and two PVCs." Three minutes into the scenario, the patient develops ventricular tachycardia, which persists until the patient is treated with a second dose of sodium bicarbonate and intravenous magnesium. The scenario focuses on the management of tricylic antidepressant poisoning.

Clinical Information	Emergency Interventions
• A: nasopharyngeal airway in place, normal airway sounds • B: SpO2 95% with oxygen via mask, RR 12, normal breath sounds on lung auscultation • C: BP 60/35, HR 110, with ventricular tachycardia: HR 210. Wide QRS-complexes • D: unresponsive to painful stimuli, pupils 6 mm • E: skin red, warm and dry, 37.8°C (100.0°F) • Bedside tests: lactate 6.9 mmol/L (62 mg/dl), EKG shows QRS-complexes of > 200 msec during sinus rhythm, negative concordance in the precordial leads upon ventricular tachycardia	• Crystalloid 500 ml IV • Sodium bicarbonate 200 ml IV (dose 1) • Sodium bicarbonate 200 ml IV (dose 2) • Magnesium 10 mmol IV over 2 min • Adrenalin 20 microg IV • Sodium chloride 3% 110 ml (dose 1) • Sodium chloride 3% 110 ml (dose 2) • Intralipid 100 ml IV • ECMO

Scenario 2-7
Team members receive the following introduction: "It's evening. An 84-year-old woman who presented to the ED has just had a seizure and she has been transferred to the resuscitation room. The patient has been essentially healthy except a slowly worsening anemia. She underwent a colonoscopy this morning to investigate her anemia. During the afternoon she became increasingly confused and vomited. Her husband called the ambulance. The patient received two PVCs during transport to the ED. She has been a Priority 2 until now when she developed a generalized seizure that lasted 1 minute. She has just been transferred to the resuscitation room." One minute into the simulation, the patient develops a tonic-clonic seizure and continues to seize intermittently throughout the rest of the simulation. The scenario focuses on the management of status epilepticus caused by hyponatremic encephalopathy.

Clinical Information	Emergency Interventions
• A: snoring breath sounds which resolve upon jaw thrust or placement of a nasopharyngeal/oropharyngeal airway • B: SpO2 89% on room air, RR 6, normal breath sounds on lung auscultation • C: BP 108/70, HR 75, narrow QRS-complexes • D: unreactive to voice or pain, intermittent shaking of all 4 extremities • E: normal skin, 36.8°C (98.2°F) • Bedside tests: lactate 8.2 mmol/L (74 mg/dl), sodium 115 mmol/L, glucose 11.2 mmol/L (202 mg/dl)	• Nasopharyngeal airway • Supplemental oxygen • Ventilation with bag-valve-mask • Crystalloid 500 ml IV bolus • Benzodiazepine dose 1 (e.g. Diazepam 10 mg IV) • Sodium chloride 3%: correct preparation (20-25 ml NaCl 4 mmol/ml in 250 ml NaCl 0.9%) • Sodium chloride 3% 250-300 ml • Benzodiazepine dose 2 • Levetiracetam 60 mg mg/kg, Valproic acid 30-40 mg/kg or Phosphenytoin 15-20 mg/kg IV • Deep sedation and endotracheal intubation

Scenario 2-8
Team members receive the following introduction: "A 54-year-old man has been found unconscious in his apartment. The patient has no known prior illnesses and does not take any medications. The patient suddenly started talking incoherently on the phone one hour ago. His son went to the patient's apartment and found the patient unconscious. The patient had vomited profusely in bed. During transport to the emergency room, the patient has received a nasopharyngeal airway and 2 PVCs." During the scenario, vital signs do not improve despite therapy. The scenario focuses on the management of increased intracranial pressure.

Clinical Information	Emergency Interventions
• A: nasopharyngeal airway in place, normal airway sounds • B: SpO2 91% on room air, RR 10, normal breath sounds on lung auscultation • C: SBP 100/60, HR 135, narrow QRS-complexes • D: unconscious, right pupil 3 mm, left pupil 6 mm unresponsive to light, withdraws left arm and leg to pain, no response to pain right arm and leg • E: pale,diaphoretic, 38.0°C (100.4°F) • Bedside tests: glucose 9.2 mmol/L (166 mg/dl), lactate 1.5 mmol/L (13.5 mg/dl), end-tidal CO_2 5.5 kPa (41 mm Hg)	• Oxygen ≥ 10 L/min via mask • Elevate the head of the bed • Bag-valve-mask ventilation to end-tidal CO_2 3.5 kPa (26 mm Hg) • NaCl 0.9% 500 ml IV bolus • Paracetamol 1 g IV • NaCl 3% 250-275 ml IV bolus • Endotracheal intubation • Head CT

Interventions & Simulations

Promotion

The potential benefits of checklist use and the methods and purpose of the study were presented to the heads of each ED who consented to having the study run in their ED. It was not logistically possible to present the study in advance to the staff that could potentially be part of the resuscitation teams on the study days.

Enrolment & Randomization

Study participants were resuscitation teams in active clinical duty. In the primary investigator's ED, the study was conducted during ad hoc weekday mornings when the investigator was not on clinical duty. In the other EDs, the study was carried out during five consecutive weekdays, with the goal of carrying out four simulations per day. All scenarios were carried out between 08 AM and 11 AM.

The day's resuscitation team gathered in the resuscitation room when the personnel in charge of patient flow deemed that the timing was suitable. Potential participants were briefly introduced to the study's purpose and methods and asked to enroll in the study, upon which they provided written consent and filled out a form providing their age, profession, and years of practice.

The goal was for each resuscitation team to carry out two simulations, one with and one without checklist support. Permuted block randomization was used to simulate each scenario with and without checklist support in each ED. The sequence according to which the scenarios were run was randomly generated for each ED. Whether teams ran the first of the two simulations with or without checklist access was stratified according to ED.

The investigator had no control over the composition of the study day's resuscitation teams. The challenge was to develop a scenario-allocation system that ensured that no team member ran the same scenario more than once. Based on the randomly generated scenario sequence and whether the first scenario would be with or without checklist access, a sequence such as the following was derived: 5+ 5- 3+ 3- 6+ 6- 7+ 7- 4+ 4- 1+ 1- 8+ 8- 2+ 2-. This sequence can be conceived of as a deck of cards where the top card (5+) represents scenario 5 with checklist use and the bottom card (2-) scenario 2 without checklist use. The team was allocated to the highest card in the deck corresponding to a scenario that no one in the team had done previously. If the team carried out the simulation without interruption, the "card" was removed from the deck. If the opportunity arose to carry out extra simulations, additional randomly generated scenario sequences were generated for each ED.

Introduction & Simulations

A ninth checklist (hyperkalemia) was used to demonstrate the checklist structure to the team and have the documentation nurse practice using the pop-over window function. Teams were informed that the simulations would focus on the management of a condition which would be obvious from the introductory information. Team members were explicitly allowed to use whatever cognitive aids they wished during the simulations. The same adult manikin (Laerdal Extri Kelly) was used for all simulations. Team members were enjoined to manage the manikin as though it were a real patient. They were enjoined to fetch actual medications, which were then replaced with placebo, and administer the medications through a peripheral venous catheter that had been inserted into rubber tubing on the manikin's arm. Actual equipment (e.g. oxygen masks) had to be located in the ED before being substituted with training equipment that had to be used on the manikin.

The investigator then read the introduction to the scenario. As the simulation started, the investigator brought forth the associated checklist on the tablet computer if the team had been randomized to checklist access. This methodological feature was carried out to maximize the chances that the checklist would be used.

Vitals signs were generated by a computer and displayed on the screen used locally for that purpose or a screen of the same size placed in the same location (Figure 23). During the simulation, the investigator provided clinical information upon request. The study protocol forbade the investigator from enjoining teams allocated to checklist access to use the checklist. Simulations lasted for 15 minutes or until all emergency interventions had been performed. Simulations were recorded using two audio-video cameras located at a right angle from each other.

Exclusions

Personnel in charge of patient flow had the mandate to interrupt the simulation at any time. A simulation was excluded if the team members had to depart to manage an actual priority one patient prior to end of simulation. In such a case, the scenario with the same checklist allocation had to be repeated with another team that did not include personnel that had participated in the interrupted simulation (i.e. the scenario card was left in the deck at the same spot).

Questionnaire

Following the simulations where checklists were used, personnel filled out a questionnaire regarding their subjective impression of the checklist's value. The questions were based on those used in the simulation-based trial of surgical-crisis checklists [2].

Figure 23: Set-up for Study II
Checklists were stored on a tablet computer (resting on the manikin's lap in this photo). The tablet computer was connected wirelessly to the a large screen that displayed the checklists for all team members. Another screen displayed computer-generated vital parameters for the scenario. Simulation equipment and placebo medications can be seen on the carts under the screens. One of the two video-cameras is visible. Photo by Eric Dryver.

Observations, Outcomes & Statistics

Emergency Interventions

The main outcome measure was the percentage of indicated emergency interventions performed within 15 minutes, without regard for sequence of performance. Whether an intervention was indicated depended on the specific aspects of the scenario. Not all the interventions in each checklist were indicated.

During the pilot study, teams without checklist access had a mean percentage of emergency interventions of 48% with a standard deviation $\sigma 0$ of 23%, whereas teams with checklist access had a mean percentage of emergency interventions of 76% with a standard deviation $\sigma 1$ of 20% [104]. Assuming that the standard deviations would be similar in the study, we calculated that 24 simulations in each group would be sufficient to detect a meaningful clinical difference ($\mu 1$ - $\mu 0$) of 20% in percentage of performed emergency interventions with a power of 80% (u = 0.84) and a type 1 error risk of 0.05 (v = 1.96) using the following equation [98]:

$$\text{Minimal sample size in each group} = (u + v)^2 (\sigma 1^2 + \sigma 0^2) / (\mu 1 - \mu 0)^2$$

According to this calculation, simulating eight scenarios with and without checklists in each of three EDs would be a sufficient sample size. Given the uncertainty regarding whether the simulations could be performed in all resuscitation rooms, we aimed to perform the study in four EDs.

Since the input variable was binary (checklist use) and the output variable continuous (percentage interventions) with assumed non-normal distribution, we initially analyzed the data using the Mann-Whitney *U*-test. For the final analysis, we used bootstrapping [151]. To analyze the effect of potential confounders on the impact of checklist use on interventions performed, we used mixed-effects ordinal logistic regression given that results were clustered within EDs and within teams [152].

Inter-rater agreement

Time of performance of emergency interactions for all simulations was independently extracted from audio-video footage by two investigators. In addition, an external reviewer blinded to the study methods and goals extracted data from two randomly chosen simulations with checklist access and two without checklist access from each ED. Interrater reliabilities were assessed using a kappa statistic [98] and disagreements resolved by reviewing the videos.

Dangerous/Inappropriate Interventions and Local Cognitive Aid Use

Audio-video footage was also reviewed to determine whether dangerous (e.g. unusually high medication doses that are potentially harmful) or inappropriate interventions (e.g. ordering an antidote for a medication that the patient had not overdosed with) were performed. Use of locally available cognitive aids (e.g. pocketbooks, the internet) was noted. Descriptive statistics were used to describe these observations.

Questionnaire

Descriptive statistics were used to analyze the answers to the questionnaire.

Ethical Considerations

Enrolment

Potential participants were informed that data analysis would be carried out at the team-level without reference to the identity of the ED and that individual names would not be recorded. Potential participants were also informed that the simulations would be videotaped, that the recordings and signed consent forms would be stored in a locked facility at Practicum Clinical Skills Centre and would be destroyed after 10 years.

Impact on Clinical Care

Personnel in charge of patient flow chose the timing when the simulations could be performed in the resuscitation room and had the explicit mandate to interrupt simulations if team members were needed for acute patient management. Simulations were carried out in the AM when the personnel to patient ratio is most favorable. In one ED, the department heads arranged to have an extra resuscitation team present in the ED in the AM during the study days to ensure that the simulations could be performed.

Ethics Approval

The study was approved by the heads of each ED and by Lund's Regional Ethics Committee (Dnr 2013/858). This study did not evaluate the relationship between a health-related intervention and a health outcome in people, and hence it is arguably not a clinical trial [153]. The study was therefore not registered at clinicaltrials.gov or similar trial registration sites.

Results

Settings, Participants & Simulations

Emergency Departments

The study was carried out in four EDs in Southern Sweden: Skåne's University Hospital at Lund, Skåne's University Hospital at Malmö, Helsingborg's hospital and Ystad's hospital. The EDs of Lund and Malmö jointly compose a tertiary care hospital. Helsingborg's is a large community hospital and Ystad's a rural community hospital.

Participants

A total of 138 personnel took part in the study. In one instance, a nurse did not consent to being videotaped and was replaced by another nurse with the same credentials. There were no significant differences in team characteristics between those randomized to checklist access versus no access. The professions and years of experience are presented in Table 8.

Table 8. Professional characteristics of the participants in Study II
Three of the five specialist physicians were specialists in Emergency Medicine. Twenty-one of the residents were residents in Emergency Medicine. Of the 19 residents who had done 1-5 years of training, 5 were in their second year, 2 in their third year, 4 in their fourth year and 8 in their fifth year.

Profession	Participants (n=138)	Years of experience					
		<1	1-5	6-10	11-15	> 15	Unknown
Specialist physician	5	0	0	2	1	2	0
Resident	26	3	19	4	0	0	0
Nurse	54	0	23	9	7	15	0
Nursing assistant	37	0	2	4	7	23	1
Medical secretaries	16	0	0	3	1	11	1

Simulations

Forty-one resuscitation teams were enrolled in the study between June 2019 and February 2020. In 35 instances, the teams were able to carry out two simulations, one with and one without checklist use. In the remaining six instances, the teams were only able to carry out one simulation (three with and three without checklist access) due to the arrival of a priority one patient. In one of these six instances, the second simulation had to be interrupted and the scenario was later rerun to completion with another team composed of entirely different personnel. In three of the four EDs, it was possible to run four simulations in addition to the planned 16, resulting in a total of 76 simulations (38 with checklist use and 38 without) (Figure 24). The total duration of analyzed video footage was 18 hours.

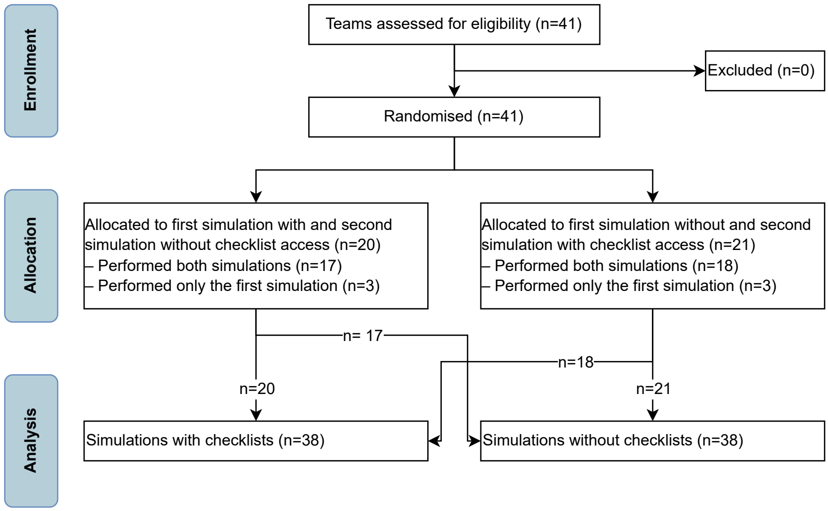


Figure 24: CONSORT flow diagram for Study II

Observations & Outcomes

Percentage of Indicated Interventions

The median percentage of indicated interventions was 38% in the group not using the checklists and 86% in the group using the checklists. The p-value associated with this difference was < 0.001 (both with bootstrapping and Mann-Whitney *U*-test). Figure 25 shows the percentage of indicated interventions performed during each of the 76 simulations. Logistic ordinal regression analysis failed to show that ED, physician age, physician degree of experience, nurse degree of experience, or use of local cognitive aids had an impact on the association between checklist use and number of interventions performed.

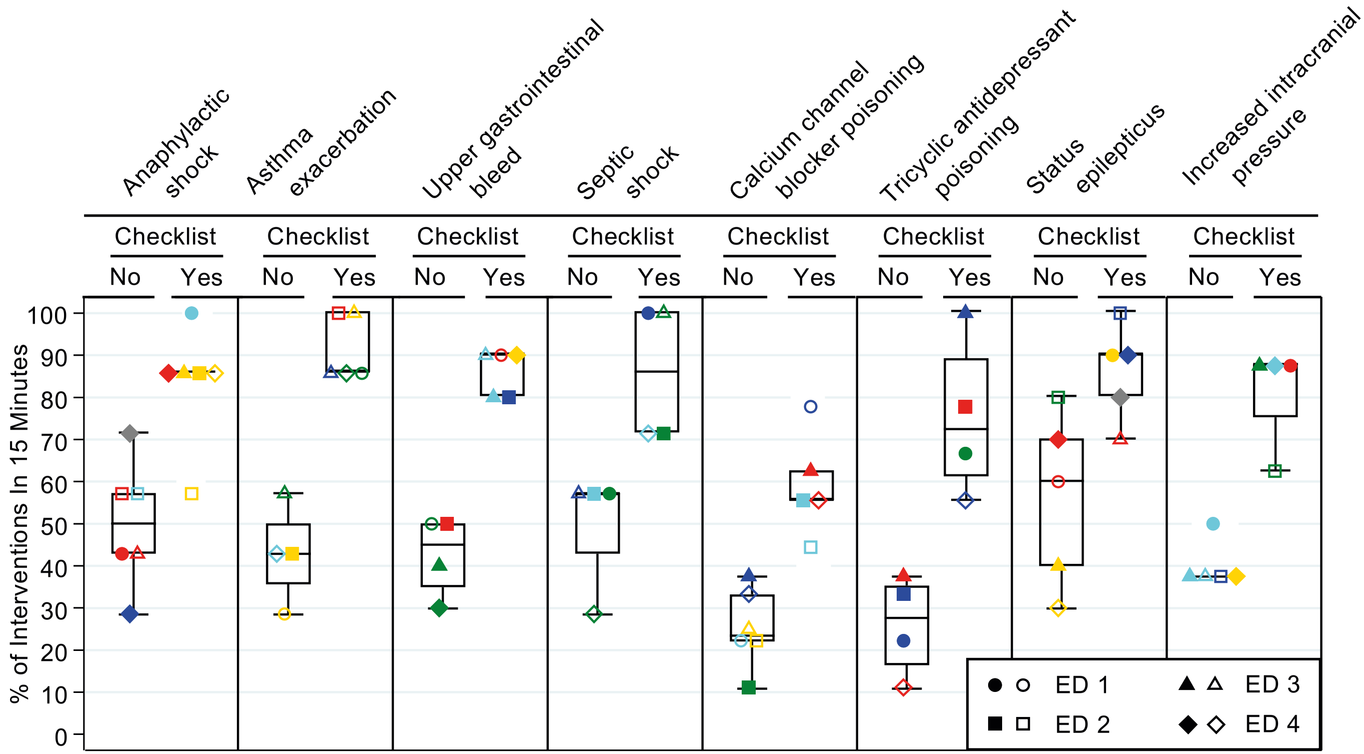


Figure 25: Percentage of indicated interventions performed

This figure displays the percentage of indicated interventions performed during each of the 76 simulations. Each icon represents a simulation. The icon's shape corresponds to the ED where the simulation was carried out. Each team is illustrated by a specific combination of shape and color. Figure 2 in Paper II.

Diagnostic Awareness

Teams randomized to checklist access were provided with a checklist for the management of the relevant condition upon simulation start. A reviewer of the manuscript questioned whether teams with no checklist were aware of the diagnosis, or whether a delay in diagnostic awareness may have affected their performance. The audio video footage was reviewed to note terms uttered or diagnosis-specific interventions ordered that indicated diagnostic awareness. These terms and interventions are listed in Table 9. Diagnostic awareness could be inferred using these terms and interventions in all 38 simulations without checklist use. Twelve of the 38 simulations were terminated before 15 minutes when the team clearly indicated that they had no further management ideas. In 13 of the remaining 26 simulations, no interventions were carried out during the last 5 minutes of the simulation. In the remaining 13 simulations, diagnostic awareness could be inferred from terms uttered or interventions ordered within 90 seconds of scenario start in 6 cases and within 2-5 minutes in 6 cases.

Table 9: Terms and interventions indicating diagnostic awareness

This table lists the terms uttered by team members and the diagnostic-specific interventions ordered that were used to infer diagnostic awareness among teams randomized to no checklist use.

Scenario	Terms	Interventions
Anaphylaxis	"Anaphylaxis" or "Anaphylactic shock"	Adrenalin IM
Asthma	"Asthma"	Bronchodilator nebulized
Upper Gastrointestinal Bleed	"Gastrointestinal" or "GI" + "bleeding"	Blood transfusion Esomeprazole IV push
Sepsis	"Sepsis" or "Septic shock"	Blood cultures
Calcium Channel Blocker Poisoning	"Calcium antagonist" or "Calcium blocker"	Calcium infusion
Tricyclic Antidepressant Poisoning	"Tricyclic"	Sodium bicarbonate infusion
Seizure from Hyponatremic Encephalopathy	"Seizure" or "Status"	Benzodiazepine IV push 3% Sodium chloride infusion
Increased Intracranial Pressure	"Brain" + "bleeding"	Acute head CT

Impact of Checklist Use on Initial Performance

To investigate whether checklist use was associated with a delay in the performance of initial first-line measures, we analyzed whether there was a difference in the rate of intervention performance during the 15 minutes between teams allocated to checklist access and those allocated to no checklist access (Figure 26). The analysis did not show that checklist access delayed the performance of first-line measures.

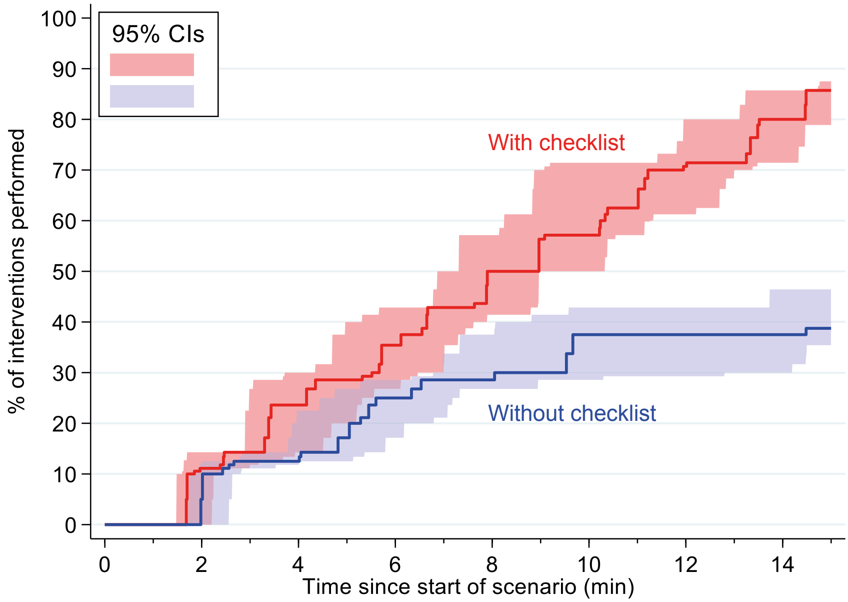


Figure 26: Rate of performance of indicated emergency interventions
This figure depicts the median percentage of indicated emergency interventions throughout the 15-minutes of simulation time for teams allocated to checklist use (pink) and those allocated to no checklist use (blue), along with associated 95% confidence intervals. Checklist use is not associated with a delay in initial management. Figure 3 in Paper II.

Inter-Rater Agreement

Video footage from each of the 76 simulations was independently reviewed by two investigators, yielding a kappa statistic of 0.92 (95% CI 0.89-0.95). An outside physician who had not been informed of the study goals then independently reviewed 16 simulations yielding a kappa statistic of 0.89 (95% CI 0.81-0.97).

Dangerous/Inappropriate Interventions

Video footage review identified fifteen interventions that were deemed dangerous or inappropriate (Table 10). All but one of these interventions occurred during the simulations where the team lacked checklist access.

Table 10. Dangerous or inappropriate interventions

Fifteen of the interventions performed were deemed dangerous (e.g. diazepam administration in the setting of life-threatening asthma exacerbation) or inappropriate (e.g. physostigmine in the setting of calcium channel blocker poisoning). All but one of these interventions were associated with lack of checklist use.

Setting	Intervention	Checklist Use	
		No	Yes
Anaphylactic chock	Adrenalin ≥ 0.3 mg IV push	1	1
Life-threatening asthma exacerbation with agitation	Diazepam IV push	3	0
	Morphine IV push	2	0
	Theophylline nebulized	1	0
Calcium channel blocker poisoning with shock and bradycardia	Physostigmine	1	0
	Adrenalin 0.2 mg IV push	1	0
	Sodium bicarbonate infusion	1	0
Tricyclic antidepressant poisoning	Tribonate infusion	2	0
	Calcium gluconate infusion	1	0
Seizure from hyponatremic encephalopathy	NaCl 23% 20 ml IV push	1	0
Total		**14**	**1**

Use of Usual Cognitive Aids

Usual cognitive aids were used during 26 simulations without and six simulations with checklist access. The cognitive aids used by teams without checklist access were the internet (12/26), a pocketbook (6/26) or a combination of internet with a pocketbook or card (8/26).

Subjective Checklist Evaluation

One hundred and fifty-eight personnel responded to the questionnaire regarding the checklists. The results are presented in Table 11. There were no significant differences in responses depending on profession.

Table 11. Subjective evaluation of crisis checklists during Study II

One hundred and fifty-eight participants were ask to grade the degree to which they agreed wtih the statements on a Likert Scale of 1 (strongly disagree) to 6 (strongly agree). Results are reported as means +/- standard deviation.

Statement	Degree of Agreement
The checklists helped me manage the scenario	5.43 ± 0.80
The checklists were user-friendly	5.61 ± 0.58
I would use the checklists if I had a similar case in real life	5.62 ± 0.69
Checklists did not hinder the acute management of the case	5.64 ± 0.69
If I were the patient, I would want the team to use the checklists	5.28 ± 0.89

Discussion

Validity

Confounders?

Randomization was used to minimize the risk that the association between checklist use and indicated interventions performed would be due to known or unknown confounders. The allocation sequence was not concealed from the primary investigator, yet 35 of the 41 teams performed two simulations—one with and one without checklist access. Mixed-effects ordinal logistic regression did not show any evidence that known confounders (e.g. physician experience) were effect modifiers.

Co-Interventions or Contamination?

Neither the participants nor the primary investigator could be blinded to the intervention—checklist access. To minimize the risk of co-interventions, the primary investigator had to follow a specific script and was not allowed to enjoin teams randomized to checklist access to use the checklist. The simulation reviewers were enjoined to identify script violations.

When a team was randomized to checklist access, the relevant checklist was brought up on the large screen upon scenario start. This strategy was used to avoid technical difficulties stemming from trouble navigating between the main menu and the relevant checklist, and to maximize the likelihood that the checklist would be used, given that the aim of the study was to determine whether checklist use improves management.

This methodological feature can be construed as a co-intervention giving teams randomized to checklists an advantage over those without. Yet all teams were informed that the diagnosis would be obvious from the given introductory information and that the simulation would focus on management, not diagnosis. It did not occur to the primary investigator that teams were unaware of the diagnosis. Additional video-footage analysis could demonstrate that teams without checklist access were aware of the diagnosis and that any potential delay in diagnostic awareness could not account for the lack of interventions performed. Notwithstanding, it would have been preferable to provide the diagnosis on an otherwise blank screen to teams randomized to no checklist access to avoid any possible co-intervention effect.

Ascertainment Bias?

Performance data was extracted from video footage using the same criteria for all simulations. Sixteen simulations were assessed by an external physician who had not been told of the study purpose. Granted, the study purpose is obvious when video footage of teams performing with and without checklist access is viewed. The kappa statistics around 0.9 argue against ascertainment bias.

Relevance

Relevant Scenarios?

The patients in the scenarios exhibited an unusual degree of acuity and refractoriness to first-line therapy, yet the scenarios were based on real cases and therefore not outlandish. The stated goal of crisis-checklists is to assist with the management of a crisis, a low-frequency, unexpected situation where appropriate, urgent management improves outcome. A 15-minute simulation cut-off is realistic—critical patients ought to be stabilized during this time frame in the resuscitation room before being transferred to the intensive care unit or step down unit.

Relevant Outcomes for Patients?

The outcomes were either treatments or investigations based on standard of care at the time of the study design. Outcome measures did not include calling for help or commenting on EKG findings but were limited to interventions that were of direct clinical value for the patient. Checklist use was not associated with delayed administration of first-line interventions, and it was associated with a lower frequency of dangerous or inappropriate interventions.

Relevant Outcomes for Personnel?

The questionnaire results suggest that personnel from all professions felt that the checklists aided patient management and did not disrupt workflow.

Generalizability

Setting

A strength of the study stems from the fact that it was carried out in four actual resuscitation rooms, where personnel had access to their usual aids, worked within their actual physical and cultural environment, and had to find their actual equipment and medications. Two of the centers were tertiary care hospitals, one a large community hospital and one a rural community hospital. Site did not modify the impact of checklist use on performance. The study's methodology and findings increase the generalizability of the study results to other resuscitation rooms and actual clinical care.

Personnel

A strength of the study stems from the fact that the teams were actual resuscitation teams in actual "working mode" as opposed to volunteers composing teams put together ad hoc. This aspect increases the generalizability of the findings to other resuscitation rooms in Sweden with similar staffing in the ED.

The physicians in the study were mostly residents and it is unclear whether the study results can be generalized to resuscitations teams where the physician is an experienced specialist. Yet our analyzes did not show that physician experience modified the effect of checklist use on performance.

In actual clinical practice, teams have the option of calling for help (e.g. to the poison control center). In the study, teams did not have the option to do so, and this detracts from the generalizability of the study findings. Yet acutely ill patients need urgent treatment and immediate help is not always available in the clinical setting.

Tasks

The study focused on the management of eight non-traumatic conditions where the diagnosis was clear from the onset. The study showed that checklist use had an impact on performance for all eight conditions, suggesting that checklists may also improve the management of other conditions with a clear diagnosis from onset (e.g. certain cases of cardiogenic pulmonary edema). However, the study results cannot be generalized to cases where the diagnosis is unclear.

Tool

The digital format makes it easy to improve and adapt the checklists and add new checklists. The study did not focus on the ability of personnel to navigate between a menu and individual checklists or between checklists, but this should be easy for personnel to learn.

Impact of Checklists: Study I vs Study II

The difference in impact of checklist access on team performance between Study I and Study II is striking. Factors that may account for this difference are itemized in Table 12.

Table 12. Possible explanations for the difference in impact of checklists on team performance between Study I and Study II.

	Study I	Study II
Pilot testing	Pilot testing was not performed. It might have led to a better adaption of the checklists to the "environment" and more impact of improved checklists.	Pilot testing led to improvement of the checklist design and replacement of one case with a case with more interventions.
Pre-simulation lecture	The pre-simulation lecture likely biased the results towards checklists having no impact.	There was no pre-simulation lecture.
Assigned reader	There was no assigned reader. The lack of impact of the checklists on the team considering hypoglycemia and administering correct doses of glucose and adrenalin suggests that the checklists were not used or not used as intended.	A nurse was assigned the task of methodically going through the checklist and opening each pop-over window, ensuring that the checklist was used.
Technical skills	Primary care personnel have less experience with actual crises and hence lower technical skills than ED personnel. Lack of technical skills cannot be remedied by checklists, and the absence of checklist impact may in part be a reflection of this fact.	ED personnel have experience with actual crises and good technical skills. Performance reflected decision-making rather than whether the interventions could be performed.
Basic vs advanced interventions	Some of the interventions were very basic (e.g. jaw-thrust, administration of oxygen, chest compressions) and these interventions may be too basic for checklists to have an impact.	The scenarios focussed more heavily on second- and third-line treatments which are more contingent upon access to facts—perfect for checklists.
Medication location	The checklists did not include the location of medications, and trouble finding glucose may have biased the study towards checklists having no impact.	The checklists provided information, tailored to each ED, regarding the location of medications seldom used.

Crisis Checklist Use During Priority One Patient Resuscitation: Study Protocol (Paper III)

Methods

Setting & Participants

Setting

The setting for this study is the ED of Skåne's University Hospital at Lund, an academic center and trauma center. The ED's resuscitation room allows for the simultaneous resuscitation of three patients.

Personnel

The personnel involved in this study are those that manage priority one patients in the ED's resuscitation room. The typical resuscitation team consists of one physician, two nurses and one nursing assistant. The typical physician during weekdays is a resident in Emergency Medicine. The specialist in Emergency Medicine in charge of patient flow is often present in the resuscitation room upon the patient's arrival and available for bedside consultation. During the nights and weekends, the physician in the resuscitation team may be a resident or specialist in Emergency Medicine, Internal Medicine or Surgery. Resuscitation teams are strengthened by personnel from other specialties (Anesthesiology, Otorhinolaryngology, Cardiology, Surgery and Neurology) during certain circumstances (e.g. cardiac arrest, level one trauma, obstructed upper airway, suspected stroke).

Patients

Consecutive patients managed in the resuscitation room during a six-month period prior to and following the implementation of a collection of crisis checklists (EM) are included in the study. The ED of Lund manages priority one patients over the age of 18 years and patients younger than 18 years with trauma, burns or threatened upper airway. The triage system in use is the Rapid Emergency Triage and

Treatment System (RETTS), the most commonly use triage system in Sweden. Patients are priority one if they fulfill one of the following criteria (http://predicare.se/):

- stridor or other signs of upper airway compromise
- SpO2 < 90% with supplemental oxygen
- RR > 30 or < 8
- HR regular > 130 or irregular > 150
- SBP < 90
- unconscious or seizure

In the setting of trauma, patients are treated in the resuscitation room as level one or level two trauma depending on physiological parameters, anatomical criteria and mechanism of injury [154].

Processes & Checklists

Processes

The management of priority one patients in the resuscitation room consists of investigations and treatments that are prompted either by the patient's problem (e.g. hypoxemia) or presumed diagnosis (e.g. sepsis). The patient's problem may be subjective (e.g. chest pain), objective (e.g. low SpO2) or potential (e.g. suspected poisoning, post-traumatic hemorrhage or fracture) [38]. Management focuses on identifying and initiating the treatment of diagnoses where prompt treatment impacts on prognosis (so-called time-sensitive conditions) [38].

The problems included in the EM are listed in Table 13. The list is informed by the content of EMs [155-158]. All checklists pertaining to poisoning and the checklist for torsade de pointes are included in the problem list for pragmatic reasons.

Table 13: Problem checklists, Study III

Patients present with problems that may be objective (e.g. hypoxemia), subjective (e.g. abdominal pain) or potential (e.g. suspected poisoning). This table lists the problems for which checklists feature in the EM that will be evaluated in the study.

Category	Problem	
General	Cardiac arrest, non-traumatic Cardiac arrest, traumatic Level 1 trauma	Crashing patient Newborn
Airway	Upper airway obstruction	Tracheostomy obstruction
Breathing	Hypoxemia	
Circulation	Hypotension Bradycardia Tachycardia Torsade de pointes	Tachycardia—narrow QRS + regular Tachycardia—wide QRS + regular Tachycardia—narrow QRS + irregular Tachycardia—wide QRS + irregular
Disability	Decreased level of consciousness Seizure	Transient loss of consciousness
Exposure	Burns and smoke inhalation	Hyperthermia Hypothermia
Electrolytes & Glucose	Hyperglycemia Hypernatremia Hyperkalemia Hypercalcemia	Hypoglycemia Hyponatremia Hypokalemia Hypocalcemia
Poisoning	Poisoning—general Poisoning—Na-channel blockade Poisoning—K-channel blockade	Poisoning—Calcium antagonist & beta-blocker Local Anesthetic Systemic Toxicity
Pain	Chest pain	Abdominal pain

Patient management in the resuscitation room may also be driven by the suspected diagnosis (e.g. cardiogenic pulmonary edema). The diagnoses included in the EM are listed in Table 14. The list is informed by the content of EMs [155-158] and studies that have inventoried the conditions managed in resuscitation rooms of EDs [159-162].

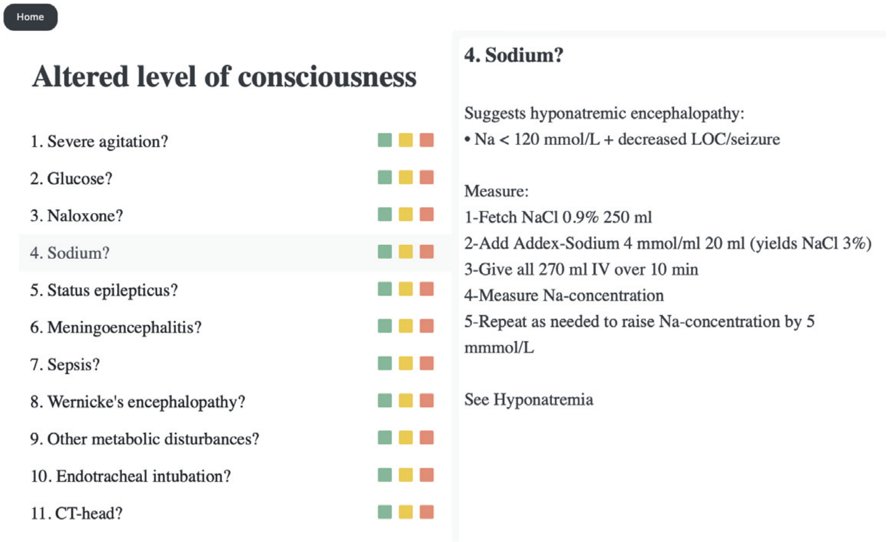
Table 14: Diagnosis checklists, Study III

Patient management in the resuscitation room may be driven by the presumed diagnosis. This table lists the diagnoses for which checklists feature in the EM that will be evaluated in the study. COPD stands for Chronic Obstructive Pulmonary Disease. STEMI stands for ST-Elevation Myocardial Infarction. OMI stands for Occlusion Myocardial Infarction.

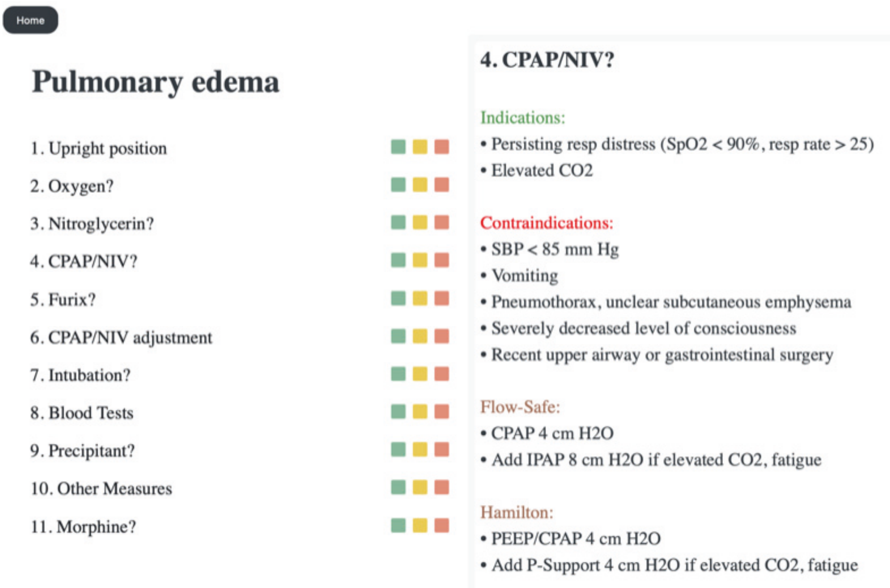
Category	Diagnoses	
Airway	Anaphylaxis Angioedema	Epiglottitis Foreign body airway obstruction
Breathing	Asthma exacerbation COPD-exacerbation	Pneumonia Pulmonary edema
Circulation	Addison crisis Anaphylaxis Aortic dissection Atrial fibrillation Cardiac tamponade Cardiogenic shock	Gastrointestinal bleeding Hemorrhagic shock Hypertensive crisis Neurogenic shock Pulmonary embolism Sepsis Tension pneumothorax
Disability	Seizure	Increased intracranial pressure
Glucose & EKG	Diabetic ketoacidosis Hyperglycemic hyperosmolar syndrome	STEMI-OMI

Print

Checklists for each of the problems listed in Table 13 and each of the diagnoses listed in Table 14 are derived from the medical literature and reviewed by specialists in Emergency Medicine and specialist nurses. All checklists are linear. Each checklist consists of a list of actions or diagnoses to consider displayed on the left side, and pop-over windows for each item featuring indications, contraindications, risks, and administration details displayed on the right. The pop-over window is activated by pressing on the text of the item itself. The order of actions considers time to administration, time to effect and engineering coherence. Time-sensitive diagnoses are listed in problem checklists to guard against premature closure. Text is kept to a minimum. The color green is used for indications, red for contraindications and risks, brown as a general heading for measures, blue for pediatric doses. Checklist 3-1 provides an example of a problem checklist. Checklist 3-2 provides an example of a diagnosis checklist.



Checklist 3-1: Problem checklist
The checklist for altered level of conscious is an example of a problem checklist.



Checklist 3-2: Diagnosis checklist
The checklist for pulmonary edema is an example of a diagnosis checklist.

To the right of each item, on the same horizontal level, there are three boxes (green, gold and red). One of these items is selected by the reader when the checklist is used in Do-Confirm mode:

- green if the intervention is deemed indicated and has been performed.
- red if the intervention is deemed unsuitable and has not/will not be performed.
- gold if the intervention is deemed indicated and is to be performed thanks to checklist use.

In addition to the problem and diagnosis checklists, the EM includes fact sheets and procedure aids (Table 15). The fact sheets provide information that can be sampled such as the dose of inhaled fentanyl for analgesia in children or images illustrating the modified Sgarbossa criteria for occlusion myocardial infarction in the setting of a left bundle branch block [163]. The procedure aids provide indications, contraindications, steps and/or images for each procedure.

Table 15: Fact sheets and procedure aids
These checklists itemize the investigations and treatments for patients with specific problems. A problem may be subjective (e.g. abdominal pain), objective (e.g. hypoxemia), or potential (e.g. poisoning).

Fact sheets		Procedure aids
CHILD • Pain • Procedural sedation • Vitals signs • WETBAG ANTIDOTES • Naloxone and Flumazenil CHOCK • Push-dose pressor • Infusion pump doses OTHER • Consent • NEWS2 • RSI	EKG • Wide QRS tachycardia • Sgarbossa criteria • Hyperacute T-waves • Lewis lead • Posterior MI • Reciprocal changes III & aVL ULTRASOUND • Pulmonary embolism	CARDIAC ARREST AND LEVEL 1 TRAUMA • Thoracotomy • Perimortem sectio AIRWAY • Upper airway obstruction • Cricothyrotomy • Jet ventilation CIRCULATION • Intraosseous needle • Cardioversion • Esophageal-EKG • External pacing DISABILITY • Lateral canthotomy • Lumbar puncture • Gastric lavage

Platform

A single-board computer (Raspberry Pi 5 4GB) loaded with the EM is locked in a box located under the pulpit at each of the three locations in the resuscitation room where priority one patients are managed. Checklists are accessed by the documentation nurse using a tablet computer mounted on a pillar extending from the pulpit to the ceiling. The Raspberry Pi is connected to the tablet using an ethernet cable, and the tablet computer is connected by cable to a large screen (90 x 47 cm; 35 x 19 inch) hanging from the ceiling that displays the checklists for the whole team (Figure 27).

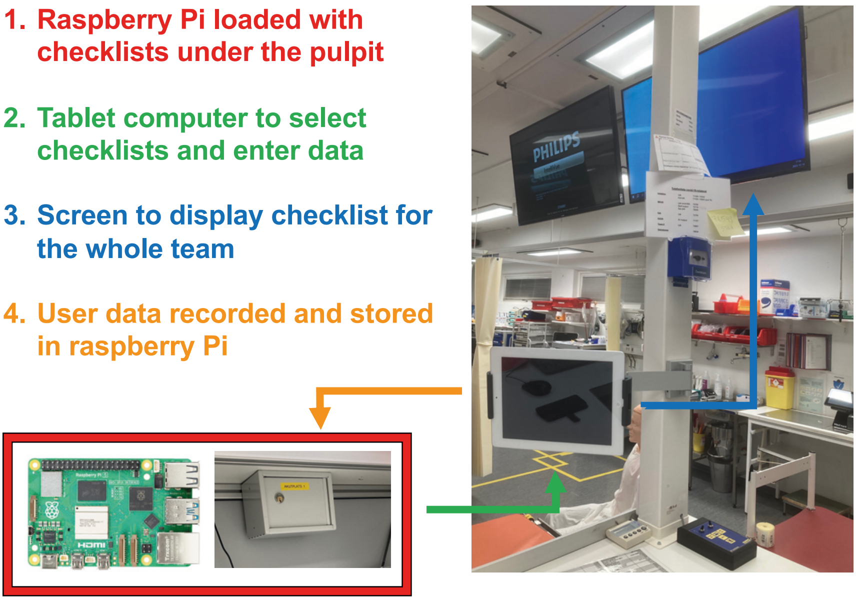


Figure 27: Hardware for Study III

1. A Raspberry Pi is locked inside a box mounted under the documentation pulpit at each of the three locations in the resuscitation room where priority one patients are managed. The computer is loaded with the checklists. 2. The reader accesses the checklists via a tablet computer mounted on a pillar stretching from the pulpit to the ceiling. 3. A large screen handing from the ceiling displays the checklists for the whole team. 4. User data is registered in the Raspberry Pi.

The checklists are written in TextEdit. A program written in JavaScript displays the checklist text according to the generic format and enables navigation between checklists. The program also encrypts the patient's personal identification number and translates user data into an Excel spreadsheet that is stored in the Raspberry Pi.

Pathways

Users navigate between menus and checklists/fact sheets/procedure aids using hyperlinks. Selecting the home icon on each page hyperlinks back to the main menu. A search box at the bottom of each page provides a list of checklists/fact sheets/procedure aids beginning with the letters entered (Figure 28).

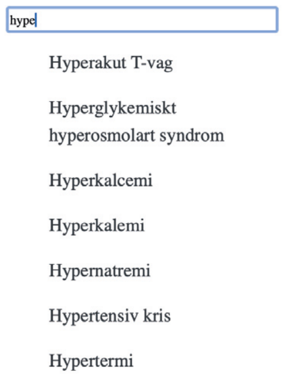


Figure 28: Search function

Protocol

Designing a study to evaluate crisis checklists during the management of real patients in the resuscitation room requires addressing several catch-22s.

1-Use vs Evidence. One cannot determine whether or when crisis checklists improve the team management of priority one patients in the resuscitation room unless the checklists are used during clinical practice and their impact evaluated. Yet there is currently no evidence that crisis checklists improve the team management of unselected priority one patients in the resuscitation room, hence their use cannot be strongly recommended, let alone mandated.

2-Proper Use vs Frequency of Use. The value of a tool cannot be determined if the tool is not used properly. Familiarity with and regular use are requisites for proper tool use. Yet crises are by nature events that seldom occur, and hence crisis checklists can be expected to be seldom used. In addition, team members are likely to shy away from using unfamiliar tools during high-stakes events. Finally, the large number of personnel that are involved in the management of priority one patients makes it logistically impossible to ensure that all personnel are familiar with a new tool.

3-Do-Confirm vs Read-Do. To assess the value-added of a checklist beyond usual care, the checklist should be used as Do-Confirm. Yet crises are situations where Read-Do checklist use or a rapid transition from Do-Confirm to Read-Do use is arguably more conducive to effective management.

Resolving these catch-22s informs the study's protocol for EM use.

1-Use vs Evidence. In the study, checklist use is recommended but not mandatory. The documentation nurse is tasked with asking the team which checklist to display and to read each item out loud should checklists be displayed. The physician has the mandate to request that no checklists be displayed, to have their use curtailed or to override the content in the checklist.

2-Proper Use vs Frequency of Use. The documentation nurse is tasked with asking the team, during the management of each priority one patient, which checklist to display. Personnel involved in the management of priority one patients will thereby familiarize themselves with the EM during the course of the study. Cases for evaluation of the degree of indication of interventions performed thanks to the checklists will be selected from the end of the six-month period. Promoting familiarity with the EM is also done through repeated educational sessions in the resuscitation room, by promoting the EM during clinic meetings, and by making it available through a website served by a node express webserver on a fourth Raspberry Pi 5.

3-Do-Confirm vs Read-Do. The recommended default mode of EM use is Do-Confirm. Given that EM use in the clinical context will initially be unfamiliar, Do-Confirm mode of use will not disrupt initial patient management. Checklist use in Do-Confirm mode allows for evaluating the added value of checklist use. Physicians may also request to use the checklists as Read-Do or in sampling mode. We anticipate that teams may increasingly use the checklists in Read-Do mode or as sampling as they become more familiar with the EM.

Pilot Testing

Study II pilot tested a generic checklist format and some of the diagnosis checklists. Further pilot testing and iterative improvement of the EM is carried out during in-situ team-training prior to study onset.

Tasks

The tasks in this study consist of the management of consecutive priority one patients during a six-month period.

Interventions

Promotion

The study is preceded by an educational campaign about the potential benefits of EM use, the protocol, demonstrations of the EM and trialing its use during in-situ team-training.

Non-Randomized Intervention

Randomized controlled trials are the best way to determine the impact of an intervention. According to this study design, half of the critically ill patients would be managed without crisis checklist access. It is ethically problematic to deprive teams and patients of a tool designed and promoted to facilitate the provision of key interventions for critically ill patients, especially if teams have started to familiarize themselves with the tool. Depriving teams of the tool 50% of the time would also impact on the personnel's ability to familiarize themselves with the tool and its use. For these reasons, we opted for a non-randomized controlled trial where the checklists are made available to all teams throughout the whole six-month period. Patients for whom the checklist was used as Do-Confirm will be compared with matched patients for whom the checklist was not used, with the recognition that confounders may account for associations between checklist access and measures performed.

EM Use

The documentation nurse logs in to the EM and enters the patient's identification number which is directly encrypted. The main menu is then displayed on the large screen hanging from the ceiling. When the physician appears to have come to a juncture where the management plan is established, the documentation nurse asks which checklists to display. If checklists are displayed, the nurse reads through each item. If checklists are used in Do-Confirm mode, the nurse selects the green, gold or red button depending on whether the measure is indicated or not/has already been done or not. If no checklists are displayed despite logging in, the nurse selects among several potential reasons for this being the case.

Subjective Checklist Evaluation

Prior to logging out, the documentation nurse records the team's evaluation of the EM's value on a Likert scale of 1-6. The nurse also indicates whether the EM was used in Do-Confirm or Read-Do mode.

Requesting Contact with Investigators

Teams are encouraged to request contact with the trial investigators to discuss specific cases where EM use had a positive or detrimental effect on team performance. In such cases, a structured interview is carried out to record the pertinent features of the case, the perceived impact of EM use on patient care and team performance, and suggestions for EM improvement.

Observations, Outcomes & Statistics

Frequency of Checklist Use and Mode of Use

The pages viewed during EM use and whether the EM is used in Do-Confirm mode are automatically recorded. Descriptive statistics will be used to report observed findings, and how use evolves over the six-month study period.

Degree of Indication of Interventions Performed Thanks to EM Use

The final fifty cases where the EM was used in Do-Confirm mode and where additional measures were performed thanks to the EM will be selected. Three specialists in Emergency Medicine will be provided with the medical journal documenting the clinical context and the management in the resuscitation room. The specialists will be provided with a list of interventions performed, but without information regarding whether the interventions were carried out before or thanks to EM use. Based on the available clinical context, the three physicians will determine whether each intervention was deemed clearly indicated, of neutral indication or clearly not indicated. The main outcome measures are the frequencies of additional measures that are clearly indicated, of neutral indication and clearly not indicated.

Sample Size Calculation

To calculate sample size, we reasoned that a clinically meaningful frequency for additional clearly indicated interventions is ≥ 10%. If EM use barely leads to any additional interventions that are clearly indicated, it will only consume time and lead to interventions that do not add value to patient care. We assumed that half of the cases selected for review would include one additional intervention and that half would include two. We do not have any data regarding the prevalence of indicated additional interventions nor their standard deviation. Statistical analyses showed that if the true rate of additional clearly indicated interventions is ≥ 21%, then the number of cases that need to be reviewed to exclude the null hypothesis that the rate is < 10% with a type 1 error probability of 5% and a power of 80% is 50.

Indication of Unperformed EM-Suggested Interventions

In addition to the fifty cases where the EM was used in Do-Confirm mode, fifty matched cases where the EM was not used during the study period and fifty matched cases from the six-month period prior to EM-implementation will be identified. Interventions that would have been performed had the EM been used will be noted. All interventions—those performed and those that would have been performed had the EM been used—will be graded for degree of indication by three specialists as described above.

Subjective Checklist Evaluation

Descriptive statistics will be used to analyze the answers to the team's subjective assessment of the EM's value.

Interviews

Data and themes extracted from the interviews will be presented using descriptive statistics.

Ethical Considerations

Patients

All published simulation-based studies of EM's have reported that EM use improves the number of indicated interventions performed without impeding workflow. According to the study protocol, the default mode of EM use is Do-Confirm, i.e. standard initial management without EM use. The physician has the mandate to interrupt EM use at any time and depart from the EM content if indicated. For these reasons, the risk that priority one patients would suffer from EM use is deemed exceedingly low. Priority one patients are not capable of providing informed consent for interventions performed in the resuscitation room. The Swedish Ethical Review Authority approved waiving requiring informed consent from priority one patients for study enrolment (Dnr 2022-01896-01). Information about the study will be available in the resuscitation room and provided to patients and relatives upon request. The patients' personal identification numbers are encrypted and stored in locked boxes.

Personnel

The identities of the team members managing priority one patients are not recorded, aside from the identity of the nurse logging in to the EM. Formal complaints regarding patient management will not be triggered from chart reviews. The names of personnel involved in the cases that lead to structured interviews will not be recorded. Study II showed that personnel working in Lund's ED overwhelmingly valued checklist access during the management of priority one cases. An interview-based study of EM use in the clinical context reported decreased stress among personnel [13]. For these reasons, the risks for personnel of participating in the study are deemed minimal.

Discussion

Validity

Study III is a non-randomized intervention trial. We will identify cases where the EM was used in Do-Confirm mode and matched cases where the EM was available but not used. Confounding variables that might or might not transpire from the medical journals will limit comparisons between these two groups of cases.

Relevance

Relevant Tasks?

Study III is a T2-translational research study, i.e. performed within the context of actual patient care.

Relevant Outcomes for the Patient?

The degree of indication of the interventions performed thanks to EM use will not be based on whether the interventions feature on the checklist, but rather on the consensus opinion of three specialists in Emergency Medicine based on the available clinical context. One of these specialists will have been involved in the development of the EM, whereas the other two will be blinded to EM content. The study is not designed nor powered to assess whether EM use impacts on morbidity or mortality.

Relevant Outcomes for the Personnel?

The team's subjective assessment of EM-value will be recorded over the six-month study period, and personnel will have the opportunity to voice concerns about the EM throughout the study.

Generalizability

Setting

The results of this study will be generalizable to other ED's providing care for patients with similar characteristics.

Personnel

The results of this study will be generalizable to other ED's where resuscitation teams have the same personnel characteristics, in particular other ED's in Skåne.

Tool

Given that the ED is digital, it can easily be tailored to other ED's.

Conclusions

Overall Conclusion

The impact of crisis checklists on resuscitation team performance is contingent upon the content of the checklists, how they are used, the tasks to be performed, the personnel performing the tasks and the setting where the tasks are performed.

Study I: Specific Conclusions

I Impediments to the performance of emergency interventions in primary care centers consist of difficulty using equipment (e.g. the adrenalin auto-injector) and finding medications (e.g. glucose) that are seldom used, delay in considering hypoglycemia as a cause of decreased level of consciousness, and incorrect dosage of emergency medications (adrenalin and glucose).

II Provision of unfamiliar checklists without an assigned reader does not improve performance by primary care personnel during crises simulated in the primary care setting.

Study II: Specific Conclusions

I Use of medical crisis checklists with an assigned reader leads to a doubling of indicated interventions performed by resuscitation teams during medical crises simulated in resuscitation rooms.

Future Perspective

Multicenter Study and Crowdsourcing

I Multicenter study of the implementation of a tailored EM in other EDs in Skåne, building on lessons learned from Study III.

II EM development through crowdsourcing.

Synergy with Simulations

Goldhaber-Fiebert and Howard write: "if emergency manuals are to be useful during critical events in ORs, then broad integration into simulation trainings for clinicians will help significantly" [8]. Arriaga et al speculates that the "integration of checklist use with simultaneous team training may augment our observed effect" [2]. Simulations are recommended for testing cognitive aids and teaching their use [78, 79]. In-situ simulations identify latent threats [164].

Based on the above, future endeavors will include:

I Simulation-training with/T1-translational research on EM use in the simulation center, to familiarize residents with the manual, observe how it is used, and evaluate potential improvements.

II Simulation-training with/T1-translational research on EM use in the resuscitation room, to familiarize resuscitation teams with the manual, identify latent threats, and evaluate potential improvements.

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