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To the COVID Heroes,

Everyday Heroes

Introduction

The Trauma

Epidemiology and Etiopathogenesis

In the course of human history, trauma has represented, together with infectious diseases, the most frequent cause of early death and disability. Even today it continues to be the main cause of death and disability in the first four decades of life [1]. The impact that the trauma has had in the health sector has further increased following the introduction and subsequent widespread use of cars and motorcycles in developing countries [2]. In addition, the economic costs, both directly related to health interventions and considered as a loss of productivity within society, are estimated in the order of billions of dollars [1]. Death due to traumatic events follows a three-phase temporal distribution. Deaths at the site of the event are typically due to catastrophic physical injuries: rupture of the aorta, massive hemorrhage and brain injuries, as well as rupture and complete obstruction of the airways, are all main causes of immediate death. These injuries can be prevented through control and prevention programs [1]. The second peak concerns patients who survive the initial event but who die during the first day due to thoracic-pulmonary and hemorrhagic complications [1]. Finally, those who survive the first day may still die later due to severe brain trauma or multi-organ dysfunction syndromes (MODS) or sepsis [3, 4]. Effective initial resuscitation, associated with a reduction in the diagnostic time of injuries and complications, can improve survival. Modern trauma management systems have reduced the numbers of deaths and disabilities due to trauma and shifted this trimodal distribution, minimizing second and third peak deaths through progressive standardization of the identification and management of potentially fatal injuries and complications [1].

Trauma Modality

Trauma can be intentional or unintentional and can be due to blunt force, blast and / or penetrating mechanisms. Knowledge of the circumstances that led to the trauma is helpful in finding hidden presentation injuries. Patients who have a certain mechanism of damage, such as blunt trauma from a car accident, may actually also hide secondary insult mechanisms, such as the ingestion of psychotropic substances for recreational or suicidal purposes. Alcohol intake, for example, is a finding that is frequently accompanied by traumatic events upon presentation [1]. The environment is also an important risk factor at presentation: hypothermia, one of the reversible causes of cardiac arrest, must be suspected in the event of prolonged pre-hospital times, especially in cold climates. Inhalation of smoke and carbon monoxide poisoning are often found in patients extracted from closed environments in the event of a fire [1]. The blunt mechanisms have rather characteristic damage patterns: falls from a height of 5 meters or more are often associated with injuries to the limbs, spine and solid organs; falls from stairs are associated with trauma of the upper limbs, face, skull and neck; pedestrians hit by cars have a high risk of having head and neck injuries (children more often have isolated trauma to the skull; with increasing age injuries to the extremities become more frequent); in frontal collisions the injuries tend to be due to rapid deceleration and direct impact; in elderly subjects, where the morbidity and mortality of lesions increase significantly [5], the clinical presentation frequently includes intracranial hemorrhages as well as lesions to the chest and extremities [1]. In addition to trauma to the brain parenchyma, facial trauma, contusive ruptures of the aorta and injuries to internal organs are also common. Side impact collisions are generally associated with injury to parenchymatous organs, limb and rib fractures, and chest trauma on the affected side [6-8]. Injuries resulting from an explosion can consist of barotraumas involving the middle ear, lungs and hollow viscera, penetrating injuries caused by fragments of splinter and blunt force trauma

in the event that the victim is hit by objects or is thrown towards them by the force of the explosion [9]. Penetrating traumas vary according to the speed of the bullet: knives and guns cause injuries along the trajectory of launching or shooting, while hunting and assault rifles are also responsible for cavitation phenomena due to the associated pressure waves. In the latter case, the damage can also extend to several centimeters away from the trajectory of the bullet and consequently the wounds increase in severity [10]. While it is often easy to recognize the traumatic origin of the injuries reported by patients, the same cannot be said for the definition of the severity of the injuries themselves. In literature, the definitions of "critical injury", "severe injury" and "critically ill patient with multiple injuries" have often been used interchangeably due to their imprecise definition. To overcome this indeterminacy of the term "polytrauma" in 2014 Pape et al. [11] organized a consensus conference from which the following definition of polytrauma was derived (Berlin Definition):

"Presence of an Injury Severity Score (ISS) >15, an Abbreviated Injury Scale (AIS) score ≥ 3 points in at least two different regions of the body and at least one of the following pathological conditions:

- hypotension defined as a systolic blood pressure ≤ 90 mmHg;*
- coma defined as a Glasgow Coma Scale ≤ 8 ;*
- acidosis defined as a Base Excess (BE) ≤ -6 ;*
- coagulopathy defined as PTT ≥ 40 seconds or INR ≥ 1.4 ;*
- age ≥ 70 years" (Fig. 1).*

Injury Severity Score (ISS)

| Body Region | Score | Abbreviated Injury Scale (AIS) |
|--------------------|-------|--------------------------------|
| Head | 1 | Minor |
| Face | | |
| Neck | 2 | Moderate |
| Thorax | | |
| Abdomen | 3 | Serious |
| Spine | | |
| Upper Extremity | 4 | Severe |
| Lower Extremity | | |
| External and other | 5 | Critical |
| | 6 | Unsurvivable |

All injuries are assigned from an internationally recognised dictionary that describes over 2000 injuries. Multiple injuries are scored by adding together the squares of the three highest AIS scores.

Figure 1. *Injury Severity Score and Abbreviated Injury Scale*

However, this definition of polytrauma presents a main limitation: it cannot be applied until the end of the secondary survey when the reports of all laboratory and radiological investigations are available and thus allow an accurate definition of the injuries reported.

Approach to the Patient with Polytrauma

According to the guidelines, the approach to the patient victim of trauma must follow the acronym ABCDE which consists of:

-*Airway*, the assessment and management of airway patency, with particular attention to the protection of the cervical spine when necessary;

-*Breathing*, the assessment and management of oxygenation and ventilation;

-*Circulation*, the assessment and management of hemorrhagic shock states and cardiovascular lesions;

-*Disability*, the assessment and management of neurological lesions;

-*Exposure*, the assessment and management of body temperature and back and extremity injuries [12].

The order of priority in ABCDE is dictated by the urgency of the treatment as injuries of "A" can lead to death of the patient more quickly than injuries of "B" and so on. It should be kept in mind that multiple potentially lethal injuries can coexist simultaneously in polytrauma.

Primary Survey

The initial assessment and the start of resuscitation procedures should take place within 1-2 minutes and be completed in their entirety within 15 minutes [13-15].

A classic process in the approach to a patient with polytrauma is:

-Ask the patient's name, administer oxygen, monitor the patient. Ensure that the cervical spine is immobilized where appropriate;

-Inspect and auscultate the chest, perform percussion and palpation, detect respiratory rate (RR) and partial oxygen saturation (SpO₂);

-Palpate an arterial pulse to determine its frequency and amplitude. Collect vital signs such as heart rate (HR), blood pressure (BP). Evaluate

external hemorrhages, fractures of the femurs and pelvis, evaluate internal thoraco-abdominal hemorrhages by bedside Extended Focused Assessment with Sonography for Trauma (E-FAST). Ask for the positioning of 2 large-caliber peripheral venous accesses;

-Evaluate symmetry and light reaction of the patient's pupils. Estimate the Glasgow Coma Scale (GCS) score; evaluate blood sugar.

-Expose the patient by removing clothing and evaluate back and extremities; measure the patient's body temperature. It is possible to carry out manipulation maneuvers, remove the stretcher if necessary, and perform a rectal examination when indicated [12]. The most useful investigation techniques to be performed promptly are chest radiographic examination, for the identification of any haemo-pneumothorax, and blood gas analysis, which provides an immediate estimate of the adequacy of oxygenation and ventilation, the extent of base deficiency and circulating levels of lactate and hemoglobin. The E-FAST examination [16] is very useful in the search for possible causes of bleeding and in the identification of pneumothorax, haemothorax and cardiac tamponade in patients in shock [12]. In the case of severe blunt trauma, performing a radiographic examination of the pelvis is extremely useful for screening for "open book" pelvic fractures and/or vertical fractures, both of which are important sources of bleeding [17]. Blood levels of ethanol are generally required routinely in the assessment of impaired consciousness. Drug and toxicological screening can be very useful at this stage [12].

Airways (A)

The investigations regarding "A" consist in the evaluation and eventual management of the patency of the airways, in the continuation or beginning of O₂ administration, in the control of the correct positioning of the cervical collar and finally in the rapid evaluation of the parts of the neck not covered by the collar. As already stated, airway management is the top priority: patients with airway obstruction can die within minutes. Upon presentation, the airway obstruction can be obvious but also concealed, especially in conditions of imminent occlusion due, for example, to inhalation injuries in a closed space during a fire. The obstruction can be mechanical, due to injury or swelling of soft tissues, or functional, associated with reduced levels of consciousness up to coma [18]. In all conditions in which cervical injuries are suspected or in any case possible, it is necessary to proceed with the immobilization of the cervical spine: in this case, these situations can occur virtually in all blunt trauma with significant injury mechanism, penetrating trauma whose trajectory can involve the cervical spine, penetrating trauma associated with blunt injuries of unknown dynamic of the accident, blast injuries in which multiple damage mechanisms are evident and coma conditions if a traumatic cause is suspected [12]. The best approach is to ask the patient for his/her name: his/her ability to respond can indicate a patent airway, adequate ventilation, adequate cerebral perfusion and absence of severe brain injury. The administration of oxygen must be evaluated in all cases [12]. In patients with impending airway obstruction, the following rules should be followed:

-GCS \leq 8: proceed with orotracheal intubation;

-GCS 9-12 with inhalation injuries and cervical hematoma: evaluate the experience of the healthcare professional, the assistance and equipment available and the transport conditions before planning a definitive or temporary intubation. Once the decision to intubate has been made, it is necessary to assess the expected difficulty: It should be remembered

that immobilization of the cervical spine makes intubation attempts more complicated, often requiring devices such as video laryngoscopes. The application of these tools in intubation processes is of critical importance in complicated cases [12]. A "simple" airway is typically characterized by a wide mouth opening, a normal sized and well placed dentition, large cheeks and jaw, and no soft tissue lesions and / or swelling on the face and neck. Predictors of "difficult airway" (i.e. difficult access to the airways) are reduced size of the mouth, cheeks and jaw, increased dental "overbite" and trauma to the face and neck. The acronym LEMON (Fig. 2) helps to remember the factors to be controlled:

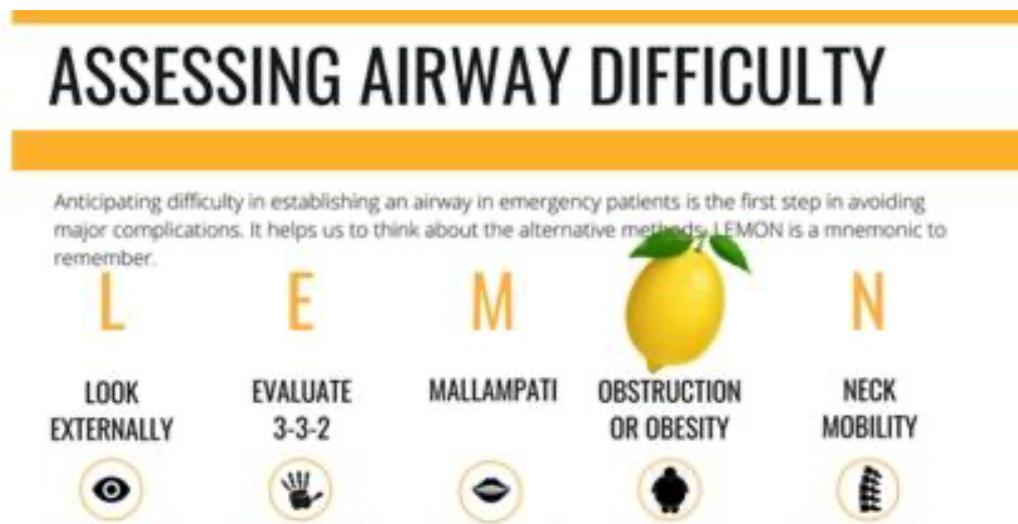


Figure 2. "LEMON" method for assessing airway difficulty

- “Look externally”, observe the aforementioned external predictors of difficult intubation;
- “Evaluate”, to evaluate anatomical distances between upper and lower incisors, between hyoid bone and chin, between thyroid shield and floor of the mouth;
- “Mallampati Score”, classification based on the distance between the base of the tongue and the palate (Fig. 3);
- “Obstruction" or “Obesity”;
- “Neck mobility” [12].



Figure 3. *Mallampati Evaluation for airway difficulty*

Where difficult intubation is suspected, delaying by carrying out ventilation with a balloon and oxygen is the next step while waiting for the arrival of expert personnel [19]. The instruments that can be used include the “gum elastic bougie”, the laryngeal mask, the fiber optic bronchoscope and video laryngoscopy. Regardless of the approach technique, if intubation attempts fail and the patient desaturates it is necessary to proceed immediately towards surgical intubation [12].

After carrying out the intubation, it is necessary to confirm its correct positioning by following the five points:

- Observe the symmetrical expansion of the chest;
- Auscultate lung sounds;
- Feeling the chest wall by checking the symmetry of the expansion;
- Oximetry to check oxygenation;
- Capnometry to check ventilation [12].

Breathing (B)

After carrying out the intubation or in any case after starting a ventilation, an assessment of the chest must be started by observing, touching and listening to the chest, counting the respiratory rate, observing the saturation and capnometry [12]. The goal is to confirm the bilateral presence of thoracic breathing sounds. Oximetry and capnometry are very useful. If breath sounds are absent, vital signs and pulse oximeter should be checked; immediate chest decompression is required in case of hypotension and desaturation. Massive pneumothorax can develop in spontaneously breathing patients; pneumothorax causing mediastinal shifting is likely in patients receiving positive pressure ventilation [12]. In the case of an intubated patient with no respiratory noises on the left, it is necessary to confirm that the cause is not intubation in the right main bronchus, by checking the position of the endotracheal tube and retracting it. If breathing noises are absent and the patient is hypotensive and rapidly desaturates, needle decompression at the level of the fifth intercostal space on the middle axilla and the placement of a 28-36 French thoracic drain is indicated. The Extended Focused Assessment Sonography for Trauma in expert hands is a useful test for identifying haemo-pneumothorax, pulmonary contusions and any incorrect esophageal intubation [20]. The thoracic drainages must be inserted with sterile technique to prevent the onset of empyema [12]. Bleeding greater than 1500 ml or 200 ml/h for four consecutive hours or more is an indication for thoracotomy. Persistent evidence of shock

and extensive haemothorax on E-FAST / Rx are also indicated for surgery [12]. The X-ray examination can help identify occult pneumothoraces, rib, clavicular, scapular and vertebral fractures, mediastinal expansion, pneumomediastinum, pulmonary contusions, diaphragmatic ruptures and subcutaneous emphysema [12].

Circulation (C)

The evaluation of the circulation begins with the assessment of any active external bleeding and then moves on to the evaluation of the color and skin temperature, of the capillary refill time, of the presence and amplitude of the pulse, of the heart rate, of the arterial pressure, and of the palpation of the abdomen of the pelvis. Pelvic binding is indicated in case of suspected traumatic involvement at this level [12]. Most patients in shock following trauma will have a bleeding cause but other causes of obstructive shock such as tension pneumothorax, distributive shock from spinal injury, cardiogenic shock from acute coronary syndrome or traumatic cardiac tamponade need to be investigated. In this first phase it is necessary, if not already performed on the territory, the positioning of two large caliber venous accesses. If this is not possible we should consider an intraosseous infusion, the insertion of a central venous catheter or the execution of a venous cutdown. Once the venous routes have been secured, it is necessary to take laboratory blood samples with cross-tests, standard laboratory tests and, where available, rotational thromboelastometry (ROTEM) or thromboelastography (TEG) to guide in a targeted way a possible massive transfusion. A limited infusion of crystalloids should be started, but the main goal is to identify and stop bleeding or correct other causes of shock. In conditions of blunt trauma with head injuries, hypotension worsens the outcome and should be prevented [12]. In penetrating trauma with ongoing bleeding, forced rehydration carried out before surgical control of bleeding can exacerbate the bleeding and coagulopathy, worsening the outcome [12]. Hypotension is a late sign of shock and in the case of hemorrhage it

generally does not manifest itself until one third of the volume of circulating blood is lost. Early signs and symptoms are anxiety, confusion, tachycardia, tachypnea, and reduced pulse [12]. The goal is to find and correct the cause of shock. If it is a question of bleeding, the first goal is to stop the bleeding. In addition to external bleeding, occult blood loss occurs in the chest, pelvis, abdomen and long bones. To highlight the bleeding sources, it is possible to use, in addition to the clinic, chest x-ray, pelvic x-ray, eFAST. If the abdominal FAST exam is positive, the treatment is immediate laparotomy in damage control mode. However, FAST is not specific for organ injury, but only identifies the presence of free intraperitoneal fluids. Relatively stable patients are therefore candidates for thoraco-abdominal CT to rule out occult lesions. In the event of a long bone fracture, immobilization and treatment with fluids are definitive interventions [21]. Pelvic fractures represent a particular challenge in emergencies: the three patterns of damage affecting this district are represented by lateral trauma with fracture of the pubic branches, “open book” fractures and vertical shear injuries. Lateral compression fractures involve the acetabulum, the urethra and the extraperitoneal portion of the bladder beyond the pubic branches, but are rarely associated with massive bleeding; “Open book” fractures occur frequently with major hemorrhages and consequently compression of the region by devices with pelvis stabilization function is recommended; vertical shear fractures generally occur in conjunction with hemorrhagic shock [12]. Early orthopedic consultation is important in these cases; if the state of shock is present, the best approach must be decided between surgery with packing and stabilization of the pelvis and then angioembolization or immediate embolization. CT angiography will be essential for choosing the most appropriate treatment. The choice can be difficult, in fact, while angiography is particularly effective in treating retroperitoneal arterial hemorrhages and parenchymatous organs, it cannot stop the venous ones. If the patient is in a deep state of shock, they should go directly to the operating room [12].

Patients with neurogenic shock should initially receive 1-2 L of bolus crystalloids and subsequently be monitored in the ICU; patients with coexisting cardiac pathology (myocardial infarction or contusion) may also require inotropic drugs [12].

Disability (D)

A reduction in the level of consciousness may indicate a decrease in oxygenation and / or cerebral perfusion or it can be caused by hypoglycemia, alcohol, sedatives and other drugs. Once these factors are excluded, the alteration in the level of consciousness must be attributed to traumatic lesions of the central nervous system [12]. The assessment of Disability (D) consists in assessing the presence of neurological lesions, especially those that are life-threatening such as severe brain damage. A quick inspection can be performed by checking the Glasgow Coma Scale (GCS, Fig 4), pupil diameter, photoreactivity and evaluation of the sensitivity and motility of the 4 limbs (and any sensory level on the soma).



Figure 4. Glasgow Coma Scale (GCS) for consciousness assessment

Severe brain lesions are characterized by GCS equal to or less than 8; asymmetrical pupils may indicate mass effect with ongoing transtentorial herniation. The presence of any of the two requires prompt neurosurgical consultation. The most effective treatment consists in preserving cerebral vitality by maintaining oxygenation and perfusion, avoiding or correcting conditions of hypotension. The use of mannitol in doses of 0.5-2g / kg can be effective in temporarily delaying swelling and brain herniation, as well as moderate hyperventilation [12]. Traumatic brain injuries can be classified into: severe (GCS \leq 8), moderate (GCS 9-12) and mild (GCS 13-15) [12]. A head CT scan should be done as soon as possible and priority goes to treatment of possible bleeding. It is also required in patients with signs of skull fractures, GCS $<$ 15 for more than 2 hours, over 65 years of age with loss of consciousness, amnesia, disorientation or vomiting. It is important to pay particular attention to imaging in those who have amnesia for more than 30 minutes [22-23]. The spine, in its cervical, thoracic and lumbar tracts, must be immobilized as long as spinal injuries are not ruled out. In many cases of blunt or penetrating injuries, radiological investigations must be performed. CT is not required in all patients but it is of enormous value in subjects with higher dynamic trauma. If CT examinations of the thorax and abdomen / pelvis are not performed, radiographs of these areas must still be performed [12]. In the case of patients without trauma with greater dynamics, the Canadian C-Spine Rule [24] provides guidelines on when to request X-ray of the cervical spine and when the clinical examination is sufficient. In the latter case, the patient must be alert and cooperative, must not present pain in the back and must be able to comfortably rotate, extend and flex the neck in an active manner [25].

Exposure (E)

Finally, it is necessary to check the musculoskeletal system and the extremities. The clothes must be removed as the patient must be assessed completely undressed, to allow a complete and easy exploration of the body surface. At the first evaluation, the priority is to identify long bone fractures. It is also important to evaluate body temperature as hypothermia could worsen coagulopathy and therefore must be evaluated and treated [12]. The management of limb fractures consists of splinting and immobilization. Open fractures require antibiotic and tetanus prophylaxis as well as orthopedic consultation. Dislocated joints should be recognized and reduced directly in the Shock Room [26-27]. Musculoskeletal injuries in patients with polytrauma are often not recognized during initial investigations but at secondary or tertiary evaluation. Re-assessments, particularly in conditions of improvement of initially compromised levels of consciousness, will be able to detect these lesions and prevent morbidity from late diagnosis [12]. After removing the clothes and completing the evaluation, it is necessary to protect the patient from hypothermia by using thermal blankets or external heating systems [12].

Complexity and Error in Medicine

Team approach

In seriously ill or injured patients, early identification and treatment of life-threatening conditions greatly improve survival rates [28-29]. Because trauma often affects multiple areas of the body simultaneously, systematic initial assessment of injured patients is crucial for the timely detection and treatment of immediately life-threatening conditions that could otherwise be overlooked [30]. Inefficient assistance during initial resuscitation can compromise the "Golden Hour", the period of time in which rapid interventions can determine the patient's survival (Fig. 5). The term Golden Hour was coined around 1975 by Dr. R. Adams Cowley, founder of the Shock Trauma Institute in Baltimore. Cowley believed that the events in the first hour after the traumatic event were strong determinants of the patient's chances of survival. In fact, several studies have shown that the speed of rescue is directly correlated with a better outcome [31-37].

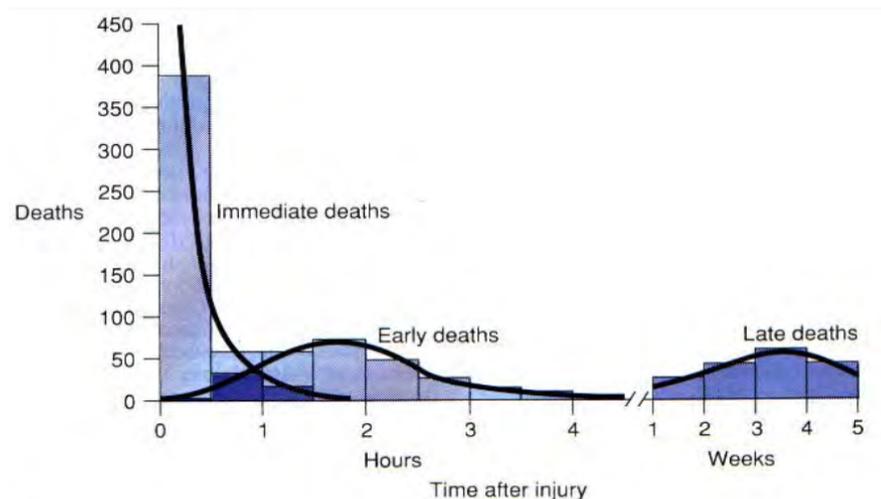


Figure 5. Relationship between number of deaths and time elapsed since trauma

From this graph (Fig. 5) we can see that over 70% of trauma deaths occur within the first 4 hours. Many of these deaths are attributable to avoidable causes or related to clinical and organizational errors (for example inadequacy of therapeutic decisions, incorrect diagnostic choices in terms and methods, underestimation of the severity of the injuries, incorrect interpretation of the tests carried out, technical errors). In order to reduce this risk as much as possible, in addition to guaranteeing the best treatment on site, it is essential that the evaluation and the first hospital management of the seriously injured patient are entrusted to a well-organized multi-specialist team. The efficiency of the latter depends not only on the technical skills of the individuals, but above all on their coordination and structured communication within and outside the team itself. It is therefore necessary that all professionals involved in the acute management of the polytrauma patient share a structured, effective training path, consistent with the objectives of clinical practice and which prepares for teamwork. Advanced Trauma Life Support (ATLS) [12], introduced in the United States in 1980 by the American College of Surgeons, standardized a safe approach to treating trauma and introduced a common language. According to the guidelines of the ATLS, the goal is to first manage and treat injuries that are immediately dangerous to the patient's life without causing further harm [12]. In Europe, a course linked to the European Resuscitation Council called "European Trauma Course" (ETC) has been introduced in recent years to meet the aforementioned needs [38]. Since then, trauma management has evolved towards a team approach, the so-called "trauma team", which involves the presence of several specialists from different backgrounds, with different skills, at the same time at the patient's bed, coordinated by a "team leader".

A team is defined as “a small number of people with complementary skills who are committed to a common purpose, performance goals, and approach for which they hold themselves mutually accountable” [39]. Weick and Roberts [40] defined medical teams as a “system of mutually

interacting interdependent members and technology with a shared goal of patient care.” According to Weinger, effective teams possess five characteristics of success (the five Cs): commitment, common goals, competence, consistency (of performance), and communication [41]. As we can see, only 20% of these characteristics are technical aspects. In modern trauma teams, multiple team members have dedicated roles and simultaneously perform separate patient-care tasks [42]. While more efficient, and leading to more rapid resuscitation, this kind of horizontal structure requires much better team coordination, leadership, and organization [42-44]. Studies in advanced trauma units have highlighted the difficulties of attaining effective teamwork, noting team breakdowns under dynamic conditions [45].

Non-Technical Skills

As patient safety has also become one of the key quality indicators in healthcare, there has been an analysis of patterns to reveal that Human Factors have been responsible for three quarters of errors in healthcare. Human Factors refer to environmental, organizational and job factors, and human and individual characteristics which influence behavior at work. Non-technical skills (NTS) are part of the human factors and specifically examine the interaction of team members.

NTS can be defined as *a constellation of cognitive and social skills, exhibited by individuals and teams, needed to reduce error and improve human performance in complex systems*. NTS have been described as generic ‘life-skills’ that can be applied across all technical domains [46]; they are deemed to be ‘non-technical’, in that they have traditionally resided outside most formal technical education curricula. While the importance of human factors in the performance of technical tasks has been appreciated for over 80 years, NTS as a formal training system is derived from aviation Crew Resource Management (originally called Cockpit Resource Management). CRM was first adopted by United Airlines in 1981 [47] after a series of high-profile air crashes in the late 1970s, in which human elements such as poor communication, teamwork and situation awareness were identified as key contributing factors. CRM is now fully integrated into all commercial pilot training worldwide; in a constant state of evolution, it is currently in its sixth generation [48].

In healthcare, it was not until the 1990s that the significance of human factors in patient safety became more widely publicized [49], coinciding with the rise in medical simulation. In 1999, an emergency medicine team training project, MedTeams, was launched [50]. The following year two landmark reports were published within weeks of each other: *To Err is Human* in the USA [51] and *An Organisation with a Memory* in the UK [52]. These inspired a burgeoning of research into applied

human factors in healthcare. Flin pioneered a behavioral marker system known as Anesthetists' NTS (ANTS) [53], followed by NTS for Surgeons (NOTTS) [54]. The disciplines of anesthesia, critical care and surgery remain at the forefront of NTS training in medicine.

NTS include the interpersonal skills of communication, leadership and followership (role responsibility) and the cognitive skills of decision-making and situation awareness.

Communication

'Effective communication' is recognized as a core non-technical skill [55], a means to provide knowledge, institute relationships, establish predictable behavior patterns, and as a vital component for leadership and team coordination [56]. It is crucial for delivering high-quality healthcare and has been acknowledged together with effective teamwork as an essential component for patient safety [56-58]. 'Communication failures' have long been recognized as a leading cause of unintentional patient harm [59]. More recently a report of 2587 sentinel medical adverse events, reviewed by the US Joint Commission over a 3-year period, cited 'communication' as a contributing factor in over 68% of cases [60].

However, 'communication' is a very broad term; pinning down a practical definition is difficult. For the purposes of developing workable patient safety tools, communication can be defined as *the transfer of meaning from one person to another* [61]. In teams comprising health professionals with different backgrounds, roles, training and perspectives on care, the main purpose of communication is to facilitate among team members a *shared mental model* of a situation: the context, the goals, the tasks, the methods to be used, who will do what, etc. (i.e. 'team situation awareness'). Thus, it is important to recognize that 'meaning' is different to 'information' or 'knowledge', and effective communication therefore depends to some extent on the existing level

of situation awareness of individual team members. While effective teamwork requires much more than communication (see below), specific failures in communication can hinder the process of building a shared understanding of the situation between team members, leading to poor performance and errors [62]. It follows that effective communication in healthcare teams can only be the result of dynamic iterative ‘two-way’ processes that lead to an ‘equilibrium of understanding’ among team members [61]. Refining these processes can be seen as the basis for developing better ‘communication skills’. The concept of ‘specific/directed/acknowledged’ communication comes from simulation training [63]. ‘Specific’ refers to speaking clearly and the use of salient unambiguous descriptions, ideally using a ‘controlled vocabulary’ of terms with unique meanings as agreed by a discrete population of practitioners. ‘Directed’ means that information or instructions are explicitly directed to a nominated person. One of the consistent elements of the World Health Organization (WHO) Surgical Safety Checklist is that team members introduce themselves by name and role [64]. A survey of OR teams showed that participants believed that knowing a team member’s name and rank was important not only for team bonding but also for patient safety [65]. ‘Acknowledged’ communication seeks to confirm that what was said was not only heard, but also that what was heard *matches* what was said. In *closed-loop communication*, also known as ‘read-back’ [66], the sender initiates communication, the receiver confirms that the communication has been heard and repeats the content, finally the sender verifies the accuracy of that content including an explicit accuracy check with the recipient [62]. Closed communication loops improve the reliability of communication by having the receiver of communication restate what was said by the sender to confirm understanding [67].

Role Responsibility

We have already said that a team is “a small number of people with complementary skills who are committed to a common purpose, performance goals, and approach for which they hold themselves mutually accountable” [39]. The concept of leadership is complex, in broad terms a leader is someone chosen (by the team itself or by others) to exercise authority and influence over the team. While good ‘followership’ requires a cooperative attitude, the followers need to know when and how to be assertive, even to their leader, when there is an overt threat to patient safety [61]. In emergency medicine the team facing a critical patient often is a multidisciplinary team. In multidisciplinary teams, people with diverse backgrounds and skills are brought together for a particular purpose. Leaders of such teams will usually not share the same background or experience with many of their team members. Members tend to have discrete technical roles rather than hold rank. In traditional command-and-control systems, a clear team structure and process is important. Trauma and resuscitation teams are more effective where there is a clearly defined team leader with other team members assuming functional roles [68-69]. Successful multidisciplinary team leaders tend to employ *situational leadership*. Leadership styles can also be classified by the steepness of the *authority gradient* between the team leader and team members. In an *autocratic* style, the authority gradient is steep, the leader expects orders to be followed without question, and team members have little or no opportunity to query, challenge, or offer input to the leader. In a *consultative* style, the authority gradient is more shallow: the leader more actively solicits views and input from the team, and it is easier for team members to question or advocate suggestions, although the leader makes the final decision.

In a theoretical model the best style depends on the situation. For example, in a complex ill-defined scenario involving an experienced mul-

tidisciplinary team, a consultative approach would seem more constructive; on the other hand, in a well-defined time-critical emergency with a novice team, invoking an autocratic drill would be more efficient. This is the concept of *situational leadership*: the good leaders adapt their style according to the available human resources and situation [70].

Situation Awareness

Situation awareness (SA) is defined as ‘the perception of elements in the environment, the comprehension of their meaning in terms of task goals, and the projection of their status in the near future’ [71]. It is composed of three levels of complexity. The first is *Perception*, which essentially consists in being aware of and/or gathering available information relevant to a situation (for example a clinical examination). The second one is *Comprehension*, that is the ability to form a mental model that makes sense of the available information. In clinical practice, this would be similar to forming a diagnosis, or a differential of diagnoses. The third degree is *Projection*, that is the ability to foresee potential future states, or as clinicians would say, to make a prognosis. In real life however, perception, comprehension and projection may not occur in that order. In many emergency situations it is possible, and potentially crucial as a matter of fact, to foresee the need to resuscitate (*Projection*) before one has made a complete examination (*Perception*) or a definitive diagnosis (*Comprehension*). This concept of *parallel* rather than *serial* cognitive processing of SA is a feature of expert cognition [72] described figuratively as ‘seeing the past, present and future at the same time’ [73]. Thus, in this model, ideal SA during an emergency is the result of a *dynamic* and *interactive* process of regularly scanning the environment, matching one’s mental model with incoming information, modifying the plan and actions accordingly, and cycling through this process repeatedly until the patient is safe and stable.

Decision Making

Efficient and accurate decision-making is critical to patient safety and it is important that the people responsible for making decisions that impact patient safety are as experienced and as expert as possible. Research on expert decision-making in complex, dynamic domains, has demonstrated that the most important step in making a decision in these domains is to accurately assess the situation through the identification of the problem, formulation of a diagnosis and evaluation of the risks [69]. Expertise impacts the decision process in several specific ways. First, expert decision makers exhibit high levels of competence and knowledge within the domain, and have experienced a wide variety of situations, instances, and cases they can draw upon [74]. This means that a current case will often have features that match an event from the expert's repertoire, facilitating quick and accurate situation assessment. Second, experts see and process information differently than novices do. They can quickly identify critical cues and attend to or categorize them. This impacts their ability to develop situation awareness and to create an accurate mental model of the situation [75]. Experts are sensitive to changing values of information and can adapt their mental models to accommodate them. They may use an iterative process, using feedback from the environment to adjust their actions and incorporate changes resulting from incremental decisions. In healthcare, for example, physicians often monitor results of a treatment to refine their diagnoses [76]. They also employ strategies to cope with dynamic situations, anticipating developments, prioritizing tasks, and making contingency plans, and employ knowledge-based control to address conflicts or contradictions [69, 77]. All of these leadership skills can be impaired during an emergency. Stress, both emotional and physical, may occur while facing a critical patient and may have a profound impact on decision-making which, in the medical context, could negatively affect clinical outcomes. Stress-related reductions in cognitive performance (e.g.

accuracy, reaction time, attention, memory) resulted in poorer patient safety outcomes such as medication errors [78].

Error Heuristics and Clinical Biases

Although quantitative mathematical models can guide clinical decision-making, clinicians can only rarely use formal computations to make patient care decisions in day-to-day practice. Rather, an intuitive understanding of probabilities is combined with cognitive processes called heuristics to guide clinical judgment. Heuristics are often referred to as rules of thumb, educated guesses, or mental shortcuts. Heuristics usually involve pattern recognition and rely on a subconscious integration of partial patient data with prior experience rather than on a conscious generation of a rigorous differential diagnosis that is formally evaluated using specific data from the literature. While in many cases these ‘fast and frugal rules’ may lead to correct choices amongst physicians [50], they may also distort our reasoning, thus increasing the risk of incorrect judgements and preventable medical error [79-83]. Heuristics are optimally used for simple tasks which are high in volume and low in impact, to reduce the cognitive load and to guide our decisions in a way in which the brain perceives to be most efficient and economical [84]. It has been theorized that medical error occurs with overuse of intuitive thinking processes in inappropriate contexts. Error ultimately results in the use of intuitive decision-making in situations where analytical thinking processes should be employed [83, 85-88]. There are many types of cognitive (reasoning) errors; being aware of common types of cognitive errors can help clinicians recognize and avoid them.

Cognitive errors may roughly be classified as those involving:

- Faulty assessment of pre-test probability (overestimating or underestimating disease likelihood)

- Failure to seriously consider all relevant possibilities.

Both types of error can easily lead to improper testing (too much or too little) and missed diagnoses.

Availability heuristic

The ‘Availability heuristic’ [89-91] is the cognitive bias associated with making a judgement of the likelihood of an event happening based on your previous experience in a similar situation resulting in risk of distorted hypothesis generation.

Confirmation heuristic

The ‘Confirmation heuristic’ [90, 91] supports ‘tunnel-vision’ searching for data to support initial diagnoses while actively ignoring potential data which will reject initial hypotheses. Closely aligned with the Anchoring heuristic, it increases the likelihood of premature closure of a diagnosis [92].

Representativeness heuristic

The ‘Representativeness heuristic’ is the increased likelihood of practitioners to utilize a cognitive protocol for diagnosis of conditions resulting in overemphasizing particular aspects of their assessment and diagnosis which support their hypothesis while missing atypical variants in the patient [93-95]. Closely associated with the prevalent relative-risk bias [51], it leads to misclassification due to overreliance on the prevalence of a condition.

Anchoring heuristic

‘Anchoring’ [90, 91] can be described as when a diagnosis is biased by a specific piece of information which a physician uses to ‘anchor’ their diagnosis without considering other presenting signs and symptoms with equal value. It can be used as a set reference point, which is useful in quick decision-making, but can negatively impact on judgement when that anchor is no longer pertinent to the situation [96].

Bandwagon heuristic

The 'Bandwagon heuristic' [90, 97] is the tendency to side with the majority in decision-making for fear of standing out. It may be closely related to and result in conservative default decision-making for patient care [98].

Overconfidence heuristic

The 'Overconfidence heuristic' [99, 100] is when a physician is absolutely convinced of his/her own conclusion to reject other possible differential diagnoses. It may result in decision-making being formulated through opinions or based on a 'hunch' as opposed to systematic approaches [92]. It occurs both with experienced doctors and inexperienced doctors in what is known as the Dunning Kruger effect.

Premature Closure

Premature closure is jumping to conclusions. This is one of the most common errors; clinicians make a quick diagnosis (often based on pattern recognition), fail to consider other possible diagnoses, and prematurely stop collecting data. The suspected diagnosis is often not even confirmed by appropriate testing.

Internal and external factors can increase the risk of cognitive error.

Internal factors include:

- Medical knowledge, training, and experience
- Fatigue/sleep deprivation
- Balance between being risk-accepting/risk-averse

External factors include:

- Workload
- Distractions

-Team resource management and peer pressures.

All of these factors can be present during the management of major trauma. Therefore it is crucial to use new tools to reduce the error.

The Checklist

Definition and Origins

The healthcare environment is a high-risk environment in which the consequences of errors that cause a delay or a missed diagnosis are more likely to have an impact on survival [101]. During the first phase of patient care, trivial but fundamental steps can often be missed, thus a systematic approach ensures that life-saving interventions are performed and that potentially lethal conditions are not neglected [102]. It is crucial to develop strategies that simplify care processes to minimize erroneous clinical judgment [103]. Modern medicine has reached such levels of complexity that they cannot be managed by a single person, if not accompanied by a method that directs the process. In the pre-hospital and military spheres it has been seen that the greater the acuity of the situation, the greater the need to overcome individual procedures and to adhere to a standard operating procedure [104-106]. One of the tools that has been proposed is the checklist, a to-do list of simple actions that must be done in the correct order to achieve a complex goal. In high-risk settings, checklists have proven to be an effective tool for standardizing care patterns [107]. The checklist was born in Aviation. The episode that started the development of the first checklist was the tragic accident of October 3, 1935, at Wright Air Field in Dayton (Ohio), involving the Boeing Model 299, a prototype aircraft that proved too complicated to be piloted by one man [108]. The United States Government organized a Test Flight aimed at identifying a new long-range bomber to be acquired for the United States Army Air Corps (USAAC). Douglas and Boeing Corporation participated with two distinctly different models in terms of characteristics. Boeing's Model 299 would have had a weapon capacity five times greater than the quantity required by the Army, at a speed far greater than previous bombers. However, the plane, with its 32-meter wingspan, stalled and crashed to the ground a few minutes after take-off. The entire crew led by Major

Ployer Peter Hill died in the accident. The investigation carried out attributed the triggering of the accident to human error. The new aircraft required the pilot to monitor four engines, to be calibrated with hydraulic controls, retractable landing gear, newly designed flaps and numerous other flight systems. Major Hill, in an attempt to manage all these parameters at the same time, had forgotten to deactivate the “Gust Lock” mechanism, which blocked the flight surfaces. Due to this forgetfulness, after takeoff the plane started to climb, stalled and crashed to the ground. Despite the accident, the Army acquired some of these aircrafts and, to avoid what had already happened, summarized all the procedures that the pilot had to carry out during take-off, flight and landing procedures. With this to-do list in hand, the pilots continued to fly the Model 299, soon renamed the B-17. The first checklist was born (Fig. 6).

APPROVED B-17F and G CHECKLIST

REVISED 3-1-44

PILOT'S DUTIES IN RED

COPILOT'S DUTIES IN BLACK

BEFORE STARTING

1. Pilot's Preflight—**COMPLETE**
2. Form 1A—**CHECKED**
3. Controls and Seats—**CHECKED**
4. Fuel Transfer Valves & Switch—**OFF**
5. Intercoolers—Cold
6. Gyros—**UNCAGED**
7. Fuel Shut-off Switches—**OPEN**
8. Gear Switch—**NEUTRAL**
9. Cowl Flaps—Open Right—**OPEN LEFT**—Locked
10. Turbos—**OFF**
11. Idle cut-off—**CHECKED**
12. Throttles—**CLOSED**
13. High RPM—**CHECKED**
14. Autopilot—**OFF**
15. De-icers and Anti-icers, Wing and Prop—**OFF**
16. Cabin Heat—**OFF**
17. Generators—**OFF**

STARTING ENGINES

1. Fire Guard and Call Clear—**LEFT** Right
2. Master Switch—**ON**
3. Battery switches and inverters—**ON & CHECKED**
4. Parking Brakes—Hydraulic Check—**On-CHECKED**
5. Booster Pumps—Pressure—**ON & CHECKED**
6. Carburetor Filters—Open
7. Fuel Quantity—Gallons per tank
8. Start Engines: both magnetos on after one revolution
9. Flight Indicator & Vacuum Pressures **CHECKED**
10. Radio—**On**
11. Check Instruments—**CHECKED**
12. Crew Report
13. Radio Call & Altimeter—**SET**

ENGINE RUN-UP

1. Brakes—Locked
2. Trim Tabs—**SET**
3. Exercise Turbos and Props
4. Check Generators—**CHECKED & OFF**
5. Run up Engines

BEFORE TAKEOFF

1. Tailwheel—Locked
2. Gyro—Set
3. Generators—**ON**

AFTER TAKEOFF

1. Wheel—**PILOT'S SIGNAL**
2. Power Reduction
3. Cowl Flaps
4. Wheel Check—**OK** right—**OK LEFT**

BEFORE LANDING

1. Radio Call, Altimeter—**SET**
2. Crew Positions—**OK**
3. Autopilot—**OFF**
4. Booster Pumps—**On**
5. Mixture Controls—**AUTO-RICH**
6. Intercooler—Set
7. Carburetor Filters—Open
8. Wing De-icers—**Off**
9. Landing Gear
 - a. Visual—Down Right—**DOWN LEFT**
Tailwheel Down, Antenna in, Ball Turret Checked
 - b. Light—**OK**
 - c. Switch **Off**—Neutral
10. Hydraulic Pressure—**OK** Valve closed
11. RPM 2100—Set
12. Turbos—Set
13. Flaps $\frac{1}{2}$ — $\frac{1}{2}$ Down

FINAL APPROACH

14. Flaps—**PILOT'S SIGNAL**
15. RPM 2200—**PILOT'S SIGNAL**

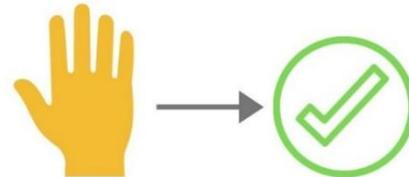
Figure 6. The first checklist.

There are numerous types of checklists but they can be divided into two groups:

read → execute;



execute → read.



The first type requires reading the list of actions to be carried out on the checklist and then executing them, the second type requires first the execution of the actions and then the control by viewing the checklist.

The use of the checklist in medicine

The use of the checklist in medicine is a relatively recent phenomenon. Long adopted by the aviation and nuclear industries, checklists have recently proven to be invaluable for standardizing and improving clinical care. One of the first hospital checklist trials began in 2001 at Johns Hopkins Hospital where Peter Pronovost experimented a checklist for the prevention of central venous catheter infections. He asked the nurses in his intensive care unit to observe the doctors during the insertion of the central venous catheter (CVC) [109], to note if all the steps on the checklist had been followed, and eventually to stop the doctors whenever they missed a point of the list. Pronovost and his colleagues monitored the situation for a year and the results showed that the infection rate went from 11% to 0%. They followed the patients for another 15 months during which only two of them developed an infection: the checklist had prevented 43 infections and 8 deaths, saving the hospital an expense of 2 million dollars. Following these results Pronovost recruited more colleagues and tested other checklists in the intensive care units. A checklist was aimed at ensuring that nurses observed patients

who were experiencing pain at least once every four hours, promptly providing a drug capable of extinguishing or relieving symptoms: this checklist led to the reduction of the likelihood of having patients with chronic pain not treated from 41% to 3% [110]. Another checklist was tested for patients with mechanical ventilators to ensure that antacids were prescribed to prevent stomach ulcers and that the patient's head was always kept elevated by at least 30° to prevent oral secretions from passing into the trachea: the percentage of patients not subjected to normal procedures dropped from 70% to 4%, leading to a significant reduction in the occurrence of pneumonia and deaths compared to the previous year [111]. The results obtained are proof of how the checklist allows a significant improvement to a system where good reliability is required. Checklists were created to meet three intrinsic factors of every human being: the fallacy of memory, the attention deficit and the tendency to skip actions that are part of a complex operation, in the belief that they are useless or in an attempt to take a shortcut. One of the main proponents of the creation and use of checklists in medicine was the US surgeon Atul Gawande. In 2006, Dr. Gawande was contacted by the WHO to participate, together with other health professionals, in drawing up a program for safety in the operating room. Surgery is an integral part of health management around the world, with an estimated 234 million operations performed annually [30] and performed in every community: rich and poor, rural and urban. Although surgery can prevent mortality and morbidity for many diseases, it is also associated with a significant risk of complications, including fatalities. Studies conducted in industrialized countries have shown a perioperative death rate in patients hospitalized for surgery of 0.4 to 0.8% and a major complication rate of 3-17% [112, 113]. Given these data, the WHO set the goal of finding a way to improve the management of operating rooms. The first meeting was held in January 2007 in Geneva which was attended by surgeons, anesthetists, nurses, safety experts and patients from all over the world. The examples and suggestions for increasing

the safety rate in the operating room were numerous but none could cover and ensure a satisfactory result for all types of operations carried out all over the world. During the meeting, Gawande proposed the introduction of a checklist to improve the reliability of the operating room. A working group, putting together other types of checklists, created the first prototype which included 3 pause points: one before administering the anesthesia, one before the initial incision and one before the patient leaves the room. Upon his return to Boston, Gawande himself tested this prototype and soon noticed that the checklist was too long and unclear, which is why he abandoned it. After this first failure, Gawande began to research how it was necessary to organize and design a working, quick and clear checklist. He read an article by Daniel Boorman of the Seattle Boeing Company in which he explained how to write down a checklist. Then Gawande asked him for a meeting. Boorman clarified to Gawande how a checklist should be designed and how it could be used, ultimately paving the way for what would be the final Surgical Safety Checklist. The Operating Room Patient Management Checklist was tested between October 2007 and September 2008 in a study including eight hospitals in eight different cities (Toronto, Canada; New Delhi, India; Amman, Jordan; Auckland, New Zealand; Manila, Philippines; Ifakara, Tanzania; London, England; and Seattle, WA) [114]. The primary endpoint was the rate of complications, including death, during hospitalization within the first 30 days after the operation. To evaluate the effectiveness of the use of the checklist, data on clinical processes and results in terms of patient outcomes were collected prospectively from 3733 patients of 16 years of age or older undergoing non-cardiological surgeries. Subsequently, the same data (in terms of clinical processes and patient outcomes) were collected from 3955 patients after the introduction of the surgical safety checklist in operating theaters. At the end of the study, the results showed that the 30-day mortality rate was 1.5% in patients treated in the absence of the checklist, while it decreased to 0.8% following the introduction of the

checklist ($p = 0.003$). As for hospital complications before the introduction of the checklist, these had occurred in 11% of patients, while they dropped to 7% after the introduction of the checklist ($p < 0.001$). This checklist was also approved and introduced in Italy in October 2009. In his book "The Checklist Manifesto: how to get things right" [108] Gawande illustrates and documents the advantages of using checklists, the need to adopt them in the medical field, to simplify the complexity of actions, to develop teamwork and to induce the group to feel and act as such [115]. An increasing number of papers have shown the value of the checklist in general hospital care, suggesting that their use could be extended to other clinical areas prone to human error [103]. Checklists are now commonly used to support a range of complex medical activities, including airway management, resuscitation, diagnosis and treatment of life-threatening injuries [96-99], all of which are too critical to rely on human memory alone. For example, the initial management of a major trauma patient is an extremely time-dependent high-risk process with a four times greater risk of death by mistake than the general population [106]. Due to the rapid and complex nature of the process, the adoption of decision support systems and cognitive aids in this environment, including the checklist, has been slow. To achieve and maintain the skills necessary for optimal management, medical staff rely on individual and group training, but training alone was judged insufficient to ensure patient safety and long-term compliance with protocols [105]. Recently, however, several US trauma centers have begun to implement the use of checklists in pediatric trauma showing their positive impact on team performance and protocol compliance [107, 108, 110]. The checklists protect against wrong and counterproductive attitudes and have a high educational value, as the very fact of following them implies a behavioral discipline. It distracts from the centrality of the individual, who works as a team, enhancing the group itself and the various professional disciplines. This generally increases the chances of success of the actions performed and ensures the best patient care.

As Gawande writes: “They didn’t believe in the wisdom of the single individual, of even an experienced one. They believed in the wisdom of the group, the wisdom of making sure that multiple pairs of eyes were on a problem and then letting the watchers decide what to do. Man is fallible, but maybe men are less so”.

To be effective and accepted, these checklists however need to be carefully designed and simulation becomes fundamental to criticize, improve and validate these tools.

The Simulation

Origin, Definition and Application

Simulation is an educational method based on the virtual reproduction of real situations. The term "simulation" has been defined as "the design process of a real system model within which to conduct experiments in order to understand the behavior of the system or to evaluate various strategies for its functioning" [116]. Its use dates back to the early 1900s in aviation with the invention of the first flight simulators in response to the need to deal with potential emergency situations in the real world that would otherwise not be experienced in conditions of absence of risk. The aeronautical and aerospace industries have been using simulation as a teaching tool for many years, but also the armed forces, commercial airlines, nuclear power plants to date use this technique [115]. In the 1980s, following the intuition of an American anesthetist-pilot, Dr. David Gaba, simulation was introduced in the healthcare sector as a new learning technique. Dr. Gaba has redefined the term "simulation in medicine" as "a technique, not a technology, to replace or amplify real experiences with guided experiences that evoke or replicate substantial aspects of the real world in a fully interactive way" [117]. The term "simulation in medicine" corresponds to the use of a material (simulator mannequin or procedural software) that, in a virtual reality, creates a standardized patient. Healthcare simulation is used to reproduce situations and care environments in order to teach diagnostic and therapeutic procedures, to repeat medical processes and concepts, and make decisions by a healthcare professional or team of professionals. Simulation is considered a pedagogical tool capable of addressing all fields of medical teaching [118].

However, medical education has been slow to take this teaching method into consideration. The situation has changed in the last twenty years due to a growing sensitivity to patient safety. "To Err Is Human", a historical report published by the Institute of Medicine (IOM) in 1999 [51],

estimated that medical errors cause harm to approximately 3% of hospitalized patients and result in as little as 44,000 and up to 98,000 deaths per year in the United States. Another relevant finding was obtained from the Harvard Medical Practice Study, in which the authors reviewed over 30,000 randomly selected medical records in New York State in 1984 as part of an interdisciplinary study on medical injury and malpractice litigation. The authors found that adverse event injuries occurred in 3.7% of hospital admissions, 27.6% of which were due to negligence and of which 13.6% resulted in death [119]. Medical errors also contribute to the cost of medical care around the world. The annual cost attributable to all adverse drug events and preventable drug adverse events for a 700-bed US teaching hospital was estimated by one study to be \$ 5.6 million and \$ 2.8 million, respectively [120]. Demands for a change in teaching methods have led to innovative curricula. The new curricula emphasize the importance of competences in different clinical skills, technical and non-technical, by medical graduates rather than the mere acquisition of theoretical knowledge [121]. These must be acquired before specialization and maintained afterwards, especially for those relatively rare, life-saving and potentially harmful skills that require constant training. In this sense, simulation has the advantage of being able to reproduce countless times and in conditions of absolute safety, rare and/or potentially dangerous events that a professional may have to face in daily practice. It is appreciated as simulation tools replace the real patient, allowing learners to make mistakes and learn from them without fear of harming the patient [122]. Simulation-based medical education provides the opportunity to train in various medical and surgical procedures and provides an empirical "hands-on" educational modality that allows for controlled proactive exposure of trainees to common routine clinical scenarios and rare complex scenarios [123]. Experiential learning is an active process during which the learner builds skills by connecting new information and new experiences to previously acquired knowledge. Experiential learning has proven to be

the most effective method of teaching adults and uses simulated clinical scenarios as the basis for learning [8, 9, 124, 125].

Simulation Methods

There are various types of simulation which differ from each other in modality. The simulation commonly understood, which uses mannequins, differs in similarity to reality (or "fidelity") and purpose. There are high, medium or low fidelity simulators that can be built ad hoc to carry out a single procedure (for example a simulated anatomical piece for the positioning of the venous access) or "full body" simulators. The latter can be low, medium or high fidelity, based on the functions performed (movements, responses to drugs, modifiable vital parameters, dynamic anatomical variations, vocal interaction with learners, etc.). Such mannequins can reproduce the adult, traumatic adult, pediatric, neonatal or pregnant patient. The simulation, however, is not limited to the use of mannequins but can also exploit the "simulated patient" which is based on the use of suitably trained human actors. This mode is preferred for communicative and / or relational objectives such as the handover or the communication of bad news. The simulation with a mannequin can also be integrated with that of a simulated patient in "hybrid" simulations in which part of the practice is carried out with the actor and part with the mannequin (for example, simulation of an accident requiring assistance to more patients). Finally, there is also a digitalized simulation, widely developed in the last year of the pandemic, which uses computerized media to interact with the patient or the environment (for example, online patient or digital simulation of disaster emergency). According to the place where they are carried out, simulations are then divided into two broad categories: the "traditional" ones, carried out in a simulation center suitably equipped to reproduce the usual work environment, and the "in situ" ones carried out on the actual workplace (for example in the emergency room). The in situ mode has

the indisputable advantage of being more real and more engaging and emphasizing the ergonomics of the workplace. On the other hand, they are not always easy to organize, especially in crowded work environments.

The practice of scenarios can be done individually but is mostly done by a team composed of health professionals of the same or different specialties or even by different health professionals (for example: doctors and nurses). The simulations take place in an environment set up in such a way as to resemble as much as possible the intended work environment in order to immerse the students in an experience as close as possible to real life. The "classic" simulations based on clinical cases and using high fidelity simulators require:

- a team of learners in charge of managing the "patient";
- one or more instructors whose role is to decide the clinical case to be carried out (based on real cases or on specially constructed cases, which can concern any type of emergency-urgency situation), to manage the simulation and to manage the patient's responses to the actions of the team;
- the simulation room (Fig. 7) equipped with a high-fidelity mannequin (Fig. 8) capable of responding, under the command of the operators responsible for managing the simulation, to the actions that are carried out on it. The room is equipped with all the electronic devices and all the tools necessary for the monitoring and primary management of the patient;
- the control room from where the simulator is managed and controlled (Fig. 9);
- a third room or a space inside the simulation room used for the final debriefing part (Fig. 10).



Figure 7. *Example of a simulation room*

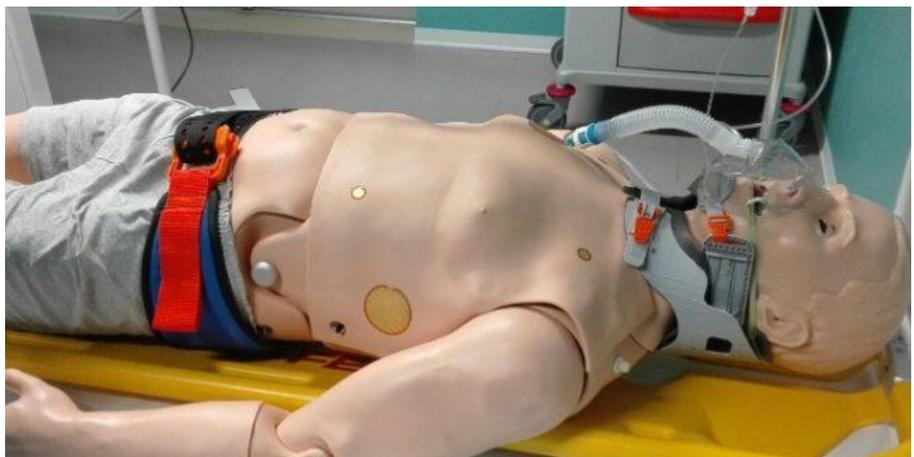


Figure 8. *Example of a high fidelity mannequin*



Figure 9. *Example of a control room*



Figure 10. *Example of debriefing room*

During scenario-based training, the student not only acquires technical skills, but can also learn fundamental non-technical skills such as interpersonal communication, teamwork, leadership, decision making, the ability to prioritize tasks under pressure and stress management, all aspects that are difficult to acquire from books [126].

Each high fidelity simulation is divided into three phases:

-The first, the so-called "briefing", is the introductory phase in which the instructor introduces the clinical case and the initial context to the team.

-The second phase is the simulation itself, which begins when the team approaches the "patient". During case management, instructors will be tasked with providing data and exams when requested by the team, managing vital signs, patient verbal responses and organic responses to team actions. During the simulation some technical skills are physically performed such as defibrillation or endotracheal intubation in order to increase fidelity to the real practice.

-The third phase or "debriefing" is the critical and constructive discussion of the simulation just carried out. This last phase is the most important part of the training activity, so much so it has been said that "The simulation is just the excuse to do a quality debriefing". During the debriefing the learner reflects on the reasons for their actions and explores possible more appropriate and effective alternatives in order to improve their knowledge and performance. It can focus on both technical and non-technical aspects [127]. To carry out an effective debriefing it is essential that the simulations are recorded with audio-video systems, in order to objectify what happened during the simulation. The other fundamental element for the success of debriefing is that it is conducted by an experienced instructor. Various more or less rigid, differently oriented and structured debriefing techniques have been proposed.

The debriefing technique can be tailored on the basis of the pre-established training objectives and on the basis of the characteristics of the learners: from the simple analysis / correction of technical skills to finer and more complex cognitive-behavioral techniques. The Italian Society of Simulation in Medicine (SIMMED) proposed in its position paper [118] a standardized approach to debriefing divided into three successive phases:

1) Reactions: in this phase the goal is to "release" the emotions of the participants to allow them to focus on a constructive discussion. The impressions and emotions are investigated and the clinical case is summarized from a medical point of view.

2) Understanding: The goal of this phase is to understand which mental processes led the participants to act in a certain way. The instructor must assertively propose a fact, an action, or a result observed during the simulation that is relevant to the individual and the group and must promote a discussion that brings to light the underlying mental processes. The discussion must be addressed both with the individual and with the group and must lead to awareness of what has happened and, if it was an error, to the identification of possible solutions.

3) Summary: this phase summarizes what has been learned during the simulation and the take-home messages are identified.

The knowledge acquired with simulation is based on interactive learning, which is more effective in adult learning. Studies have been carried out on the efficacy of simulation in medicine compared to traditional clinical medical education, in particular with the Halstedian approach "see one, do one, teach one" [128]. In these studies, a clear superiority of simulation was highlighted in numerous fields of application of medicine: laparoscopic surgery, cardiac auscultation, insertion of the catheter for hemodialysis, thoracentesis and insertion of the central venous

catheter. The simulation allows to train both technical and non-technical skills, to learn to relate to a group, to learn to recognize some patterns and, through debriefing, it gives the possibility to understand mistakes and to improve more and more the ability to act in an effective way.

Aim of the study

The purpose of this project study is to evaluate in a simulated environment if the introduction of a checklist improves adherence to the guidelines in the management of patients with major trauma, if it modifies the execution times of critical actions and if it has a positive impact on non-technical skills of the team.

Methods

Design of the study

The study was conducted at Careggi University Hospital, Florence, Italy. It started in December 2018 and ended in October 2021. In the first period, the literature concerning trauma, checklists, simulations and combinations of these three topics was extensively reviewed. On the basis of these elements, a checklist for trauma management was designed (Figure 11). In particular, the 2016 WHO trauma checklist was used as a basis. This document is organized in a time-dependent ABCDE approach with essential actions. This main format has been partially implemented on the basis of more comprehensive guidelines on trauma [129].

| | | |
|---|---|---|
| A | Advanced Airway Management Indicated? - Hypoxia / hypercapnia despite non-invasive support? - Severe trauma / burn of neck / face / chest? -GCS \leq 8? | <input type="checkbox"/> Yes, done <input type="checkbox"/> Not indicated |
| A | Spinal Immobilization indicated? | <input type="checkbox"/> Yes, done <input type="checkbox"/> Not indicated |
| B | Tension Pneumothorax? | <input type="checkbox"/> Yes, chest tube positioned <input type="checkbox"/> No |
| B | Complete monitoring with oximeter | <input type="checkbox"/> Yes, done <input type="checkbox"/> Unavailable |
| C | Two venous large bore / intraosseous accesses inserted and fluid started? | <input type="checkbox"/> Yes, done <input type="checkbox"/> Unavailable |
| C | Comprehensive evaluation and control of external bleeding, included | <input type="checkbox"/> Scalp <input type="checkbox"/> Back <input type="checkbox"/> Perineum |
| C | Pelvic Fracture Evaluation with | <input type="checkbox"/> Clinical <input type="checkbox"/> X-Ray <input type="checkbox"/> CT scan |
| C | Internal Bleeding Evaluation with | <input type="checkbox"/> Clinical <input type="checkbox"/> X-Ray <input type="checkbox"/> CT scan |
| D | Neurologic evaluation 4 limbs | <input type="checkbox"/> Yes, done |
| D | Pupils Evaluation | <input type="checkbox"/> Yes, done |
| E | Hypothermic Patient? | <input type="checkbox"/> Yes,warmed up <input type="checkbox"/> No |
| E | Further evaluations | <input type="checkbox"/> Echo <input type="checkbox"/> EKG <input type="checkbox"/> Blood gas <input type="checkbox"/> No |

Figure 11. The Checklist

If we compare our checklist with the 91 recommendations of the NICE guidelines [129] it can be easily seen that the actions listed do not include all the recommendations. Our checklist, in fact, does not aim to list all the actions to be carried out but only to remember the fundamental steps to be performed during the primary assessment to allow the patient to survive. Our checklist focuses on the critical actions that during our regular in-situ simulations in the Emergency Room were more frequently overlooked.

Four scenarios concerning trauma were then drawn. Each clinical case was set up as a case of cardio-respiratory arrest or peri-arrest caused by two correctable causes. In particular:

Scenario 1 → Penetrating dorsal trauma complicated by tension pneumothorax and haemothorax inducing mixed genesis shock.

Scenario 2 → Trauma of the pelvis complicated by hip fracture and ureteral bleeding inducing haemorrhagic shock

Scenario 3 → Cardiorespiratory arrest induced by severe head injury and hypothermia;

Scenario 4 → Closed abdominal trauma with ruptured spleen and haemorrhagic shock during hypoglycemia

All the scenarios were previously carried out and assessed in order to make the complexity homogeneous.

Before starting the recruitment, a short video was created in which the checklist was presented and instructions for its use were given. This video was projected at the beginning of each simulation session, so that each participant of each team received the same information.

Therefore, 25 simulation sessions were scheduled, each lasting 4 hours, carried out weekly. The recruitment process was hampered by the pandemic wave of SARS-CoV-2 which prevented activities in presence for a long time.

Participants were recruited among the emergency medicine trainees, between the first and fifth year, at the University of Florence and Padua, Italy, for a total of 100 people. The simulations conducted at the Ca-reggi University Hospital were all carried out at the Advanced Medical Simulation Center. In Padua the simulations took place at the Simulation Center of the Padua Hospital.

For the sessions performed in Florence, a Laerdal 3G mannequin was used; for the sessions performed in Padua, a Gaumard Trauma Hal 3040.100 mannequin was used.

The trainees were divided into 25 teams of four members, within which the most experienced had the role of team leader.

Each team participated in a high-fidelity simulation session, which involved the management of 4 scenarios about major trauma patients. In half of the scenarios the team worked drawing on their own experience, while in the other half their work was based on the use of the checklist. In the simulations where the checklist was used, two copies were given to the participants, one to the team leader and another one was made available for the whole team.

Each member of the team, before the simulations, signed a privacy form to give consent to the video footage.

Each team played all 4 scenarios (named CheLTS 1-4).

The order of the cases was defined randomly at each session with a random sequence generator (<https://www.random.org/sequences/>).

The teams had the checklist available either for the first two cases or for the last two, by default, according to the scheme in Table 1, in order to eliminate the bias according to which the repetition of serial simulations improves performance.

| | Team 1 | Team 2 | Team 3 | Team 4 |
|-------|----------|----------|----------|----------|
| Sim 1 | CheLTS 4 | CheLTS 2 | CheLTS 1 | CheLTS 4 |
| Sim 2 | CheLTS 1 | CheLTS 4 | CheLTS 3 | CheLTS 2 |
| Sim 3 | CheLTS 3 | CheLTS 3 | CheLTS 2 | CheLTS 1 |
| Sim 4 | CheLTS 2 | CheLTS 1 | CheLTS 4 | CheLTS 3 |

Table 1: Case randomization and assignment of cases with and without checklist (simulations with checklist in red, simulations without checklist in black).

Video Review and Team's Performance Assessment

The simulations were filmed using the SimView software (<https://www.laerdal.com/it/products/simulation-training/operate-assess--debrief/simview/>).

All simulation videos were subsequently reviewed by two operators. Considering the fact that, as mentioned above, the actions listed in the checklist do not cover all the recommendations of the guidelines, it was necessary to evaluate the performance of the team on the basis of a more complete list of critical actions. The purpose of the study, in fact, is to evaluate whether the use of the checklist improves adherence to the guidelines, not to the checklist itself. Consequently, a list of 52 critical actions was drawn up (Table 2). The critical actions considered for the purpose of the study are fewer than the NICE recommendations [129]. This is explained by the fact that the guidelines establish a series of recommendations that refer to the pre-hospital setting, while the study is aimed at the first approach in hospital. Another reason for this difference is that several guideline recommendations have been summarized into more general critical actions. For example, the guidelines detail in multiple recommendations how to give information to relatives, while in the list of critical actions it is summarized in a single action.

The reviewers were responsible for establishing whether and how quickly the single critical action was performed. For each simulation a time zero was set as the moment in which the participants approached the mannequin. The execution time of every single action was calculated as latency between time zero and the moment of execution of the action itself.

| ACTIONS | YES | NO | Min | Sec |
|--|-----|----|-----|-----|
| Assessment of airways patency | | | | |
| Assessment of Glasgow Coma Scale | | | | |
| Assessment of the neck | | | | |
| Assessment/Treatment of pneumothorax | | | | |
| Complete monitoring | | | | |
| Assessment of need of oxygen | | | | |
| Placement of two venous accesses | | | | |
| Respiratory physical examination | | | | |
| Assessment of respiratory rate | | | | |
| Assessment of oxygen saturation | | | | |
| Blood gas analysis | | | | |
| Refill evaluation | | | | |
| Pulses evaluation | | | | |
| Cardiovascular physical examination | | | | |
| Assessment/Treatment of external bleeding | | | | |
| Assessment/Treatment of head bleeding | | | | |
| Assessment/Treatment of back bleeding | | | | |
| Assessment/Treatment of perineum bleeding | | | | |
| E-FAST execution | | | | |
| Physical/radiological examination of the hip | | | | |

| | | | | |
|---|--|--|--|--|
| Cervical Spine immobilization | | | | |
| Four limbs neurological assessment | | | | |
| Pupils assessment | | | | |
| Blood glucose assessment | | | | |
| removal of all clothes | | | | |
| Log roll and spine assessment | | | | |
| Body temperature assessment | | | | |
| Blood test collecting for lab | | | | |
| Blood test collecting for type and screen | | | | |
| EKG execution | | | | |
| Evaluation of bladder catheter indication | | | | |
| Evaluation of nasogastric tube indication | | | | |
| Evaluation of chest tube indication | | | | |
| administration of tranexamic acid | | | | |
| administration of coagulation factors | | | | |
| administration of blood products | | | | |
| Call for surgeon consultant | | | | |
| Call for interventional radiologist | | | | |
| Call for anesthetist consultant | | | | |
| Call for orthopedic consultant | | | | |
| Call for other consultant | | | | |
| CT scan request | | | | |
| Echography request | | | | |

| | | | | |
|--------------------------------------|--|--|--|--|
| Antibiotics administration | | | | |
| Antitetanus administration | | | | |
| Re-evaluation of imaging | | | | |
| ABCDE Re-evaluation | | | | |
| Vitals parameters re-evaluation | | | | |
| Analgesia re-evaluation | | | | |
| Transfer agreement taken | | | | |
| Interview with the patient/relatives | | | | |
| Orotracheal intubation | | | | |

Table 2: Evaluation of execution and execution times of critical actions

Evaluation of non-technical skills

For each simulation, the team's performance in non-technical skills was assessed through the use of the Clinical Teamwork Scale (CTS, Fig. 12).

CTS - Clinical Teamwork Scale

Please note: **Not relevant**- The task was not applicable to the scenario.

| Overall | Not Relevant | Unacceptable | Poor | | | Average | | | Good | | | Perfect |
|--|--------------------------|--------------|------|---|---|---------|---|---|------|---|---|---------|
| 1. How would you rate teamwork during this delivery/emergency? | <input type="checkbox"/> | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

| Communication | Not Relevant | Unacceptable | Poor | | | Average | | | Good | | | Perfect |
|-------------------------------|--------------------------|--------------|------|---|---|---------|---|---|------|---|---|---------|
| Overall Communication Rating: | <input type="checkbox"/> | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| 1. Orient new members (SBAR) | <input type="checkbox"/> | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| 2. Transparent thinking | <input type="checkbox"/> | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| 3. Directed communication | <input type="checkbox"/> | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| 4. Closed loop communication | <input type="checkbox"/> | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

| Situational Awareness | Not Relevant | Unacceptable | Poor | | | Average | | | Good | | | Perfect |
|---------------------------------------|------------------------------|-----------------------------|------|---|---|---------|---|---|------|---|---|---------|
| Overall Situational Awareness Rating: | <input type="checkbox"/> | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| 1. Resource allocation | <input type="checkbox"/> | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| 2. Target fixation | <input type="checkbox"/> Yes | <input type="checkbox"/> No | | | | | | | | | | |

| Decision Making | Not Relevant | Unacceptable | Poor | | | Average | | | Good | | | Perfect |
|---------------------------------|--------------------------|--------------|------|---|---|---------|---|---|------|---|---|---------|
| Overall Decision Making Rating: | <input type="checkbox"/> | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| 1. Prioritize | <input type="checkbox"/> | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

| Role Responsibility | Not Relevant | Unacceptable | Poor | | | Average | | | Good | | | Perfect |
|---|--------------------------|--------------|------|---|---|---------|---|---|------|---|---|---------|
| Overall Role Responsibility (Leader/Helper) Rating: | <input type="checkbox"/> | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| 1. Role clarity | <input type="checkbox"/> | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| 2. Perform as a leader/helper | <input type="checkbox"/> | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

| Other | Not Relevant | Unacceptable | Poor | | | Average | | | Good | | | Perfect |
|---------------------|--------------------------|--------------|------|---|---|---------|---|---|------|---|---|---------|
| 1. Patient friendly | <input type="checkbox"/> | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

Additional Notes (Anything regarding individual performance, assertion of position, etc?):

On-Site

Reviewer *Print Name*

Sign

Date

Figure 12. Clinical Teamwork Scale, for the evaluation of non-technical skills

Satisfaction survey

At the end of the four simulations, each participant was asked to fill in the following survey (Fig. 13) about the satisfaction of the checklist in a completely anonymous way.

1) I believe that the checklist has made me feel more confident in managing the trauma patient
Total Disagreement 1 2 3 4 5 Total Agreement

2) I believe that the checklist has an important clinical relevance
Total Disagreement 1 2 3 4 5 Total Agreement

3) I believe that the checklist takes too much time from the patient's clinical evaluation
Total Disagreement 1 2 3 4 5 Total Agreement

4) I believe the checklist should always be used in major trauma management
Total Disagreement 1 2 3 4 5 Total Agreement

5) The checklist was easy to use
Total Disagreement 1 2 3 4 5 Total Agreement

6) If I were the patient I would like the emergency physician to use the checklist
Total Disagreement 1 2 3 4 5 Total Agreement

I have been certified in trauma management (ATLS, PHTLS, PHTC, ETC...) Yes No

I am enrolled in the _____ |year of specialization

Figure 13. Anonymous Satisfaction Survey about the checklist

Statistical Analysis

SPSS version 26 software, Statistical Package for Social Science (<https://www.spss.it/>) was used for the statistical analysis.

The comparison of the percentage of actions performed in the scenarios with the checklist versus without checklist was performed with the χ^2 test, while the comparison of the execution times of the critical actions was performed by the Student's T test for paired data.

The simulations were evaluated alternatively by two examiners. To evaluate the reproducibility of the measurements, 8 videos were viewed by both operators in parallel. The concordance of the results was assessed with the χ^2 test for the evaluation of the execution (yes versus no) of the single actions and through the measurement of Cronbach's α for the evaluation of the execution times of the critical actions.

Comparison of CTS scores in simulations with versus without checklist was performed with Friedman's non-parametric test. A p value <0.05 was considered significant.

Results

Evaluation of the checklist

The evaluation of the reproducibility between the two operators gave the following results: the agreement in identifying the actions performed or not was 100%, out of a total of 416 actions, with 229 performed and 187 missed. The determination of the execution times also showed excellent reproducibility, with an intraclass correlation coefficient of 0.995 on the single measurements and 0.997 on the average, Cronbach's α 0.997.

The study involved the enrollment of 25 teams for a total of 100 scenarios, out of which 50 were performed without the checklist and 50 performed with the checklist.

Table 3 shows the comparison of the number of critical actions completed in the scenarios performed without and with the use of the checklist. The comparison was not carried out in 3 cases as these actions were never carried out neither with nor without the CL.

In the scenarios performed with the aid of the CL, the number of completed actions was significantly higher than in the scenarios without CL (27 ± 9 vs 24 ± 7 , $p < 0.001$). By restricting the analysis to critical actions relating to the primary assessment, this result was confirmed again (22 ± 5 vs 19 ± 4 , $p < 0.001$).

Analyzing the individual actions, in 7 cases they were performed significantly more often in the scenarios performed with the help of the checklist (Table 3), and in particular they were: evaluation / treatment of external bleeding, evaluation / treatment of back bleeding, evaluation / treatment of perineum bleeding, removal of all clothes, evaluation of body temperature, immobilization of the cervical spine, evaluation of the neurological status of the 4 limbs.

| ACTIONS | WITHOUT CL | WITH CL | p |
|--|------------|-----------|--------------|
| Assessment of airways patency | 45 (90%) | 50 (100%) | 0.066 |
| Assessment of Glasgow Coma Scale | 39 (78%) | 44 (80%) | 0.287 |
| Assessment of the neck | 41 (82%) | 42 (84%) | 1.000 |
| Assessment/Treatment of pneumothorax | 39 (78%) | 39 (78%) | 1.000 |
| Complete monitoring | 49 (98%) | 50 (100%) | 1.000 |
| Assessment of need of oxygen | 40 (80%) | 40 (80%) | 1.000 |
| Placement of two venous accesses | 39 (78%) | 44 (88%) | 0.287 |
| Respiratory physical examination | 50 (100%) | 49 (98%) | 1.000 |
| Assessment of respiratory rate | 20 (40%) | 21 (42%) | 1.000 |
| Assessment of oxygen saturation | 47 (94%) | 47 (94%) | 1.000 |
| Blood gas analysis | 50 (100%) | 49 (98%) | 1.000 |
| Refill evaluation | 23 (46%) | 14 (28%) | 0.098 |
| Pulses evaluation | 33 (66%) | 31 (62%) | 0.835 |
| Cardiovascular physical examination | 13 (26%) | 19 (37%) | 0.350 |
| Assessment/Treatment of external bleeding | 36 (72%) | 45 (90%) | 0.041 |
| Assessment/Treatment of head bleeding | 15 (30%) | 28 (56%) | 0.015 |
| Assessment/Treatment of back bleeding | 17 (34%) | 22 (44%) | 0.412 |
| Assessment/Treatment of perineum bleeding | 8 (16%) | 23 (46%) | 0.002 |
| E-FAST execution | 49 (98%) | 49 (98%) | 1.000 |
| Physical/radiological examination of the hip | 38 (76%) | 41 (82%) | 0.623 |
| Cervical Spine immobilization | 18 (36%) | 31 (62%) | 0.016 |
| Four limbs neurological assessment | 6 (12%) | 19 (38%) | 0.006 |
| Pupils assessment | 33 (66%) | 40 (80%) | 0.177 |
| Blood glucose assessment | 28 (56%) | 31 (62%) | 0.684 |
| Removal of all clothes | 34 (68%) | 46 (92%) | 0.006 |

| | | | |
|---|----------|----------|--------------|
| Log roll and spine assessment | 23 (46%) | 23 (46%) | 1.000 |
| Body temperature assessment | 30 (60%) | 41 (82%) | 0.028 |
| Blood test collecting for lab | 33 (66%) | 38 (76%) | 0.378 |
| Blood test collecting for type and screen | 28 (56%) | 32 (64%) | 0.540 |
| EKG execution | 26 (52%) | 34 (68%) | 0.153 |
| Evaluation of bladder catheter indication | 16 (32%) | 14 (28%) | 0.827 |
| Evaluation of nasogastric tube indication | 1 (2%) | 7 (14%) | 0.065 |
| Evaluation of chest tube indication | 15 (30%) | 13 (26%) | 0.824 |
| administration of tranexamic acid | 33 (66%) | 31 (62%) | 0.835 |
| administration of coagulation factors | 17 (34%) | 17 (34%) | 1.000 |
| administration of blood products | 35 (70%) | 34 (68%) | 1.000 |
| Call for surgeon consultant | 23 (46%) | 29 (58%) | 0.317 |
| Call for interventional radiologist | 2 (4%) | 7 (14%) | 0.162 |
| Call for anesthetist consultant | 19 (38%) | 24 (48%) | 0.419 |
| Call for orthopedic consultant | 6 (12%) | 9 (18%) | 0.575 |
| Call for other consultant | 7 (14%) | 5 (10%) | 0.758 |
| CT scan request | 16 (32%) | 15 (30%) | 1.000 |
| Echography request | 0 (0%) | 0 (0%) | # |
| Antibiotics administration | 0 (0%) | 0 (0%) | # |
| Antitetanus administration | 1 (2%) | 0 (0%) | 1.000 |
| Re-evaluation of imaging | 8 (16%) | 6 (12%) | 0.773 |
| ABCDE Re-evaluation | 27 (54%) | 31 (62%) | 0.543 |
| Vitals parameters re-evaluation | 34 (68%) | 39 (78%) | 0.368 |
| Analgesia re-evaluation | 4 (8%) | 7 (14%) | 0.523 |
| Transfer agreement taken | 7 (14%) | 9 (18%) | 0.819 |
| Interview with the patient/relatives | 11 (22%) | 10 (20%) | 1.000 |

| | | | |
|------------------------|----------|----------|-------|
| Orotracheal intubation | 29 (58%) | 29 (58%) | 1.000 |
|------------------------|----------|----------|-------|

Table 3: Comparison of the number of critical actions performed in the scenarios with versus without checklist

Table 4 shows the time needed to carry out the critical actions respectively in the scenarios without checklist and with checklist. Among the 49 evaluable actions, a significant reduction in time was observed for only 4 items, in favor of the scenarios without checklist: objective examination of the chest, placement of two venous accesses, collection of samples for blood count and coagulation, evaluation of the pulses.

| ACTIONS | WITHOUT CL | WITH CL | p |
|--|------------|---------|--------------|
| Assessment of airways patency | 00:30 | 00:43 | 0.129 |
| Assessment of Glasgow Coma Scale | 02:57 | 02:15 | 0.164 |
| Assessment of the neck | 00:58 | 01:35 | 0.171 |
| Assessment/Treatment of pneumothorax | 01:51 | 01:20 | 0.149 |
| Complete monitoring | 00:46 | 00:38 | 0.175 |
| Assessment of need of oxygen | 01:56 | 02:07 | 0.640 |
| Placement of two venous accesses | 01:18 | 02:37 | 0.010 |
| Respiratory physical examination | 01:09 | 01:34 | 0.044 |
| Assessment of respiratory rate | 01:57 | 02:43 | 0.288 |
| Assessment of oxygen saturation | 01:44 | 01:51 | 0.710 |
| Blood gas analysis | 01:59 | 02:12 | 0.467 |
| Refill evaluation | 02:14 | 03:47 | 0.059 |
| Pulses evaluation | 02:56 | 04:50 | 0.014 |
| Cardiovascular physical examination | 02:37 | 03:14 | 0.355 |
| Assessment/Treatment of external bleeding | 03:42 | 03:57 | 0.662 |
| Assessment/Treatment of head bleeding | 05:09 | 03:42 | 0.102 |
| Assessment/Treatment of back bleeding | 08:59 | 06:44 | 0.113 |
| Assessment/Treatment of perineum bleeding | 04:43 | 04:48 | 0.941 |
| E-FAST execution | 03:43 | 04:39 | 0.052 |
| Physical/radiological examination of the hip | 04:33 | 05:03 | 0.496 |
| Cervical Spine immobilization | 01:54 | 01:52 | 0.982 |
| Four limbs neurological assessment | 03:50 | 05:18 | 0.418 |

| | | | |
|---|-------|-------|--------------|
| Pupils assessment | 04:22 | 04:45 | 0.621 |
| Blood glucose assessment | 04:20 | 04:28 | 0.847 |
| Removal of all clothes | 02:04 | 02:59 | 0.088 |
| Log roll and spine assessment | 08:40 | 07:24 | 0.301 |
| Body temperature assessment | 05:52 | 06:14 | 0.787 |
| Blood test collecting for lab | 02:40 | 04:23 | 0.013 |
| Blood test collecting for type and screen | 04:06 | 04:49 | 0.348 |
| EKG execution | 06:11 | 06:51 | 0.550 |
| Evaluation of bladder catheter indication | 08:08 | 07:25 | 0.618 |
| Evaluation of nasogastric tube indication | 07:29 | 08:31 | 0.783 |
| Evaluation of chest tube indication | 06:01 | 07:24 | 0.188 |
| administration of tranexamic acid | 07:01 | 06:59 | 0.962 |
| administration of coagulation factors | 08:19 | 08:47 | 0.684 |
| administration of blood products | 06:15 | 07:10 | 0.145 |
| Call for surgeon consultant | 08:12 | 08:54 | 0.424 |
| Call for interventional radiologist | 05:12 | 10:49 | 0.102 |
| Call for anesthetist consultant | 08:01 | 07:46 | 0.772 |
| Call for orthopedic consultant | 07:20 | 08:38 | 0.421 |
| Call for other consultant | 09:15 | 06:38 | 0.297 |
| CT scan request | 11:05 | 09:34 | 0.265 |
| Echography request | -- | -- | ° |
| Antibiotics administration | -- | -- | ° |
| Antitetanus administration | -- | -- | ° |
| Re-evaluation of imaging | 11:02 | 11:39 | 0.711 |
| ABCDE Re-evaluation | 09:46 | 09:44 | 0.984 |
| Vitals parameters re-evaluation | 09:20 | 08:49 | 0.506 |

| | | | |
|--------------------------------------|-------|-------|-------|
| Analgesia re-evaluation | 05:43 | 04:45 | 0.726 |
| Transfer agreement taken | 10:23 | 11:44 | 0.376 |
| Interview with the patient/relatives | 01:59 | 04:38 | 0.085 |
| Orotracheal intubation | 07:50 | 06:22 | 0.083 |

° : the p value is not generated because there are no cases

Table 4: Comparison of the execution time of critical actions in the scenarios without versus with checklist.

Non-Technical skills assessment

Table 5 and Figure 14 show the data relating to the performance of the teams in non-technical activities, assessed using the Clinical Teamwork Scale, in the scenarios without and with checklist, respectively. We observed a significant improvement for the global score, while for the individual subscores the variation was not significant.

| CTS Items | WITHOUT CL | WITH CL | P |
|----------------------------|------------|-------------|-------|
| Total | 90 (77-99) | 95 (83-102) | 0.050 |
| Global Communication | 27 (23-30) | 28 (24-30) | 0.280 |
| Global Situation Awareness | 15 (12-17) | 15 (12-16) | 0.451 |
| Global Decision Making | 12 (11-15) | 14 (12-16) | 0.522 |
| Global Role Responsibility | 21 (18-24) | 23 (20-26) | 0.324 |

Table 5: Comparison of non-technical skills assessed using the Clinical Teamwork Scale in the scenarios without and with checklist

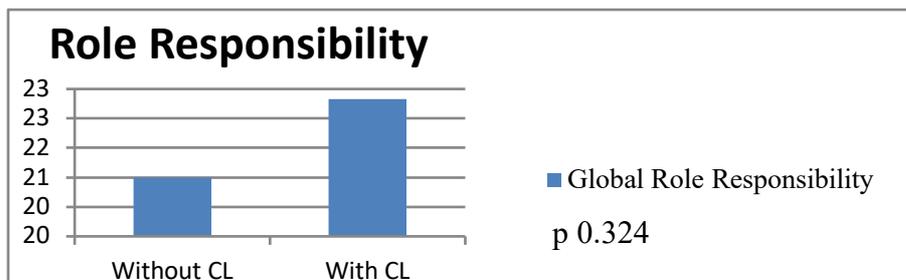
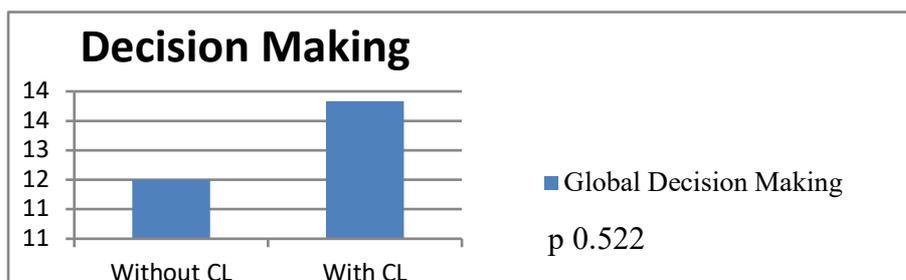
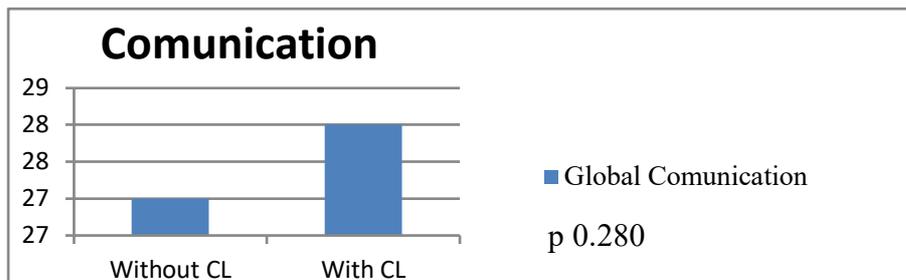
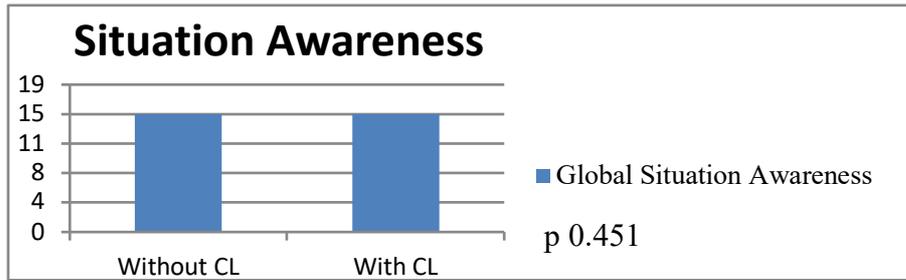
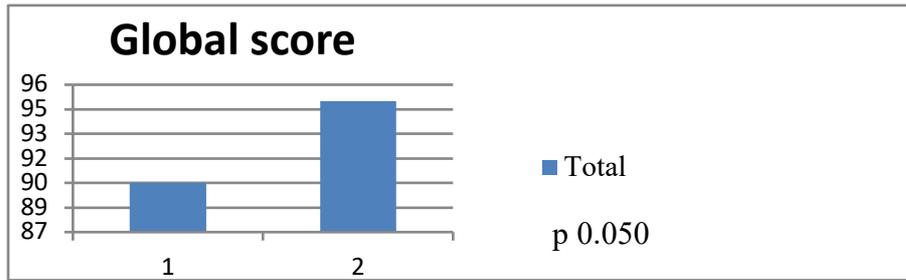


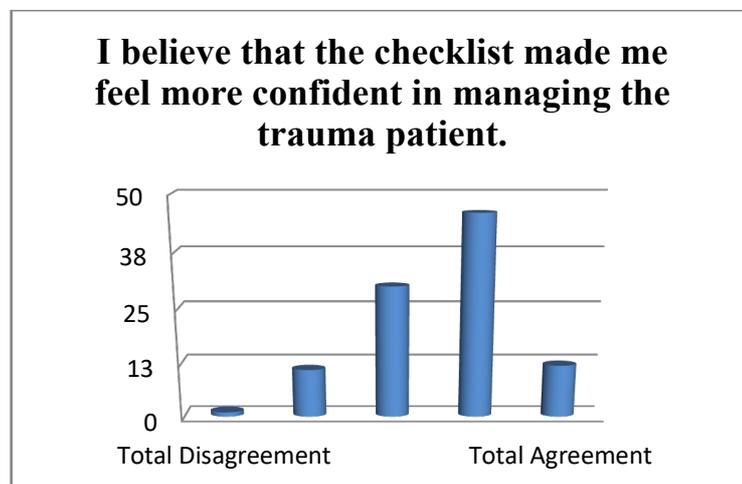
Figure 14. Non-technical skills analysis using the Clinical Teamwork Scale

Evaluation of satisfaction

From the anonymous data obtained by the satisfaction questionnaire of 100 participants, we had the following results:

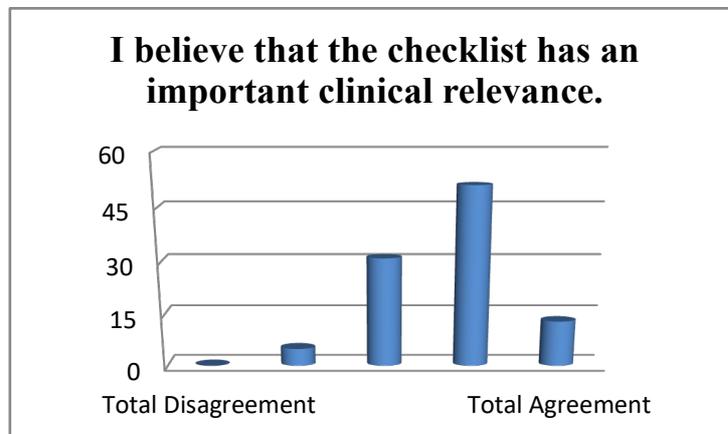
- 1) I believe that the checklist made me feel more confident in managing the trauma patient.

| Score | 1 | 2 | 3 | 4 | 5 |
|-----------|---|----|----|----|----|
| Frequency | 1 | 11 | 30 | 46 | 12 |



2) I believe that the checklist has an important clinical relevance.

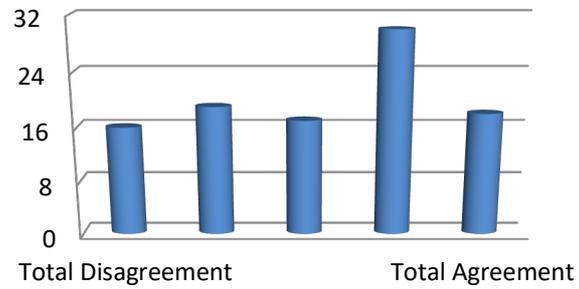
| | | | | | |
|-----------|---|---|----|----|----|
| Score | 1 | 2 | 3 | 4 | 5 |
| Frequency | 0 | 5 | 31 | 51 | 13 |



3) I believe that the checklist does not take too much time from the patient's clinical evaluation

| | | | | | |
|-----------|----|----|----|----|----|
| Score | 1 | 2 | 3 | 4 | 5 |
| Frequency | 16 | 19 | 17 | 30 | 18 |

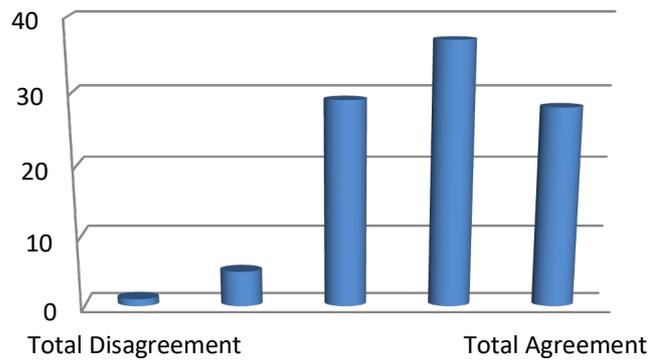
I believe that the checklist does not take too much time from the patient's clinical evaluation.



4) I believe that the checklist should always be used in major trauma.

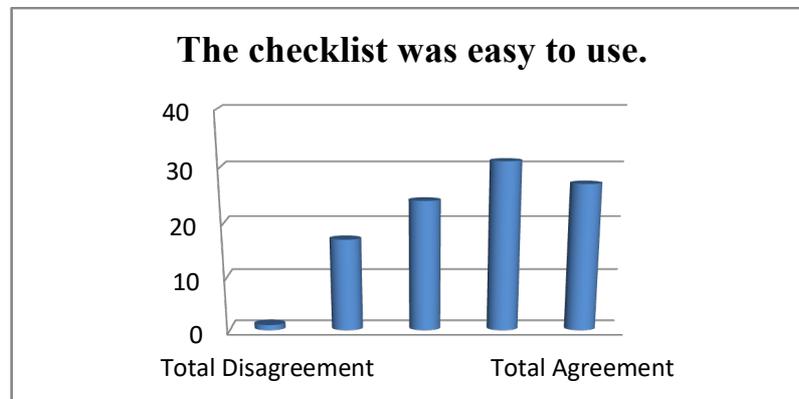
| Score | 1 | 2 | 3 | 4 | 5 |
|-----------|---|---|----|----|----|
| Frequency | 1 | 5 | 29 | 37 | 28 |

I believe that the checklist should always be used in major trauma.



5) The checklist was easy to use.

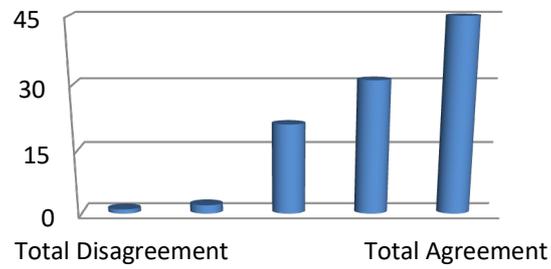
| Score | 1 | 2 | 3 | 4 | 5 |
|-----------|---|----|----|----|----|
| Frequency | 1 | 17 | 24 | 31 | 27 |



6) If I were the patient, I would like the Emergency Physician to use the checklist.

| Score | 1 | 2 | 3 | 4 | 5 |
|-----------|---|---|----|----|----|
| Frequency | 1 | 2 | 21 | 31 | 45 |

**If I were the patient I would like the
Emergency Physician to use the
checklist.**



For all items, most of the participants considered the usefulness of the checklist to be very good or excellent.

Discussion

Critical events in high-risk professions require rapid, coordinated and accurate maneuvers as a prerequisite for successful management. In high-stress environments, where it is necessary to process a lot of information, including contemporary ones, such as in the management of the polytraumatized patient, mistakes are often made. These are not so much due to a lack of knowledge but more as to cognitive deficits such as forgetfulness or inattention related to human factors and exacerbated by stress [130].

The use of the checklist in an emergency is a relatively poorly studied context. One of the first papers was written by Arriaga and coll. [131] who developed a checklist for the management of intraoperative critical events and tested it in a high-fidelity simulation environment involving 17 surgical teams in 106 scenarios. The checklist used by the authors led to a 75% reduction in non-adherence to critical steps in the management of crises in the operating room (6% of steps not performed with the use of the checklist compared to 23% of steps not performed without the use of the checklist, $p < 0.001$). These results were confirmed in different types of scenarios. In particular, three types were identified: scenarios that provided for the application of the Advanced Life Support (ALS) algorithm, scenarios that provided for the application of the same algorithms preceded by a pre-cardiac arrest situation and other than ALS situations (for example malignant hyperthermia).

Moving on to a more specific reality concerning the management of trauma, in 2004 the WHO published the Guidelines for the Management of Major Trauma [132], defining the resources necessary to guarantee a minimum level of assistance to the major trauma patient anywhere in the World. In the years that followed, numerous efforts were made in this field to identify sources of error and preventable deaths. Possible interventions for improvement were identified during airway

management [18], during volume resuscitation [133], and during the diagnosis of life-threatening injuries [134]. Following these findings, the WHO has promulgated a Checklist for the traumatized patient, to standardize and reinforce some aspects of the initial management of the trauma, in order to reduce the likelihood of neglecting critical actions. A minimal set of actions which should be performed in all trauma patients has been identified, regardless of the economic context. From 2010 to 2012, the impact of using this checklist was assessed in 11 different hospitals, by comparing the pre- and post-intervention period, with start dates randomly assigned to the different centers [30]. The authors reported a significant improvement for 18 of the 19 planned actions, including a greater likelihood of carrying out an abdominal physical examination, listening to the chest and examining the distal arterial pulses. This improvement did not lead to a significant reduction in complications, while a weakly significant reduction in mortality was observed in the group of patients with Injury Severity Score > 25. It is not easy to understand which factors led to this improvement and the authors report that they were different in the different centers. In this context, the detractors of the checklist report that the successes highlighted in the studies are not related to the use of the checklist itself but to an overall improvement in the patient safety program in the various hospitals in which it was tested [135]. It is certainly confirmed that the introduction of checklists requires training and an important change of mentality among operators.

With regard to our study, we wished to use the checklist introduced by the WHO, implemented with critical actions considered essential by the subsequent NICE guidelines for trauma management [129]. The data obtained from the simulations we performed document that, during major trauma in high-fidelity simulations, the use of the checklist has brought a significant improvement in the performance of the team, especially in regard to adherence to guidelines in the execution of critical

actions. In particular, we assessed this improvement in the completeness of the primary evaluation. Our data are in line with the data presented by Arriaga regarding the improvement in the completeness of management and therefore in patient safety due to the introduction of surgical checklists in operating theaters. Another important finding in our study concerns the positive impact that the checklist had on the non-technical skills of the team. In fact, our data showed a significant improvement in the global score of the Clinical Teamwork Scale, with a non-significant improvement, even if present, of the individual sub-areas. From this point of view, the checklist seems to improve teamwork, favoring communication through the systematic verbalization of the critical actions to be taken and the sharing of the results.

Finally, with regard to the anonymous evaluation of satisfaction, the participants in the simulations recognized the clinical validity of the checklist. In particular, 97% of the learners stated with at least a good degree of agreement that, if they were a victim of trauma, they would like the emergency doctor to use a checklist. Less clear-cut results were instead obtained with regard to the questions on ease of use and, above all, on the speed of use. In fact, more than one in three participants disagree with the phrase “I believe that the checklist does not take too much time from the patient's clinical evaluation”. This opinion of the participants is corroborated by the results obtained on the evaluation of the execution times of critical actions; in fact, we note that the checklist never improves speed, but rather the control group was significantly faster in the execution of four critical actions (objective examination of the chest, placement of two venous accesses, collection of samples for blood count and coagulation, evaluation of the pulses). The largest timing difference between these four items is the pulse assessment, which attests to a difference between averages of less than two minutes (2:56 without CL vs 4:50 with CL) so we believe it is difficult for this delay to affect the patient outcome. However, it remains a fact that the clinical evaluation of the polytrauma patient with a checklist is slower. It almost

seems that learners, and therefore clinicians in the management of major trauma, have to choose whether to be quick and incomplete using their clinical experience or slow and precise using the checklist tool.

This is not a condition that surprises us. The psychologist Daniel Kahneman, 2002 Nobel Prize-winner for economics, theorized in his book "Thinking, fast and slow" [136] that our mind works in two ways: System 1 and System 2. System 1 is primitive, unconscious and automatic. It is always functional, it is emotional, intuitive, very fast and impulsive. It can perform multiple tasks at the same time and it uses little energy. For these reasons it is the system we use the most during an emergency. The problem is that System 1 is very easily influenced, sometimes it is superficial and prone to error as soon as the context becomes more complex.

System 2, on the other hand, is the opposite of System 1. It is aware, rational, methodical and cautious. It cannot deal with several processes at the same time, it is slow, requires a lot of energy and, for these reasons, it is scarcely used even if it is very precise. System 2 in an emergency would allow us to be complete and precise, not to lose any element or not to interpret it incorrectly. According to Kahneman, System 2 is difficult to activate under pressure or in the presence of strong emotions or physical fatigue. The Author cites an interesting study in which, to demonstrate the different functioning of System 2 based on the energies present in our body, monitored the actions of 8 judges carrying out their duties. Whereas one morning these 8 judges granted conditional release to 65% of the inmates who presented themselves in front of them in the morning, after lunch this percentage dropped to 10%. Considering that, in the management of the trauma emergency, emotional pressure and stress are often present and frequently associated with physical fatigue in the current shift, therefore the doctor is often in conditions in which it is almost impossible to activate System 2 without support. In this sense, the checklist could be exactly the tool the clinician needs. An easily usable list of critical actions that prevents mental

shortcuts and inaccurate heuristic, responsible for omissions and evaluation errors.

Obviously this is a tool that can take a longer time for assessment but the final result, as shown by our data, is significantly better in terms of completeness in adhering to critical actions. Considering the demonstrated clinical importance of the checklist, it would therefore be important to identify strategies to optimize the relationship between the clinician and this instrument. Gawande, in his book "The checklist manifesto"[108] highlighted the reticence of his colleagues in the use of the checklist when it was first introduced in the operating theater. The path identified for a successful adjustment, according to the Author, involves two steps.

The first is that of self-criticism: the checklist must be easy to use, it must be a form of help and not a problem. Gawande writes that, after the first unsuccessful attempt to introduce a checklist, "I set my research team to work making our fledgling surgery checklist more usable. We tried to follow the lessons from aviation. We made it clearer. We made it speedier. We adopted mainly a Do-Confirm rather than a Read-Do format, to give people greater flexibility in performing their tasks while nonetheless having them stop at key points to confirm that critical steps have not been overlooked". These are all suggestions that are also adaptable to the checklist used in our study

Another aspect that can be improved is the methodology, as in the study it was asked to use a Read-Do approach, rather than a Do-Confirm, considered by the checklist theorists to be a more streamlined format.

The second step is that of a necessary change of mentality of the operators. While carrying out some simulations with a checklist, we noticed how it represents for now an unfamiliar tool for clinicians, the use of which may not be taken for granted, especially during an emergency. In the anonymous satisfaction survey, some adversities of the participants towards this tool were reported, especially on the part of the more

experienced trainees, who considered the checklist a forcing of the usual and consolidated clinical practice. Also in this area Gawande comes to help us. In the concluding chapter of "The Checklist Manifesto", he writes that doctors and surgeons, especially those with more experience, are less likely to use a checklist, although it has been shown that anyone could benefit from its use. In fact, we read that the checklist "is regarded as an irritation, as interference on our terrain. This is my patient. This is my operating room. And the way I carry out an operation is my business and my responsibility. So who do these people think they are, telling me what to do?".

The checklist, in a generic sense, could soon become a fundamental tool for all complex procedures, for all clinical activities in which there is complexity and the need for a standardized approach. Any area, especially in emergency medicine, could greatly benefit from the use of checklists. The real question is whether the current medical culture is able to seize this opportunity.

Tom Wolfe's "The Right Stuff" [137] tells the story of the first astronauts and charts the demise of the maverick Chuck Yeager test-pilot culture of the 1950s. It was a culture defined by how unbelievably dangerous the job was. Test pilots strapped themselves into machines of barely controlled power and complexity, and a quarter of them were killed on the job. The pilots had to have focus, daring, wits, and an ability to improvise, the right stuff. But as knowledge of how to control the risks of flying accumulated -as checklists and flight simulators became more prevalent and sophisticated- the danger diminished, values of safety and conscientiousness prevailed, and the rock star status of the test pilots was gone.

Gawande, in conclusion, draws a parallel between this aerospace culture of the 1950s and the current medical culture: "We have the means to make some of the most complex and dangerous work we do -in surgery, emergency care, ICU medicine, and beyond- more effective than

we ever thought possible. But the prospect pushes against the traditional culture of medicine, with its central belief that in situations of high risk and complexity what you want is a kind of expert audacity. Checklists and standard operating procedures feel like exactly the opposite, and that's what rankles many people".

To confirm this mentality also in our context we have noticed how, during the simulations with the checklist, the team leader tended to ignore the checklist in moments of greatest criticality.

The study design included, during the pre-briefing, the screening of a short film with instructions for using the checklist. This may not be enough and a more specific training on how to use the checklist may be essential to reap the maximum benefits from this tool.

The change of mentality is a complex process, which takes place in the long term. We believe that a specific training of emergency trainees on the correct use of the checklist and the subsequent introduction of this tool in daily clinical practice can help to initiate this fundamental change.

Limitations

Checklists are used in a variety of clinical settings to improve patient safety. The design of this study, however, is limited to a simulation environment. Our findings suggest that checklists have the potential to reduce errors also in trauma management, but further clinical studies are required to confirm the effective utility of this tool in improving patient safety.

Conclusions

In conclusion, in a high-fidelity simulation environment, the introduction of a checklist for managing the patient with major trauma was shown to improve team performance in guideline adherence and non-technical skills.

The checklist, however, being a tool which is not currently used in the clinical practice of the emergency physician, could slow down the management of major trauma patient.

Specific training on the use of this tool already during residency and its subsequent introduction into the daily clinical practice of the emergency physician could lead to a marked improvement in the safety of the patient.

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Acknowledgments

These three years of PhD have been challenging from all points of view. Years of great events and great changes, which have taught me that the Method is the most useful tool to face any difficulty.

In this complex context, the drafting of this work would not have been possible without the contribution of many people, whom I want to thank. The Trainees in Emergency Medicine from the University of Florence were fundamental, in particular Irene and Federico, who participated in the study with passion. I thank my colleague Giulia Mor-mando for having contributed to making this study multicenter. I thank Dr. Francesca Innocenti, for her fundamental help in conducting the study and revising the statistics and Giorgia Piatti for revising the language. I thank my tutor, Professor Riccardo Pini, who inspired and patiently revised the work, even accepting too many delays. Finally, I thank my Wife and my Family for the support that was necessary to reach this goal.