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## Development of trauma systems in Europe—reports from England, Germany, the Netherlands, and Spain

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# Development of trauma systems in Europe—reports from England, Germany, the Netherlands, and Spain

Tim JS Chesser, FRCS<sup>a,\*</sup>, Chris Moran, FRCS<sup>b</sup>, Keith Willett, FRCS<sup>c</sup>, Bertil Bouillon, MD<sup>d</sup>, Johannes Sturm, MD<sup>e</sup>, Sascha Flohé, MD<sup>f</sup>, Steffen Ruchholtz, MD<sup>g</sup>, Suzan Dijkink, MD<sup>h</sup>, Inger B. Schipper, MD, PhD, FACS<sup>h</sup>, Juan Carlos Rubio-Suarez, MD<sup>i</sup>, Francisco Chana, MD<sup>j</sup>, Julio de Caso, MD<sup>k</sup>, Enrique Guerado, MD<sup>l</sup>

## Abstract

Major trauma systems have evolved in many European countries and have resulted in improved care in terms of mortality and morbidity. Many of the systems have similar history, with reports of either poor services, or a single disaster, driving change of policy and set up. We report on 4 European systems, looking at the background, set up and some of the results. Similar issues are identified including the importance of triage, the concentration of specialist skills which require patients to bypass hospitals, and the standardization of treatment protocols. The issues of rehabilitation and the increasing importance of measuring outcome with patient reported metrics are discussed.

**Keywords:** major trauma systems

## 1. Introduction

Injuries are the most common cause of death and disability of those under 40 years of age with survivors often suffering long-term disability.<sup>[1]</sup> Many trauma systems evolved through slow adaptation of hospital systems and, more recently, with increasing specialization and interventional care, all health care systems have had to adapt. It is unfortunate many systems have changed after reports of inadequate care, but all have recognized the

importance of involving the whole pathway, from initial triage, prehospital care, systems of resuscitation treatments, and rehabilitation. These system changes have led to both improved mortality and morbidity in patients sustaining trauma, though, rehabilitation remains a work in progress for most. The report from 4 European nations summarizes the background and outcomes.

## 2. Major trauma networks in England

### 2.1. Background and set up

Each year there are 40,000 cases of major trauma and 5400 deaths in England.<sup>[2]</sup> A national report published in 2007,<sup>[3]</sup> identified serious failings in the organization of trauma care in England. This had evolved since the inception of the National Health Service in 1948 and was based upon the ambulance service transporting the patient to the nearest Accident and Emergency Department, irrespective of the capability of the hospital to provide resuscitation and definitive care. There was great variation in the standard of care and comparative studies showed that the outcome following trauma did not meet the standards of other countries.<sup>[4]</sup>

Every region has developed a network of hospitals based upon geography, available facilities, and transfer times and this has led to the designation of 3 tiers of hospitals providing trauma care: major trauma centers (MTCs), trauma units (TUs), and local emergency hospitals. Prehospital teams now use major trauma triage tools to identify patients who may have suffered severe injuries. Triage positive patients who are within 60 minutes transfer time of a MTC are taken directly there, by-passing all hospitals on route unless there is an immediate life-threatening condition. MTCs have all the facilities to provide comprehensive emergency and definitive care with consultant-led trauma teams 24/7.<sup>[5]</sup> In England, there are now 27 designated MTCs: 11 for adults and children, 11 for adults, and 5 for children. National standards of care include being received by a consultant led

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<sup>a</sup> Department of Trauma and Orthopaedics, North Bristol NHS Trust, Bristol, <sup>b</sup> National Clinical Director for Trauma, Professor of Orthopaedic Trauma Surgery, Nottingham University Hospitals NHS Trust, Nottingham, <sup>c</sup> National Director for Acute Care to NHS England, Professor of Orthopaedic Trauma Surgery, University of Oxford, Oxford, UK, <sup>d</sup> Department of Trauma and Orthopaedic Surgery, University of Witten/Herdecke, Cologne Merheim Medical Center, Cologne, Germany, <sup>e</sup> AUC—Akademie der Unfallchirurgie, Berlin, <sup>f</sup> Department of Trauma and Orthopaedic Surgery, City Hospital Solingen, <sup>g</sup> Department of Trauma and Orthopaedic Surgery, University Hospital Marburg Germany, <sup>h</sup> Department of Trauma Surgery, Leiden University Medical Center, Leiden, The Netherlands, <sup>i</sup> Hospital Universitario La Paz. University Autonoma of Madrid, Madrid, <sup>j</sup> Hospital Universitario Gregorio Marañón. University Complutense of Madrid, Madrid, <sup>k</sup> Hospital Universitario Santa Creu i Sant Pau. University Autonoma of Barcelona Barcelona, <sup>l</sup> Professor and Chairman Department of Orthopaedic Surgery and Traumatology, Hospital Universitario Costa del Sol. University of Malaga. Marbella Malaga, Spain

\* Corresponding author. Address: Department of Trauma and Orthopaedics, Brunel Building, Southmead Hospital, Bristol, BS10 5NB, United Kingdom. E-mail address: tim.chesser@nbt.nhs.uk (Tim JS Chesser).

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trauma team, computed tomography (CT) scan within 60 minutes on arrival, intubation for those patients with a Glasgow Coma Scale 8 or below, tranexamic acid to be given within 3 hours of injury, protocols for massive transfusion in hemodynamically unstable patients, and patients receiving a rehabilitation prescription on discharge, as well as up load of data to the national data set (Trauma Audit Research Network—TARN).

Patients with a transfer time longer than 60 minutes to the nearest MTC are taken to the nearest TU. These designated hospitals (n = 127) have the facilities to provide resuscitation and manage immediate life-threatening conditions. However, they lack specialist services such as neurosurgery, cardiothoracic surgery, and pelvic surgery and cannot provide comprehensive definitive care for all injury patterns. Within the network, the function of the TU is to resuscitate the patient and provide expert triage so that appropriate patients are then transferred safely and rapidly to the MTC for definitive care. The regional networks went live in April 2012; quality assurance is ensured by a national audit (TARN), which produces comparative data and a national dashboard. A comprehensive peer-review program, including annual site visits to all MTCs and TUs with clearly defined standards for quality, provides assurance and quality improvement. All MTCs and networks have robust clinical governance.

## 2.2. Outcomes

The major trauma networks in England have resulted in a significant 20% increase in the probability of surviving trauma for the 54 million population of England,<sup>[6]</sup> and this equates to about 500 additional survivors per year. Prehospital triage and transfer protocols have resulted in a significant increase in patients treated at a MTC from 13,358 in 2011 to 26,486 in 2016. The networks have also facilitated rapid dissemination of evidence-based practice (e.g., massive transfusion protocols, rib fracture fixation). Independent, socioeconomic analysis has calculated the cost effectiveness of the system at £2500 (\$34,000) per QALY.<sup>[7]</sup> With the system change it has led to advances in care with resuscitation, orthopaedic management of multiple trauma, rib fracture fixation, and orthoplastics for the delivery of care for open fractures. The healthcare system is free at the point of delivery for all, being funded through the centralized tax system.

## 3. Major trauma networks in Germany

### 3.1. Background and set up

Germany has more than 7 million accidents every year with 35,000 patients sustaining severe injuries. Data from 2004 showed that infrastructure, treatment modalities, and outcomes significantly varied between hospitals. The mortality rate after traffic accidents differed between provinces in Germany (0.5% up to 2.7%). Because of the increasing economic pressure in health care after introducing the Diagnosis Related Groups (DRG) system in Germany in 2003, an increasing number of hospitals refrained from trauma care. The problem was that the treatment of severely injured patients was inadequately reimbursed, with hospitals concentrating on more profitable elective cases.

The German Trauma Society (DGU) therefore initiated a project for regionalization of trauma care called “TraumaNetwork<sup>DGU</sup>.” The aim of the project was to secure and, if possible, improve the care of the severely injured by implementation of defined standards of care nationwide.

In 2006 the project was started with publication of the “Whitebook—Medical Care of the severely injured.” It defined the standards of cooperation and communication within a regional trauma network, the standards of resources for equipment, and personnel for the different levels of Trauma Centers, outlining the concepts of the “TraumaNetwork<sup>DGU</sup>.” The aim was not only to certify individual hospitals but also rather the regional network, with individual hospitals applying for participation in a regional network as Trauma Centers (levels I–III). If they fulfilled the defined standards, centers were audited and subsequently participated in the German Trauma Registry (with quality of their documentation being regularly checked by random examination of patient charts and data entry in the registry). In addition, centers had to prove the implementation of in-hospital quality and their participation in the regional quality conferences. Only if the regional trauma network was active were the participating trauma centers granted level I–III certificates. Re-certification, including re-auditing of the individual Trauma Center and regional trauma network are performed every 3 years.

### 3.2. Whitebook—Medical Care of the severely injured

The white book defines the standards of care in system structure and process.<sup>[8]</sup> It defines the criteria to become a level I–III trauma center, including equipment and quantity and quality of staff. It defines the modes of interaction within a regional trauma network, including those responsible for prehospital care and emergency medical services (EMS). The white book was published in 2006 and updated in 2012 and is published in German and English.

The audits of trauma centers are performed by independent companies specializing in health care certification processes according to a predefined protocol. The audit evaluates if a trauma center fulfils the defined standards according to the white book (levels I–III). The audit includes a comprehensive questionnaire and a local visit of the facilities. All the different specialties and professions participating in the trauma care processes are interviewed. The audit ends with the assignment of the hospital as level I–III trauma center. If a hospital does not fulfil the criteria for a level III trauma center, it is not part of the regional trauma network.

### 3.3. Level 3 guideline on the treatment of patients with severe/multiple injuries

The aim of this high level clinical practice guideline is to provide the latest evidence on the management of the severely injured patient. The level 3 guideline is evidence based and was endorsed by the representatives of all 20 participating medical societies.<sup>[9]</sup> The guideline provides 307 key recommendations for the management of severely injured patients in 3 different phases: prehospital management (70 key recommendations), emergency department management (135 key recommendations), and early operative management (102 key recommendations). Each key recommendation is followed by the rationale, with the evidence explained in more detail. The latest update of the guideline was published in German in 2016. The English-language version is available through “free access.” The white book suggests that all trauma centers should have trained personnel in the emergency department fulfilling the ATLS Standard. In prehospital management, an increasing number of EMS organizations are adopting the Prehospital Trauma Life Support (PHTLS) Standard, which facilitates communication between EMS and emergency department.

All the participating trauma centers must participate in internal and external quality improvement projects. The internal quality mechanisms have to define and update the local standards of care. Centers should perform morbidity and mortality conferences and should discuss their local annual reports from the trauma registry. Every regional trauma network has to perform a minimum of 2 regional trauma conferences, and every participating trauma center has to participate in these regional trauma conferences. Quality improvement projects should be initiated by the groups within the region. Most conferences perform case discussions, present new papers on selected topics relevant to trauma and others include hands on workshops for fracture care or emergency department procedures. The regional reports from the trauma registry are also discussed.

In order to facilitate communication and cooperation between trauma centers, the DGU initiated a project on tele-cooperation. It allows transfer of radiographs, CT scans, and magnetic resonance imaging and medical reports. It follows the standards of the German Society of Radiology and German law and allows support from level I centers to level II or III centers as needed. It helps to decide if a patient needs to be transferred. This has proven extremely useful for level II trauma centers, particularly taking advantage of neurosurgical consultation via telecommunication.

The trauma registry was initiated in 1993, long before the TraumaNetwork<sup>DGU</sup> started. The data are collected prospectively in 4 successive phases: prehospital, emergency department, intensive care, and discharge. The data entry is performed online. The documentation includes demographics, injury patterns, comorbidities, preclinical and clinical management, course in the ICU, and outcome. All severely injured patients (admission to intensive care after trauma or death in the emergency department after trauma) are included. All active trauma centers must report to the trauma registry, which is reviewed during the audit. Today, more than 33,000 severely injured patients are documented in the trauma registry annually. Today, the database includes more than 250,000 patients. The trauma registry provides a detailed annual report for every participating hospital. Participating trauma centers are also allowed to perform scientific evaluations on the complete database according to defined standards. The administration of the TraumaRegister<sup>DGU</sup> is provided by the DGU and its academy (AUC—Akademie der Unfallchirurgie).

In 2009, TraumaNetwork<sup>DGU</sup> started an annual meeting. The newest topics relevant to the care of the severely injured are presented, including the newest evidence. It is also used as a platform to give feedback and discuss new projects, and the newest annual global report from the trauma registry is reviewed. Finally, all participating trauma centers receive their individual annual reports from the trauma registry.

### 3.4. Outcomes

The first regional trauma network in Germany was certified in 2009. Since then, it has taken 6 more years to complete this nationwide trauma system with 51 regional trauma networks and more than 650 participating trauma centers (14% level I, 29% level II, and 57% level III). Over the years, new trauma centers have joined the trauma network, while others have left. The typical regional trauma network consists of 14 (5–29) trauma centers, with 2 level I trauma centers, 4 level II centers, and 8 level III centers.<sup>[10]</sup>

Many centers have reported changes in their organization and resources. In a survey, 43% of all trauma centers reported

organizational changes such as local trauma room protocols, quality mechanisms, and communication with EMS. Such reported changes were noted in 29% of level I centers, 54% of level II centers, and 44% of level III centers. Changes in staff qualification were reported in 24%. Participation in ATLS courses was the most frequent change. Changes in equipment were reported in 17% of centers, being more frequent in level III centers. The reason for these changes was predominantly that hospitals that wanted to become a trauma center had to fulfil the standards. Interestingly enough, since introduction of TraumaNetwork<sup>DGU</sup>, hospitals that previously wanted to back out of the system have since wanted to be part of this new movement. When hospitals were asked why they wanted to participate in this new trauma system, the top 3 answers were: improvement of trauma care, improvement of patient transfer policies, and having a backup available whenever needed. The prehospital EMS system reported that cooperation had improved significantly between EMS systems and trauma centers since the introduction of TraumaNetwork<sup>DGU</sup>.

Participation of trauma centers in the trauma registry has increased since the introduction of the TraumaNetwork<sup>DGU</sup>, as it is compulsory for all participating trauma centers. Around 4541 severely injured were included in 2006 compared to 33,374 in 2016. The standardized mortality rate has steadily declined since its implementation. Therefore, the TraumaNetwork<sup>DGU</sup> appears to have improved patient care, which was its initial goal.

## 4. Major trauma systems in the Netherlands

### 4.1. Background and set up

Despite many years of documented deficits in trauma care, it was not until an airplane crash in a densely populated area in Amsterdam (“The Bijlmer Disaster,” 1992) that changes in trauma systems began to occur. In 1995, the Public Health Inspectorate published a compromising report on the “Unsound chain” of care, in which it pointed out that solid organizational structures connecting prehospital and in-hospital care were lacking, not only in the case of disasters, but also in daily practice.<sup>[11,12]</sup> In 1997, the Dutch Association for Trauma Surgery published its recommendations for a Dutch trauma system. In 1998, the Dutch government appointed 10 (later 11) Trauma centers and their trauma regions in the Netherlands. The aim was to better organize and regionalize trauma care throughout the chain of care providers, coordinated by the appointed trauma centers.<sup>[13,14]</sup> Although the main task of the coordinating trauma centers is to provide care for the severely injured patients in their region, they are also appointed to establish a trauma care network within their own region and to serve as a knowledge center, collecting and distributing knowledge and skills, performing trauma related research, and coordinating the regional trauma registration.

Since 2000, similar to the trauma center concept for regionalization of care, other acute care providers also have developed integrated health care pathways within regions and have organized themselves. This has resulted in the establishment of the “Regional Consultation of Acute Care” (Regionaal Overleg Acute Zorgketen [ROAZ]) in which all partners contributing to acute care are involved and cooperate. There are currently 11 ROAZ regions, similar to the trauma regions, in which ambulance services, general practitioners, hospitals, trauma centers, all acute care professionals, and the government work together to improve the integrated care for the acute patient.

## 5. Current perspective on organization of trauma care

The all-inclusive trauma network comprises designated trauma centers and acute care networks, working closely with regional ambulance services (EMS) and mobile medical teams (helicopter emergency medical services [HEMS]). Currently, there are 11 trauma regions in the Netherlands with a coordinating level 1 trauma center and a minimal catchment area of 1.2 million inhabitants. The 11 trauma regions, their level 1 coordinating trauma center and surrounding hospitals form acute trauma care networks that cover the entire Netherlands. Spread over the different regions are 42 level 2 hospitals and 33 level 3 hospitals.<sup>[15,16]</sup>

During the establishment of the Dutch trauma system, the focus was broader than just in-hospital trauma care pathways; it comprised the complete chain of trauma care – from prehospital care and transport through to the hospital stay and the initiation of rehabilitation.

### 5.1. Prehospital care

As a consequence of the new Temporary Ambulance Care Bill (Tijdelijke Wet Ambulancezorg), introduced in 2013, the prehospital care also became regionalized resulting in 25 regional ambulance organizations that are responsible for organizing the ambulance care within their region.<sup>[17,18]</sup> In general, the ambulance is staffed with 2 health care professionals: a driver and a paramedic. All paramedics are PHTLS certified and can perform medical interventions, such as defibrillation, intubation, needle decompression of the chest, administration of drugs, and a modified tracheostomy, all according to the national prehospital protocols.<sup>[17,19]</sup> On indication, again according to specified criteria, they are assisted by a Mobile Medical Team (MMT). The MMT, staffed with an ATLS-certified physician (trauma surgeon or anesthesiologist), is often brought to the scene by helicopter (HEMS). The team provides advanced prehospital care for the severely injured at the accident scene and during transportation to the hospital.<sup>[20]</sup> Due to the short distances and good infrastructure in the Netherlands, only 3% of the patients are transported to the hospital by helicopter.<sup>[21]</sup> Currently, there are 4 locations from which the HEMS are dispatched, covering the entire country 24/7.

### 5.2. In-hospital care

It is mandatory for hospital specialists to be ATLS certified if they are involved in the initial management of the severely injured. A dedicated trauma team supervised by the trauma surgeon is always available and responsible for the initial care of the injured patients.<sup>[17]</sup> In addition to the trauma surgeon and the emergency physician, the trauma team consists of a surgical resident, an anaesthesiologist, an ICU doctor and nurse, radiologist, 2 ED nurses and an OR nurse.<sup>[22]</sup>

The trauma surgeon takes the lead role in the care of the injured patient, from hospital admission to hospital discharge. Trauma surgeons in the Netherlands are general surgeons who followed extensive training to treat thoracic, abdominal, and musculo-skeletal injuries. Currently, trauma surgeons are responsible for 75% of the fracture treatment, operative and nonoperative, and orthopaedic surgeons for 25%.<sup>[23]</sup> Closer collaboration in a multidisciplinary TU where trauma surgeons and orthopaedic surgeons fulfil the same requirements is in the process of being developed nationally. With the improved outcomes and the

decreased mortality, increasing attention is given to the postacute care, with more focus on rehabilitation to improve quality of care after injuries.<sup>[24]</sup>

### 5.3. Outcomes

In the Netherlands, the implementation of an all-inclusive trauma system has significantly improved the outcomes of trauma patients. The trauma system has resulted in an overall mortality risk reduction of 16%, which increases to 21% mortality risk reduction in the severely injured patients.<sup>[16,25,26]</sup> The short lines of communication and the well-organized all-inclusive trauma systems in all 11 regions make the Dutch trauma system unique and of high quality. By focusing on integrated health care in which various health care providers work together to achieve the best possible outcome for the patient, the Dutch trauma system has improved substantially since its implementation 20 years ago. Of the many challenges that future trauma care will bring about, 2 in particular deserve further discussion.

First, the volume-outcome relationship for improved trauma outcomes has been controversial since the introduction of trauma systems. A minimal number of admitted severely injured trauma patients is a criterion in many systems, and in the Netherlands a level-1 trauma center has to admit at least 100 polytrauma patients (ISS  $\geq$  16) annually—a relatively low number in comparison to the United States. The American College of Surgeons Committee on Trauma requires that level-1 trauma centers admit a minimum of 1200 trauma patients each year, of which at least 20% must be qualified as polytrauma patient (Injury Severity Score  $\geq$  16).<sup>[27,28]</sup> Despite these differences in volumes, recent studies show similar outcomes in patients with blunt and penetrating trauma in the Netherlands and the United States.<sup>[29]</sup> Recent reports suggest that the implementation of a trauma system leads to the standardization of complex care, high level of education, training and resources, and influences outcome independently of the volume.<sup>[30,31]</sup>

Second, although the prehospital care in the Netherlands is well organized with regional ambulance services, national protocols and the availability of HEMS/MMTs, improvements can be made in the quality of the prehospital triage to ensure that the right patient is transported to the right hospital. In 2015, the Netherlands National Health Care Institute (Zorginstituut Nederland) published their report on quality indicators for the care for the severely injured patient, in which they stated that at least 90% of the polytrauma patients should be primarily brought to a level-1 trauma center.<sup>[32]</sup> However, recent reports from the Dutch National Trauma Registry show that almost none of the trauma regions match those numbers, with on average about 30% of patients being under-triaged, with severely injured patients brought to a level 2 or 3 trauma hospital rather than a level 1 facility.<sup>[32]</sup> On the other hand, in about 30% of the cases, over-triage occurs where patients with less severe injuries are brought to higher level centers.<sup>[33]</sup> In general, reducing under triage is given priority over over-triage, as under triage increases the risk of mortality and morbidity.<sup>[34]</sup> Due to this new 90% indicator and the increasing awareness of the importance of triage, tools are being developed to improve the quality of prehospital triage in severely injured patients.<sup>[32,34]</sup>

Overall, the Dutch trauma system has resulted in improved care, yet challenges remain. Substantiated volume criteria for trauma centers, tools for improvement of prehospital triage, and new, validated outcome measures would help make further

improvements and deliver true optimal care for the injured patient.

## 6. Major trauma networks in Spain

### 6.1. Background and set up

Spain is a well-developed country with good economic and social indicators,<sup>[35]</sup> where all citizens have free provision of health care, including urgent medical and surgical treatment, that are funded by taxes. There is no reimbursement system, but health institutions have a budget per population. Spain is formed by 18 autonomous communities (ACs)—described as a federation of regions—that have their own health systems, which are not always as well coordinated with each other as they could be. There has been a creation of Reference Centres, Services and Units (CSUR) for several diseases and treatments, which has improved health care. The definition of these CSUR Units is made by an interterritorial commission representing every AC, and is based on assigned criteria related to experience, level of activity, equipment, training and results.<sup>[36]</sup>

Despite the increasing importance of trauma patients and their high consumption of resources,<sup>[37]</sup> there is a lack of consideration of the traumatic injuries in the CSUR program (except for spinal cord injury, limb re-implantation, and critically burned patients). In practice, some ACs have organized networks for severely traumatized patients organized around a network of trauma centers,<sup>[38,39]</sup> while in neighboring territories, such networks are lacking, leading to inefficiencies in care.

Additional improvements have been made to address the further development of communication and information systems. Updated information on intensive care unit bed availability and specialized hospitalisation together with teleconsultation protocols are currently being established that, with the transmission of imaging, documents and videoconference, make it possible to perform prompt consultations to the appropriate hospital, avoiding unnecessary transfers. As a part of the collaborative effort, biannual joint sessions are held between hospitals and departments. One collective goal is to create a National Trauma Centres Network in order to achieve a homogeneous standard of care for trauma patients and trauma-related injuries within the CSUR units.

Presently, notification of a serious trauma situation occurs by a telephone. The alert can be triggered by a citizen, the State Security Forces, firefighters, or any other institution or person. The management and coordination of calls is performed by the *Center for the Coordination of Emergencies*. There are 4 types of priorities:

*Priority 1:* Emergency. Situations where the patient's signs and symptoms are consistent with an imminent vital risk, requiring immediate attention. This priority may require alert police, firemen, or others.

*Priority 2:* Urgency, not delayable. Suspicion of an acute or exacerbation of a chronic disease without immediate vital or functional threat, but requiring medical attention as soon as possible.

*Priority 3:* Urgency, demonstrable. Suspicion of a disease not requiring immediate attention.

*Priority 4:* Home visit.

After the evaluation at the accident site, the patient and care needs are assessed, and the patient is transferred to an appropriate hospital (taking into account proximity and level

of care). For example, in the case of risk of massive bleeding, the patient is transferred to the nearest hospital; but in the case of brain trauma the patient is taken to a specialized hospital. All hospitals are equipped with CT scanners, but contrast CT scanning can only be performed in specialized hospitals. Depending on proximity and accessibility, a helicopter or an ambulance is activated from the coordination center.

Depending on the patient's vital signs, the anatomical lesions, mechanism of injury, and the distance to each type of hospital, the patient is transferred to either a type I (the highest level with all specialities), a type II (with on call general surgeons, neurosurgeons and orthopaedic surgeons) or a type III (the most basic) hospital. Helicopter transportation is used for those patients in need of transfer to a level I or level II hospital if more than 40 minutes away by land transfer.

### 6.2. Outcomes

Over the last few years, important changes in road safety policies have been made in Spain that have led to a significant and continuous decline in fatality and accident-related rates of hospitalization, decreasing to the lowest annual recorded totals in 2015. Yet, there has been a marked increase of road traffic accidents on urban roads that affect the most vulnerable groups, particularly pedestrians, cyclists, and motorcyclists. In 2016, the population of Spain was 46.4 million inhabitants, the vehicle fleet was 33.6 million and there were 26.5 million registered drivers.<sup>[40,41]</sup> Emergencies are organized according to the AC governmental body. As an example, in Andalusia, the most populated AC with more than 8 million people, there were 6383 trauma cases out of 52,909 responses, with an average response time of about 10 minutes in urban areas. Prevention programs through education on drug and alcohol abuse, handling telephones, and other programs, have helped diminish the trauma burden. Road traffic fatalities have decreased from 9344 cases in 1989 to 1810 cases in 2016.<sup>[40]</sup> Further, in the last decade, hospitalized injury casualty rates per million population decreased from 637 to 299,<sup>[40]</sup> the fifth lowest rate in Europe after Sweden, United Kingdom, Netherlands, and Denmark. Nonetheless, in spite of good comparative standards to the other European Union nations, more attention should be paid to the organization of a unified Spanish Trauma System.<sup>[42-44]</sup> Although provision of care is currently outstanding, efficiency and return of patients from a different AC to their original home city are less than optimally organized.

On the other hand, specialized training in orthopaedic trauma with specific certification would also provide better support for the management of orthopaedic trauma. Uniform orthopaedic trauma training, consistent across countries would also be beneficial. The Spanish Orthopaedic Trauma Association, within the Spanish Society for Orthopaedic and Trauma Surgery, is planning to start an ambitious project to address this issue by the end of 2019. The role of the national sections or orthopaedic trauma societies, within an international collaboration would be of overwhelming importance.

## 7. Conclusions

Continuing to improve the quality of care is paramount in any system, and learning from our current practice requires continued reflection and audit. Collecting meaningful data on both the process of trauma care and, more importantly, patient outcomes is paramount. Standardization and engagement are shown to be

key in the delivery of any system. Currently, most outcome metrics involve actual survival rates with predicted survival rates. However, with more patients surviving their severe injuries, there is a shift toward more attention on patient reported outcomes, with or without morbidity. Countries are introducing measurements of quality of life as outcome tools. The analysis of these data should then challenge the current standards of care.

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