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Research Article

## The Minimum Dataset and Inclusion Criteria for the National Trauma Registry of Iran: A Qualitative Study

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#### **Abstract**

**Background:** Burden of injuries is an important public health problem, especially in developing countries. However, a national standard tool for data collection of trauma registry has not been developed in Iran yet.

**Objectives:** The present study aimed to describe the steps undertaken in the development of the minimum dataset (MDS) and define the inclusion and exclusion criteria for a case of trauma registry by the national trauma registry of Iran (NTRI).

**Methods:** The working group consists of sixteen elected expert representatives from seven established countrywide active trauma research centers. Following a structured extensive review of the literature, the working party identified the data variables that included key registry goals for pre-hospital and hospital, outcome and quality assurance information. We used data variables from three trauma registry centers: National trauma data standard questionnaire, European trauma care (UT stein version), and Sina trauma and surgery research center. Then, we performed two email surveys and three focus group discussions and adapted, modified and finally developed the optimized MDS in order to prepare the quality care registry for injured patients.

**Results:** The finalized MDS consisted of 109 data variables including demographic information (n = 24), injury information (n = 19), prehospital information (n = 26), emergency department information (n = 25), hospital procedures (n = 2), diagnosis (n = 2), injury severity (n = 3), outcomes (n = 5), financial (n = 2), and quality assurance (n = 1). For a patient sustained one or more traumatic injury in a defined diagnostic ICD-10 codes, the inclusion criteria considered as one of the followings: If the patient stayed > 24 hours in the hospital, any death after hospital arrival, any transfer from another hospital during the first 24 hours from injury.

**Conclusions:** This study presents how we developed the MDS in order to uniform data reporting in the NTRI and define our inclusion and exclusion criteria for trauma registry. Applying the MDS and the case definition in pilot studies are needed in next steps.

Keywords: Focus Group Discussion, Iran, Patient Selection, Registries, System, Wound and Injuries

## 1. Background

The implementation of comprehensive regional trauma systems has led to substantial risk reduction of mortality and complications associated with severe injury (1, 2). These systems need continued improvement through careful supervision and monitoring. Trauma registries are comprehensive databases documenting hospital treatment (2, 3). A trauma registry system provides not only quality assessment work but also a framework

for development and evaluation of injury prevention strategies and clinical guidelines. They provide optimizing methods for clinicians and policy makers to care of injured patients (4, 5). Researchers suggest that organized trauma registries significantly reduce in-hospital and postdischarge mortality rates among major trauma injured patients (6, 7).

There are significant discrepancies in resources and content of each registry (8). In order to achieve quality improvement, continuity care, and optimal care to injured

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patients, comparison of the performance of trauma systems is essential and this is possible if there is standardization (9). However, without a uniform collection of inclusion criteria, variable definitions, and coding system, there will not be the possibility of comparisons between trauma systems and an available integrated national trauma system. For example, in an international comparison of seventeen regional trauma registries, a crude mortality rate was significantly increased in patients with an ISS > 15 (10). In Iran, all trauma stakeholders with policy-making councils lead trauma system management that is considered as the main key in integrating resources and establishing trauma systems. Evaluation, improvement, and desirable future in the trauma system all need a comprehensive trauma information system and a pathway map (11). Every country develops its own trauma minimum data set. Nevertheless, the minimum data set introduced in this article can provide a national trauma minimum data set (MDS) as an important step, especially at the initial steps of trauma system development. Recently, Iranian ministry of health and medical education has made investments to reinforce the establishment of the national trauma registry of Iran (NTRI).

#### 2. Objectives

This study was designed to describe the steps undertaken by the working team of the NTRI to develop the national trauma MDS along with defining inclusion and exclusion criteria for a case of trauma registry.

#### 3. Methods

#### 3.1. Administration

Responsibility for the NTRI was formally awarded to the Sina trauma and surgery research center (STSRC) by the ministry of health and medical education in 2014. First, the STSRC decided quality care objects instead of epidemiologic objects for trauma registry. Then, we focused on the national trauma registry questionnaire which demonstrates a concerted and sustained effort to develop an MDS provided by accredited experts in our country to enable us for the comparison of trauma system performance nationwide and possibly internationally.

### 3.2. Selection of Working Party Team

First of all, the STSRC invited the other six associated research centers with the relevant authorities in the ministry to participate in the process. The research centers

invited were the followings: Motahari burn research center of Tehran (MBRC), Baqiyatallah trauma research center (BTRC), Kashan trauma research center (KTRC), Yazd trauma research center (YTRC), Gilan trauma research center (GTRC), and Shiraz trauma research center (ShTRC). The working group selected a total of sixteen experts from all seven established countrywide active trauma research centers along with some other related experts.

Considering the need for different types of knowledge, expertise, and skills to plan and implement the registry, a team of working party was presented to contribute the necessary expertise. The team consisted of experts in traumatology, trauma epidemiology, health information system, surgery and emergency medicine. The team consisted of major trauma stakeholders. They were primarily selected because of their experience in a trauma registry system containing quality of care, data summaries, entry, analysis and interpretation. This gave the team the ability to expand an understanding of the research goals, the data required and use of all latest published clinical data to determine the registry elements. They were not only able to determine necessary, useful, desirable, or superfluous components, but also evaluate which fields were feasible in the country. An extensive literature review was performed. Through searching databases, relevant data variables were identified by working team. Data variables met key registry objectives for prehospital, hospital and patients' outcomes. Subsequently, a total of three sessions were held: the first meeting was held on major decisions, the second was held to determine the MDS and the third meeting was held to define inclusion criteria and finalize the description of coding each field.

#### 3.3. Initial Determination of Variables

There are a number of identified international trauma databanks with different contents and structures. After extensive literature review and considering the world health organization recommendation (12), we chose national trauma data standard (NTDS) questionnaire 2016 provided by the American college of surgeons committee on trauma (ACSCOT) (13). In the next step, correspondence with the Iranian collaborating centers was asked to send us their trauma data gathering questionnaires. Meanwhile, we got two Iranian versions of trauma database provided by STSRC (from 1999 to 2004) and KTRC (ongoing database). Consequently, all variables for possible inclusion in the MDS were collected from four aforementioned sources. Then, fields were processed during the following steps: At first, all necessary fields were extracted from the NTDS questionnaire (14). The national trauma data standard (13) is a comprehensive collection of needed variables

in trauma registry, extended definition of variables, instructions for data bank completion, quality control data entry, etc. In addition, since the questionnaire was written for different countries, this makes it possible for them to use the international classification of disease 9th Rev. Clinical modification (ICD-9-CM) (12) or the ICD-10 (15). Since the ICD-9 version (14) is not currently used in our country, we did not consider its codes in our questionnaire. The questionnaire was translated into Persian by a person who was familiar with the special related terminology. Then, its backward translation (into English) was given to another person who lived in an English-speaking community and was familiar with both Persian and English languages. Finally, another expert compared the original, Persian and retranslated versions and edited the translated questionnaire. Later, all additional fields in the questionnaires which provided by STSRC, KTRC, and BTRC were added. Finally, information was collected in 10 categories containing 137 initial fields.

#### 3.4. Selection and Finalizing of Variables

On October 27<sup>th</sup> 2015, an email survey was conducted to determine the MDS. The experts were asked to review the draft of variables and if intended to change, delete or add a variable for a specific purpose, they should write an acceptable reason and send back the file via email in fourteen days. Email responses were received from 10 members. In the next step, the meeting was held and all offered items were discussed in detail, one by one. Finally, after performing the necessary reforms, the revised paper-based draft of MDS was developed containing 109 data variables which was served as the basis for further meeting.

# 3.5. Defining Inclusion and Exclusion Criteria for a Case of Trauma Registry

Reviewing the national and international literature, we found the following three main case definition criteria: NTDS (13), European trauma care (UT stein version) (16), and the previous Iranian national registry criteria used by STSRC (1999 - 2004). The UT stein version is a revised standard template in 1999, in order to create a uniform reporting and compare major trauma data across different countries in Europe. It was carried out through a structured consensus process by Scandinavian networking group for trauma and emergency management, the UK trauma audit and research network, German society of trauma surgery and the Italian national registry of major injuries (16). The described inclusion and exclusion criteria had many differences in each of the three trauma registry system (Table 1).

3.6. Finalizing of the Description of Variables and Inclusion Criteria

On December 20th 2015, the second email survey was conducted. The experts were asked to review the draft of the description of nominal variables and send back any idea about how to code the fields and explain them via email in two weeks. Also, sending the details of the three inclusion and exclusion criteria, the representatives were asked to write their ideas about selecting the best system for our country. Email responses were received from 6 centers and analyzed before the meeting. The expert panel was formed and after the discussion about the description of variables, the MDS was finalized. At this point, after necessary reforms, the paper-based dataset of trauma registry was created. The current MDS will be incorporated into a designed web-based information bank. For defining the inclusion and exclusion criteria, all three resources were discussed in the last meeting and after the representative's ideas, the final inclusion criteria was created too.

#### 4. Results

Table 2 lists the named variables for each of the ten categorized information as finalized on January 7th 2016 containing demographics (n = 24), injury characteristics (n = 19), prehospital information (n = 26), emergency department information (n = 25), hospital procedures (n =2), diagnosis (n = 2), injury severity (n = 3), outcomes (n = 3) = 5), financial (n = 2), and quality assurance (n = 1) (Table 2). Most of the variables in the current MDS had most correspondence with the NTDS (12). Seventy-three of 109 variables were described in NTDS (12), whereas 25 variables were adopted from STSRC, BTRC and KTRC questionnaires. The remaining variables were added during the second focus group discussion. At different stages of development of MDS, there were a number of efforts to draw required variables in order not to create optional data. In other words, MDS aimed to create adequate variables for trauma data collection.

The inclusion criteria of the UT stein were not agreed by the expert panel. Finally, the algorithm, shown in Figure 1, was selected by merging and modifying inclusion criteria of the NTDS and the STSRC.

#### 5. Discussion

The present paper represents a developed MDS following extensive discussion with a range of related expertise over a period of time. It is a collection of variables believed to be essential and sufficient to support NTRI and reflects a need for uniform reporting of major trauma information.

Table 1. Inclusion and Exclusion Criteria in the Three Described Registry Systems

Trauma Registry Questionnaire Custodians	Inclusion Criteria	Exclusion Criteria	
	The answers to all of the following questions should be positive.		
	Did the patient sustain one or more traumatic injuries?		
NTDS	2. Is the diagnostic code for any injury included in the following range; ICD-9-CM: 800-959.9 or ICD-10-CM: S00-S99, T07, T14, T20 - T28, T30-T32 and T79.A1-T79.A9?	None	
	3. Did the patient sustain at least one injury with a diagnostic code outside the range of codes listed below? 905 - 909.9, 910 - 924.9, or 930 - 939.9? S00, S10, S20, S30, S40, S50, S60, S70, S80, S90		
	4. Did injury result in death? OrWas the patient transferred to (or from) your hospital via another hospital using EMS or air ambulance? OrWas the patient considered an admission based on your trauma registry inclusion criteria?		
STSRC	Admission > 24 hours	None	
European trauma care (UT stein) (15)		-First hospital admission > 24 hours after injury	
	NISS <sup>a</sup> > 15	Death before hospital arrival, or with no signs of life on hospital arrival and no response to hospital resuscitation.	
		-Asphyxia.	
		-Drowning.	
		-Burn patients if: 1. the burn represents the predominant injury, or 2. patient treatment in a specialized burn unit (15).	

<sup>&</sup>lt;sup>a</sup> New Injury Severity Score (16).

The uniform dataset and standardized inclusion criteria and an essential list of exact fields defined created to evaluate the comparison between trauma registries and may be sufficient to assert an NTRI. Data quality in trauma registries plays an important role in valid benchmarking of trauma systems, trauma system evaluation, decision making and health policy (5, 18, 22, 23). Incomplete data creates poor quality care and gaps in a trauma registry so that may undermine whole conception of value of that registry (23, 24). A successful dataset should be able to meet related users in trauma systems and create a balance between obtain desirable data and restricts the fields that would be act as opposing forces (24, 25). In addition it minimizes any ambiguity regarding the variables' definition and classification in trauma registries. Binational MDS for trauma registries in Australia and New Zealand provided the criteria and was beneficial, acceptable, easy to collect, and related to a substantial proportion of population (24). In Hawes et al. (17) study, MDS met a collection of comprehensive and accurate data so that it was able to have an effect on care and life quality, and decrease the length of stay in hospital.

There are many different trauma registry data sets

around the world, some of which are large like the United Kingdom (20), national registries of Canada (19), the United States (13), and Germany (26). Although datasets are to follow some common goals, there are many factors that may affect the establishment of any national or international trauma registry using its variables. Some factors are matters of governance, ethics, and privacy as considered in Australian trauma registry (24). These appear a necessity to develop an MDS as local or national. The literature review shows a lack of standard tool in order to collect trauma data in Iran, which it can make national and international benchmarking challenges. It is expected that the MDS and the inclusion criteria will be applied in pilot studies in future. There were two limitations in our study. First, it is may be needed to measure some variables at a specific region depending on their condition that have not included in the MDS. Moreover, we had invited more number of experts in the trauma field, but some of them were not able to contribute in our project due to their other tasks. Importantly, their idea could promote the quality of our work.

In conclusion, this study demonstrates development of an MDS in order to uniform data variables in NTRI. The

**Table 2.** Finalized Trauma Registry System Dataset, Categorized by the Data Bank

The Names of the Variables by Phase of Patient Care	Variable Descriptions	The Resource of Variables by the Numbers <sup>a</sup>		
		NTDS	STSRC	KTRC
Demographic information (17)	Hospital records number, hospitalization records number, national health records codes, national code, patient's home porsuce, patient's home convince, patient's home county, alternate home residence, city of birth, date of birth, age at injury, sex, martial status, education, school years, nationality, passport number, citizenship, home address, work address, phone number, alternative contact number, contact number of patient's relative, history of hospitalization due to trauma	7	7	15
Injury information (18)	Injury incident date, Injury incident time, If the accident occur on a special occasion or holidays, trauma mechanism, height of approximately fall in meter, work related, Job (status, category), report of physical abuse, disasters, person's activity at the time of accident, place of occurrence external cause, protective devices, airbag deployment, ICD-10 primary external cause code, incident (province, county, city)	14	7	10
Prehospital information (19)	EMS dispatch (date, time), EMS unit arrival at scene or transferring facility (date and time), EMS unit departure from scene or transferring facility, EMS unit departure from scene or transferring facility (date and time), transport mode, other transport mode, inter-facility transfer, informative source of information about the described incident, Blood pressure, pulse rate, respiratory rate, percent oxygen saturation, initial field (GCS-eye, GCS-verbal, GCS-motor, GCS-total), pre-hospital cardiac arrest, CPR, intubation, fixation, blood transfusion, liquid injection, drug injection, Victims of more than one person	18	12	3
ED information (20)	ED/hospital arrival (date, time), the interval between the accident to a hospital, ED admission type, if the patient is taking certain frugs, note the drug's name, initial ED/hospital (systolic blood pressure, pulse rate, temperature, respiratory rate, respiratory condition, percent oxygen saturation, GCS-eye, GCS-verbal, GCS-motor, GCS-total, whether the patient has received sedative?, initial ED/hospital estimated (height (Cm), weight (Kg)), alcohol use indicator, drug use indicator, ED discharge (date, time), The interval death for dead patients in the ED (ED arrival time until death)	20	15	8
Hospital procedure information (2)	Sugary, ICD-10 hospital procedures	2	2	1
Diagnosis information (2)	Comorbid conditions, ICD-10 injury diagnoses	2	2	0
Injury severity information (3)	AIS (21) pre dot code, AIS (21) severity, ISS (10)	2	1	2
Outcomes information (5)	Total ICU length of stay, total ventilator days, hospital discharge (date, time, disposition),	5	2	3
Financial information (2)	Payment method, total cost	2	0	2
Quality assurance information (1)	Hospital complications	1	0	1

<sup>&</sup>lt;sup>a</sup> Some of the variables were similar in the two or three registry systems. Therefore, the total number in the left column was not necessarily equal to the sum of the numbers in the right columns.

expertise of the working group provided a new model for defining inclusion criteria for a case of trauma registry in Iran. Our ongoing program is to apply the MDS and case definition in the six hospitals as a pilot study.

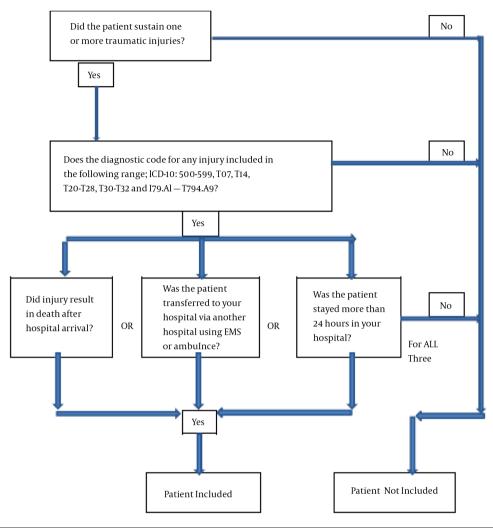


Figure 1. Approved Inclusion and Exclusion Criteria

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#### **Footnote**

**Authors' Contribution:** Payman Salamati and Zahra Ghodsi contributed to the study concept and design, and performed the 1st and final drafting of the manuscript. Payman Salamati and Vafa Rahimi Movaghar contributed to critical revision of the manuscript for important intellec-

tual content. The other authors contributed in preparation of minimum dataset and approved the manuscript.

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