# “International Alpine Trauma Registry”

# 1. Overview

## *1.1 Project title*

International Alpine Trauma Registry

## *1.2 Project coordination and direction*

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# 2. Project description

## *2.1 Background*

Rescue of a severely traumatized patient in mountain and/or in remote areas represents a particular challenge, especially due to environmental conditions, difficult terrain, long rescue and transport times and the lack of standardized guidelines [1-2]. To this day only few studies have been published on this topic, nevertheless display the importance of logistical and medical difficulties. During a retrospective study in Switzerland the Swiss helicopter rescue service (REGA) had 600-700 rescues using a rope winch because of difficult terrain, which represents 15.8 to 18.4% of all rescues (n=3800) [3]. Furthermore, 52% of rescued patients were seriously injured (NACA Score IV; National Advisory Committee for Aeronautics) and 2% had a NACA Score V [3].

Another study in Switzerland estimated that 22% of patients rescued by the Helicopter Emergency Medical Service (HEMS) and rope winch were seriously injured [4]. Kaufmann et al. showed that between 2001 and 2003 in the Tyrolean Alps 235 people rescued had a NACA Score $\geq$IV [5]. In South Tyrol it has been estimated that 10% of air rescue operations have been performed in difficult terrain. According to the general ATLS (Advanced Trauma Life Support) protocols of ILCOR (International Liaison Committee on Resuscitation) the applied strategies for treatment of seriously injured victims vary from “scoop and run” for a rapid treatment to “stay and play” for stabilization of the patient on site [1,2,6].

There are still no uniquely defined guidelines for the rescue of traumatized patients in mountain areas. However, the medical commission of the International Commission for Alpine Rescue (ICAR MEDCOM) has conducted a study on treatment strategies in Europe and North America [7] and has published a series of recommendations for management of the respiratory system [8], infusion therapy in case of haemorrhagic shock [9], techniques of immobilization [10], use of HEMS in mountain rescue [11] and emergency therapy of hypothermic patients and avalanche burial [12].

## *2.2 Purpose of the study*

1) The primary aim of the International Alpine Trauma Registry research project is to collect all applied strategies for the care of traumatized patients in mountain areas. The collected data will enable an international comparison between different strategies applied during the rescue of

traumatized patients in high altitudes and remote areas. Furthermore, these data could support the evidence-based definition of specific problems of pre-hospital treatment of traumatized patients in remote areas.

2) The second aim of the study is to collect the effects of pre-hospital and hospital treatment strategies and parameters on the survival and outcome of patients. Thus, the registry is based on the Utstein Style Protocol for uniform reporting of data [13].

## *2.3 Study type*

This is a perspective, observational study and is a multi-centre collaboration between different countries in Europe and North America.

## *2.4 Study protocol*

### 2.4.1 Inclusion criteria

The study inclusion criteria are: a) pre-hospital NACA-Score ≥IV, b) New Injury Severity Score (NISS) >15 or c) accident site in extra urban, mountainous or remote areas not accessible by emergency medical services.

Data collection will include individuals both who are capable of judicious decisions (i.e. people who are able to understand the contents and aims of the study and therefore to give their consent to participate in the study) as well as those incapable of judicious decision. For data collection of individuals who deceased in the accident or lost their capability for judicious decisions the consent of a legal representative is not mandatory, as according to the data privacy act of 24.07.2008 *in the case of particular ethical, methodological or organisational limitations that make informing the participant impossible, data collection without the patient's consent is still possible under the premise that the project has full approval by the appropriate ethical committee.*

### 2.4.2 Exclusion criteria

The study exclusion criteria are: a) patients already in cardiac arrest upon arrival of rescue team, b) burn patients if the burn represents the predominant injury and c) drowning patients. Furthermore, all patients who are capable of judicious decisions but who have decided not participate in the study will be excluded (Fig.1).

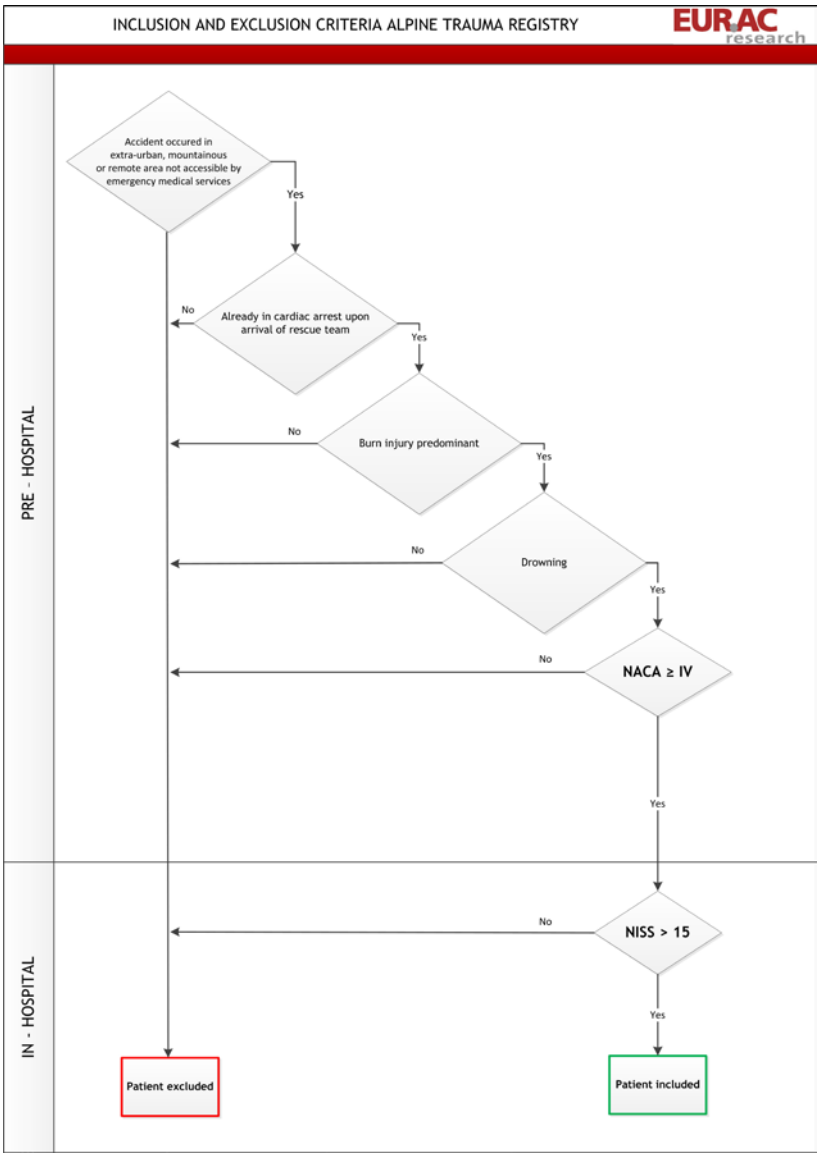


Fig. 1: Inclusion and exclusion criteria. NACA denotes National Advisory Committee for Aeronautics; ISS, Injury Severity Score; BP, blood pressure; ROSC, return of spontaneous circulation.

## *2.5 Data collection*

- The Emergency Service of the Province 118/115 and the rescue services of South Tyrol will assist in data collection by alerting the Local Data Manager (LDM) of the responsible hospital of possible cases, upon which the LDM is responsible for reviewing the eligibility of the case. This ensures both a comprehensive review of all potential cases and a verification of the suitability of included cases.

- Participants who are capable of judicious decisions will be informed personally by the LDM (in written or oral form) and required to sign two copies of the informed consent. In the case of an underage participant the LDM will contact the legal guardian or representative who will be responsible for signing the informed consent. For data collection of individuals who deceased in the accident or lost their capability for judicious decisions the consent of a legal representative is not mandatory according to the data privacy act (see paragraph 2.4.1). Data collection in this study has no direct influence on the treatment and outcome of included patients; however, the results of this study may in future help improve the treatment of traumatized patients during the pre-hospital phase in mountain areas.

- The LDM will collect all data included on the Case Report Form (CRF; see attachment) for all patients included in the study. From a total of 40 data points on the CRF, 22 concern the pre-hospital condition of the patient and 5 the details of the rescue. All information regarding the pre-hospital timing and the modalities of rescue will be provided by the local rescue services. The remaining data points concern the clinical status of the patient at hospital admission (11 points) and the outcome of the patient (2 points).

- The LDM will insert the data in the database of the European Academy Bolzano (EURAC) by a web application installed and secured by the Information & Communication Technologies at the EURAC. For the insertion of data every patient will be provided with an alphanumerical code (ID) that makes it impossible to retrospectively determine the identity. Access to the database will be secured with a password and an encoded connection (Secure Socket Layer, SSL). The password will be periodically changed as stated by law.

- Each document revealing the identity of the patient will be archived in the hospitals and in the archives of the rescue services and of the Emergency Service of the Province 118/115. Only the director of data handling and data administration have the ability to access the ID and the corresponding personal data.

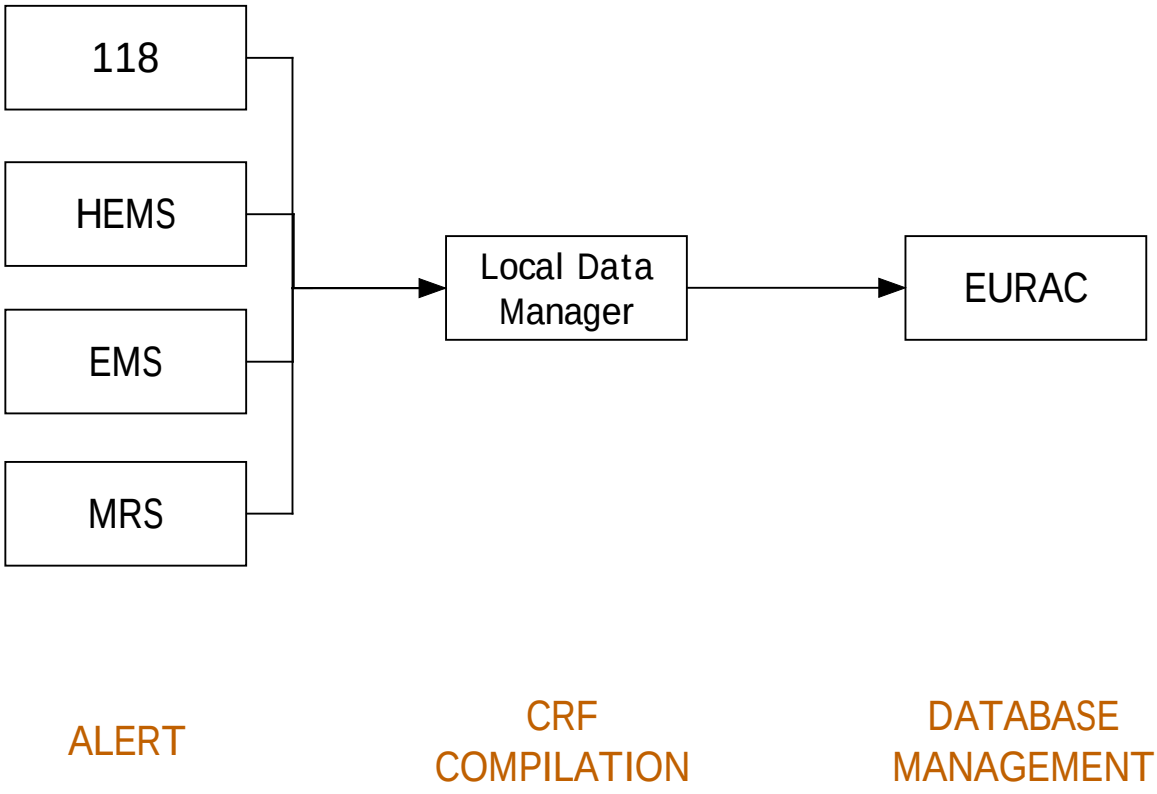


Fig. 2: Data flow. 118 denotes the dispatching centre of the Emergency Service of the Province; HEMS, Helicopter Emergency Medical Service; EMS, emergency medical service; MRS, mountain rescue service.

## *2.6 Timeline of the study*

The study will begin with a pilot period in which the applicability of the registry and problems related to data acquisition will be tested. The pilot period commenced in autumn 2010. The following data acquisition centres participated in the pilot period:

- South Tyrol, Italy, in collaboration with the Health Care Centre of the Province, the Emergency Service of the Province 118/115, the Mountain Rescue Service of the Alpine Club of South Tyrol (Bergrettungsdienst im Alpenverein Südtirol) and the National Corp for Mountain and Cave Rescue (Corpo Nazionale del Soccorso Alpino e Speleologico);

- Tyrol, Austria, in collaboration three bases of the HEMS and the Mountain Rescue Service of Tyrol.

The following data acquisition centres are planned to commence participation in the second phase of this project:

- Switzerland, in collaboration with three bases of the HEMS;
- Great Britain, in collaboration with the British Mountain Rescue Council;
- Canada, in collaboration with the local Search and Rescue Service (SAR).

After insertion of the first 100 cases the director of the study together with the scientific collaborators will make a first statistical analysis in order to discuss and evaluate the quality of data and the completeness of the CRF. This procedure will help improve the data collection and the study protocol. Following this the project can be extended to other centres and rescue organizations. Data collection will be continued until 2015. The number of cases necessary for the statistical evaluation depends on the formulation of the specific research questions. However, in general, due to the nature of the study and the variability that is expected between cases and regions, a minimum of 750 cases would be required to achieve a clinical significance of 10%. Based on available epidemiological studies [3,4,5] it can be expected that this number could be achieved within one and a half years.

# 3. Ethical and judicial principles

The study protocol corresponds to the directives of the Declaration of Helsinki (amended in Edinburgh in 2000 and in Washington in 2008) of the Convention of Human Rights and Biomedicine (Oviedo 2007), of the Italian Law on Science and the international CIOMS guidelines (2002).

Participants or legal guardians should refer to paragraph 2.5 of this document for an overview of the goals and perspectives of this study. To participate in the study the patients must sign an informed consent which is attached to the detailed information sheet. A patient may revoke their consent at any time, fully or partially, written or oral (followed by written confirmation) without stating any reasons. In this case all personal data will be destroyed.

The treatment of personal data corresponds to the Italian legislation stating in accordance with the Legislative Decree n. 196/03 with regard to data privacy and protection of individual rights that the personal data of every participant will be collected and archived in the respective hospitals and will be used for research purposes only.

The medical data will be identified through an alphanumerical code (ID) and will be transferred to the Institute of Mountain Emergency Medicine only in an encoded form. All information will be treated strictly confidentially. All data can be sent only in an encoded form to the collaborators. In case the results of the study will be published in scientific journals or presented at congresses, all information related to the identity of the patients will be made unidentifiable.

To maintain records for future clarification and/or follow-up personal and clinical data will be stored in the hospitals and their respective departments and in the archives of the Mountain Rescue Service and Emergency Service of the Province 118/115. Access to these records is only possible by retrieval of the patient's name through the alphanumerical code, which is the responsibility of the study director only.

## *3.1 Information and informed consent*

Participants or legal guardians may refer to paragraph 2.5/3 of this document for an overview of the aims and possible developments of the project. To participate in the study the patients must sign an informed consent which is attached to the detailed information sheet. A patient may revoke their consent at any time without stating any reasons (see paragraph 3 above).

### *3.2 Revocation of consent*

The participants have the possibility to revoke their consent at any time. In this case all data in reference to that person will be destroyed.

### *3.3 Compensation for study participants*

There will be no compensation for participation in this study. The participants do not have to undergo an additional examination. The results of this study may in future help in the development of guidelines and/or improve the treatment of traumatized patients during the pre-hospital phase in mountain areas.

### *3.4 Insurance*

This is an observational study with no risks for the participants and thus participants do not require specific or additional insurance.

## 4. Conflict of interest

The objective of this study remains solely for the purposes of medical research and does not anticipate any economic profit for the participants or their relatives.

## 5. Financing

This study will be financed by the Institute of Mountain Emergency Medicine of the European Academy Bolzano (EURAC). The EURAC is an innovative research centre that is both publically and privately funded. The projects of the Institute are undertaken in collaboration with the national Medical Service, the local Mountain Rescue Service and the Medical University of Innsbruck (Austria), but also in collaboration with other associations in the alpine areas, such as the medical commission of the International Commission for Mountain Emergency Medicine ICAR MEDCOM.

# 6. Publication and authorship

All publications that include data taken during this study must report the name of the responsible LDM and the person involved in the data collection and administration. If this person has made a significant scientific contribution ("substantial contribution") he/she has rights to potential authorship based on the guidelines for the elaboration of scientific material of the International Committee of Medical Journal Editors (ICMJE) [14].

# 7. **References**


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task force of the American Heart Association, the European Resuscitation Council, the Heart and Stroke Foundation of Canada, and the Australian Resuscitation Council. *Circulation* 1991; 84:960-975.

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# 8. Signatures

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# Attachments

Case report form

Informed consent