Guide to completion

data entry form

TraumaRegister DGU®

version 1.4 for V2015.1

2. May 2019
Content

Version history .................................................................................................................................. 5
General comments .............................................................................................................................. 6
Inclusion criterion .............................................................................................................................. 6
Data entry forms ................................................................................................................................ 6
Standard form ...................................................................................................................................... 6
QM form of TraumaNetzwerk DGU® ................................................................................................. 6
Description of parameters in this guide .......................................................................................... 6
Form S – Master Data ....................................................................................................................... 8
Patient code ......................................................................................................................................... 8
Internal remark ................................................................................................................................... 8
Box Sex ............................................................................................................................................... 8
Sex ...................................................................................................................................................... 8
If female, pregnancy pre-existing? ...................................................................................................... 8
Box Accident anamnesis .................................................................................................................. 8
Date of accident .................................................................................................................................. 8
Box Hospital transfer .......................................................................................................................... 8
Hospital transfer ............................................................................................................................... 8
Box State of health before accident .................................................................................................. 8
ASA before accident ........................................................................................................................... 8
Anticoagulation? ................................................................................................................................. 8
Box Type of accident ......................................................................................................................... 9
Type of accident – Fall High > 3 m ....................................................................................................... 9
Type of accident – Hit by blunt object (object, branch, …) ................................................................. 9
Form A – Pre-clinical Data ............................................................................................................... 9
Box Time of rescue ............................................................................................................................ 9
Arrival of on-scene-emergency physician ........................................................................................ 9
Transport ............................................................................................................................................ 9
Box Vital signs ..................................................................................................................................... 9
Capnometry performed? ..................................................................................................................... 9
Glasgow Coma Scale ........................................................................................................................... 9
Pupil ..................................................................................................................................................... 9
Reaction to light ................................................................................................................................. 9
Box Therapy ........................................................................................................................................ 10
Endotracheal tube ............................................................................................................................... 10
Alternative airway management ........................................................................................................ 10
Analgesedation........................................................................................................... 10
Chest tube .................................................................................................................... 10
Tranexam acid .............................................................................................................. 10
Pelvic binder ................................................................................................................ 10
Box NACA score ........................................................................................................... 10
NACA score .................................................................................................................. 10
Form B – Emergency room and OP phase ................................................................. 10
Box Vital signs ............................................................................................................. 10
Already ventilated at admission? .................................................................................. 10
PaO₂ ............................................................................................................................... 11
Pupil ............................................................................................................................... 11
Reaction to light .......................................................................................................... 11
Box Laboratory ............................................................................................................. 11
Haemoglobin ................................................................................................................ 11
Platelets ......................................................................................................................... 11
Base Excess (-/+). ......................................................................................................... 11
Ca (ionised) ................................................................................................................... 11
Ethanol (Plasma) .......................................................................................................... 12
Fibrinogen ...................................................................................................................... 12
Box Hemostasis Treatment ....................................................................................... 12
Packed red blood cells (RBCs) administration: Time of first RBCs ....................... 12
Fresh frozen plasma (FFP) .......................................................................................... 12
Platelets ......................................................................................................................... 12
Box Medical Coagulation Treatment ...................................................................... 12
Tranexam acid .............................................................................................................. 12
Calcium .......................................................................................................................... 13
Factor XIII ...................................................................................................................... 13
Start of coagulation management .............................................................................. 13
Box Diagnostic ......................................................................................................... 13
Free liquid in FAST? ................................................................................................. 13
MRI ............................................................................................................................... 13
ROTEM® ...................................................................................................................... 13
EXTEM-CT ................................................................................................................... 13
EXTEM-MCF .............................................................................................................. 13
FIBTEM-A10 ............................................................................................................... 13
Teleradiology used? ................................................................................................. 13
Box Volume administration ................................................................. 14
Box Therapy Emergency Room ........................................................... 14
Endotracheal intubation ................................................................. 14
Box Emergency surgeries prior to ICU admission .................................. 14
Operative liquor drainage / Brain decompression .................................. 14
Thoracotomy ................................................................. 14
Box Management ........................................................................... 14
Management Time ........................................................................... 14
Form C – Intensive Care Unit ............................................................ 14
Box Laboratory / Vital signs............................................................... 14
Haemoglobin ........................................................................ 14
Platelets .................................................................................. 14
Base Excess (−/+). ...................................................................... 15
Ca (ionised) .............................................................................. 15
Fibrinogen .................................................................................. 15
Box ROTEM® ................................................................................. 15
EXTEM-CT ................................................................................. 15
EXTEM-MCF ................................................................................. 15
FIbTEM-A10 ................................................................................. 15
Box Hemostasis Treatment ................................................................. 15
FFP ........................................................................................ 15
Box Medical Coagulation Treatment ..................................................... 16
Tranexam acid ........................................................................... 16
Fibrinogen .................................................................................. 16
Calcium .................................................................................... 16
Factor XIII .................................................................................. 16
Box Length of ICU stay / Ventilation ..................................................... 16
Intensive care therapy (without IMC) ................................................... 16
Mechanical ventilation .................................................................. 16
Box Therapy ICU ........................................................................ 16
ECMO (Extracorporeal Membrane Oxygenation) ................................ 16
Box Organ failure ........................................................................ 16
Organ failure ............................................................................. 17
MOF .............................................................................................. 17
Sepsis .............................................................................................. 17
If Sepsis yes: Focus? ...................................................................... 17
Version history

<table>
<thead>
<tr>
<th>Date</th>
<th>Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>22.06.2017</td>
<td>Editorial changes at chapter “Box Outcome” (p 19)</td>
</tr>
<tr>
<td>20.02.2019</td>
<td>Change in content of sheet S &quot;Anticoagulation&quot;:</td>
</tr>
<tr>
<td>(version 1.4)</td>
<td>• now a multiple selection is possible</td>
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<tr>
<td></td>
<td>Change in content of sheet D &quot;OPS code&quot;</td>
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<tr>
<td></td>
<td>• OPS code specification has been removed and replaced with a list of possible surgeries (surgery groups).</td>
</tr>
<tr>
<td></td>
<td>Addition of Annex 1 (list of surgery groups)</td>
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General comments

This guide explains how to complete the TraumaRegister DGU® data entry form in the version V2015, which has been published in December 2015. The online masks went live on 18 January 2016.

Inclusion criterion

All those patients have to be enclosed, who are admitted to hospital via emergency room with subsequent ICU care or die before admission to ICU. Within TraumaNetzwerk DGU®, all those patients have to be entered, who are transferred to a hospital with a higher level of care.

Data entry forms

Standard form

The data entry sheet of TraumaRegister DGU® is available in two versions: The standard form was developed when establishing the registry and requires the entry of about 100 parameters. Especially for TraumaNetzwerk DGU®, a shortened version with about 40 parameters, the so-called QM form, is existing (see below).

The data entry form consists of five single sheets, which have to be filled out at four fixed time phases

- Form S: Master Data
- Form A: Pre-clinical Data
- Form B: Emergency room and OP phase
- Form C: Intensive Care Unit
- From D: Diagnosis and completion

QM form of TraumaNetzwerk DGU®

The data entry form available for TraumaNetzwerk DGU®, the so-called QM form, is a shortened version of the standard form (approx. 40 parameters). The QM form has the same number of pages as the standard form, but all parameters, which must not be recorded on the QM form, are disabled. This type of display is shown in the online data entry masks as well.

Description of parameters in this guide

On the following pages the completion of the standard form will be explained. Here, all parameters are mentioned, which were given a help text in the online entry mask or having been added on the revised data entry form.

The data entry form consists of five single sheets (S – A – B – C – D, see above), hereinafter referred to as “form”. On these forms the parameters are sorted in different boxes according to topics, see Fig. 1.

The listing of parameters corresponds to the structure of the standard form, starting with „Form S – Master data”. At first, the parameters of the left column were explained, subsequently those of the right column (see paper version of data entry form or online masks).

The layout of the data entry form’s paper version and the online masks has been adapted as far as possible.
Figure 1 Example of a single form: “Form” framed in blue, “box” framed in orange.

For further details on TraumaRegister DGU® please visit the homepage:

www.traumaregister-dgu.de.

There the data entry sheets are available under:

http://www.traumaregister-dgu.de/de/service/downloads/erhebungsboegen.html

The online access for entering data in TraumaRegister DGU® is available via TraumaPortal DGU:

https://intern.dgu-traumanetz.de/intern/de/login/index.jsp

Additional questions are answered by the hotline of TraumaRegister DGU®:

Email: support-tr@auc-online.de

Tel: +49 221 888 239 - 10
Form S – Master Data

Patient code
- The patient ID consists of the accident year and an arbitrary numbering.
- The accident year will be added automatically (it is generated from the accident date).
- For the arbitrary code only numbers can be used, serial numbering with leading zeros according to the expected number of patients is recommended (01, 02, 03, ... respectively 001, 002, 003, ...).
- Every year the numbering can start anew.

Internal remark
- To each patient you can assign an additional, unique, optional code (only numbers).

Box Sex

Sex
- The sex has to be indicated.

If female, pregnancy pre-existing?
- New variable from 2015!
- Pregnancy if female patient?

Box Accident anamnesis

Date of accident
- If accident time is unknown, please estimate at best.
- Time between accident and admission to SR should not exceed 24 h (exclusion criterion for primary patients).

Box Hospital transfer

Hospital transfer
- For transferred patients please designate the transferring hospital.

Box State of health before accident

ASA before accident
- Assess the pre-trauma condition; highest ASA levels are not considered here (5, 6).

Anticoagulation?
- New variable from 2015!
- Administration of anticoagulants before the accident?
- Multiple selection of drugs is possible (since 01/19)
**Box Type of accident**

Type of accident – Fall High > 3 m
- Means i.a. falls from a standing position, falls downstairs (also with triple rollover à la James Bond).

Type of accident – Hit by blunt object (object, branch, …)
- Means any blunt impact regardless of type, e.g. by a person, by a rock, by a branch, etc.

**Form A – Pre-clinical Data**

**Box Time of rescue**

Arrival of on-scene-emergency physician
- Arrival time first emergency doctor on scene.

Transport
- In case of a combined transportation, the more extensive one should be rewarded here.

**Box Vital signs**

- Please enter values unaffected by any therapy at the time of emergency doctor’s arrival.

Capnometry performed?
- New variable from 2015!
- Capnometry performed on intubated patient?

Glasgow Coma Scale
- Please enter values unaffected by any therapy at the time of emergency doctor’s arrival.

Pupil
- Changed variable from 2015!
- Now, pupil size will be documented without side reference.
- The new categories are: normal, anisocoria, bilateral dilated.
- Bilateral narrow and medium sized pupils are “normal”.
- Recording before anaesthesia!

Reaction to light
- Changed variable from 2015!
- Now, pupil reactivity will be documented without side reference.
- The new categories are: brisk, sluggish, fixed.
- In case of unequal response please record the poorer one.
- Recording before anaesthesia!
Box Therapy

Endotracheal tube
- The previous variable “intubation” has been splitted in "endotracheal intubation“ and "alternative airway management“.
- Here, only endotracheal intubation has to be documented.

Alternative airway management
- The previous variable “intubation” has been splitted in "endotracheal intubation" and "alternative airway management".
- Please indicate if there was no endotracheal intubation, but airway protection by larynx mask or similar.

Analgesedation
- Includes analgesics, sedative and narcotics.

Chest tube
- Chest tube includes all forms of pleural discharge.

Tranexam acid
- New variable from 2015!
- Has tranexamic acid (for hemostasis) been administered pre-clinically?

Pelvic binder
- New variable from 2015!
- Pre-clinically attached pelvic binder?

Box NACA score

NACA score
- Scoring system to characterise the severity of injuries, diseases or contamination in (emergency) medicine.
- NACA III: Moderate to severe but not life-threatening disorder. Stationary treatment required, often emergency medical measures on the site
- NACA IV: Serious incident where rapid development into a life-threatening condition cannot be excluded. In the majority of cases, emergency medical care is required
- NACA V: Acute danger
- NACA VI: Resuscitation

Form B – Emergency room and OP phase

Box Vital signs

Already ventilated at admission?
- Was patient ventilated at admission?
PaO₂

- For this variable two units are available: [mmHg] or [kPa]!
- Please check proper selection of the unit.
- The requested unit can be selected by the TR hospital administrator under the menu item "set units".

Pupil

- **Changed variable from 2015!**
- Now, pupil size will be documented without side reference.
- The new categories are: normal, anisocoria, bilateral dilated.
- Bilateral narrow and medium sized pupils are "normal".
- Recording before anaesthesia!

Reaction to light

- **Changed variable from 2015!**
- Now, pupil reactivity will be documented without side reference.
- The new categories are: brisk, sluggish, fixed.
- In case of unequal response please record the poorer one.
- Recording before anaesthesia!

**Box Laboratory**

**Haemoglobin**

- First Hb value on admission to ER.
- For this variable two units are available: [g/dl] or [mmol/l]!
- Please check proper selection of the unit.
- The requested unit can be selected by the TR hospital administrator under the menu item „set units“.

**Platelets**

- First measurement performed on admission to ER.
- For this variable two units are available: [cell count/μl] or [gpt/l]!
- Please check proper selection of the unit.
- The requested unit can be selected by the TR hospital administrator under the menu item „set units“.

**Base Excess (-/+)**

- First value after admission to ER.
- Please enter the plus/minus sign properly!

**Ca (ionised)**

- **New variable from 2015!**
- Calcium (ionised) titer at time of first blood collection in ER.
- For this variable two units are available: [µmol/l] and [mg/dl]!
- Please check proper selection of the unit.
- The requested unit can be selected by the TR hospital administrator under the menu item „set units“.
Ethanol (Plasma)
- **New variable from 2015!**
- Blood alcohol, only if having been measured.
- For this variable two units are available: [µmol/l] and [mg/dl]!
- Please check proper selection of the unit.
- The requested unit can be selected by the TR hospital administrator under the menu item "set units".

Fibrinogen
- **New variable from 2015!**
- First value after admission to ER.
- For this variable two units are available: [µmol/l] or [mg/ml]!
- Please check proper selection of the unit.
- The requested unit can be selected by the TR hospital administrator under the menu item "set units".

**Box Hemostasis Treatment**

All data refer to the period between ER and ICU, possibly comprising surgery. The preclinical phase will not be considered.

Packed red blood cells (RBCs) administration: Time of first RBCs
- **New variable from 2015!**
- Time of first administration of PRBCs in ER respectively during OP phase.

Fresh frozen plasma (FFP)
- For this variable two units are available: [units] or [ml]!
- Volume equivalent: 1 unit FFP mostly 250 ml.
- Please check proper selection of the unit!
- The requested unit can be selected by the TR hospital administrator under the menu item „set units“.

Platelets
- For this variable two units are available: [units] or [ml]!
- Volume equivalent: 1 unit TK mostly 250 ml.
- Please check proper selection of the unit!
- The requested unit can be selected by the TR hospital administrator under the menu item „set units“.

**Box Medical Coagulation Treatment**

All data refer to the period between ER and ICU, possibly comprising surgery. The preclinical phase will not be considered.

Tranexam acid
- Redefined variable from 2015!
- Previously indicated as "anti-fibrinolytics".
- Administration of tranexam acid for medical hemostasis?
Calcium
- Redefined variable from 2015!
- Previously indicated as „Other hemostatic medications“.
- Administration of Calcium for medical hemostasis?

Factor XIII
- New variable from 2015!
- Administration of factor VIII for medical hemostasis?

Start of coagulation management
- New variable from 2015!
- Time of first administration of one of the aforementioned substances.

Box Diagnostic
Please indicate the aforementioned diagnostics including starting time (start image recording).

Free liquid in FAST?
- New variable from 2015!
- Did sonography of the abdomen clearly indicated free intra-abdominal fluid?

MRI
- New variable from 2015!
- Magnetic resonance imaging (MRI) during initial diagnosis?

ROTEM®
- Please indicate values only if ROTEM® is used (no TEG®, because different data were collected there!).

EXTEM-CT
- New variable from 2015!
- Clotting time in EXTEM test (Clotting activated by thromboplastin).

EXTEM-MCF
- New variable from 2015!
- Maximum blood clot density EXTEM test (clotting activated by thromboplastin)

FIBTEM-A10
- New variable from 2015!
- Blood clot density after 10 min. running the test: Fibrin polymerisation after blocking platelet aggregation (evaluation fibrin polymerisation).

Teleradiology used?
- New variable from 2015!
- Parameter for German hospitals only!
Box Volume administration

All data refer to the period between ER and ICU, possibly comprising surgery. The preclinical phase will not be considered.

Box Therapy Emergency Room

Endotracheal intubation

- Endotracheal intubation on admission?

Box Emergency surgeries prior to ICU admission

Here, all listed surgeries (only these 8) shall be recorded, if they have been performed in ER or surgery room as emergency measures before admission to ICU/IMC. In case of several surgeries, please indicate the cutting times independently in order to facilitate generating a chronological order. Please enter these measures/surgeries under “Diagnoses” as well as all surgeries and measures not listed here.

Operative liquor drainage / Brain decompression

- From 2015 modified name for emergency surgery craniotomie.
- Craniotomie or intracranial pressure probe.

Thoracotomy

- Without chest tubes and mini-thoracotomy.

Box Management

Management Time

- Completion time of SR respectively OP phase.

Form C – Intensive Care Unit

Box Laboratory / Vital signs

Haemoglobin

- First Hb value on admission to ICU.
- For this variable two units are available: [g/dl] or [mmol/l]!
- Please check proper selection of the unit.
- The requested unit can be selected by the TR hospital administrator under the menu item „set units“.

Platelets

- First measurement performed after admission to ICU.
- For this variable two units are available: [cell count/ml] or [gpt/l]!
- Please check proper selection of the unit.
- The requested unit can be selected by the TR hospital administrator under the menu item „set units“.
Base Excess (-/+)
- First value after admission to ICU.
- Please enter the plus/minus sign properly!

Ca (ionised)
- **New variable from 2015!**
- Calcium (ionised) titer in [mmol/l] at time of first blood collection on ICU.
- For this variable two units are available: [mmol/l] or [mg/dl]!
- Please check proper selection of the unit.
- The requested unit can be selected by the TR hospital administrator under the menu item „set units“.

Fibrinogen
- **New variable from 2015!**
- First value measured on ICU.
- For this variable two units are available: [µmol/l] or [mg/ml]!
- Please check proper selection of the unit.
- The requested unit can be selected by the TR hospital administrator under the menu item „set units“.

**Box ROTEM®**

EXTEM-CT
- **New variable from 2015!**
- Clotting time in EXTEM test (clotting activated by thromboplastin).

EXTEM-MCF
- **New variable from 2015!**
- Maximum blood clot density in EXTEM test (clotting activated by thromboplastin).

FIBTEM-A10
- **New variable from 2015!**
- Blood clot density after 10 min. running the test: Fibrin polymerisation after blocking platelet aggregation (Evaluation fibrin polymerisation).

**Box Hemostasis Treatment**

Blood products administered during the first 48 hours AFTER admission to ICU.

**FFP**
- Please only indicate medication within the first 48 h on ICU.
- For this variable two units are available: [units] or [ml]!
- Volume equivalent: 1 unit FFP mostly 250 ml.
- Please check proper selection of the unit.
- The requested unit can be selected by the TR hospital administrator under the menu item „set units“.
Box Medical Coagulation Treatment

Tranexam acid
- Redefined variable from 2015!
- Previously indicated as „anti-fibrinolytics”.
- Please indicate medication within the first 48 h on ICU.

Fibrinogen
- Please indicate medication within the first 48 h on ICU.

Calcium
- Redefined variable from 2015!
- Previously indicated as „other hemostatic medications“.
- Please indicate medication within the first 48 h on ICU.

Factor XIII
- New variable from 2015!
- Please indicate medication within the first 48 h on ICU.

Box Length of ICU stay / Ventilation

Intensive care therapy (without IMC)
- Total stay on ICU (in hours or days, see below).
- If supervised by a doctor IMC is classified as ICU.
- If stay on ICU was interrupted, please indicate cumulative length of stay.
- For this variable two units are available: [number of days] or [number of hours]!
- If indicating days, please count the first and the last one as a full day.
- Please check proper selection of the unit.
- The requested unit can be selected by the TR hospital administrator under the menu item “set units”

Mechanical ventilation
- For this variable two units are available: [number of days] or [number of hours]!
- Please check proper selection of the unit.
- The requested unit can be selected by the TR hospital administrator under the menu item “set units”

Box Therapy ICU

ECMO (Extracorporeal Membrane Oxygenation)
- New variable from 2015!
- No ventilation modes!

Box Organ failure

An organ failure occurs if the organ shows 3 or 4 points on SOFA-Score. For respective criteria, please see help texts assigned to the single organs. The SOFA-Score is specified according to the definition of Vincent et al (1996, Intensive Care Med. 22: 707-710) for organ failure (should occur on 2 days minimum).
Organ failure

- **Respiratory:** PaO$_2$/FiO$_2$ ≤ 200 mmHg instead of ventilation.
- **Coagulation:** Platelets < 50,000µl respectively 50 gpt/l.
- **Hepatic:** Bilirubin ≥ 6,0 mg/dl.
- **Cardio-vascular:** Catecholamine dose dopamine > 5 µg/kg min OR administration of any adrenalin / noradrenalin.
- **CNS** Glasgow Coma Scala (GCS) ≤ 9 points.
- **Renal:** Creatinine ≥ 3.5 mg/dl or clearance per day < 500 ml/day.

MOF

- Simultaneous organ failure of two organs minimum for a longer period (two days minimum)?

Sepsis

- Sepsis is defined as SIRS plus one positive blood culture:
  - SIRS = 2 or more of the following criteria are fulfilled:
    - temperature ≥ 38.0 °C or ≤ 36.0 °C,
    - pulse: Tachycardia with heart rate ≥ 90/min,
    - respiratory rate: < 20/min or PaCO$_2$ < 4.3 kPa respectively 33 mmHg,
    - leukocytes: ≥ 20,000/mm$^3$ or ≤ 4,000/mm$^3$

If Sepsis yes: Focus?

- **New variable from 2015!**
- Please select the most probable focus.
- In case of several septic phases the first one.
- In case of indeterminate focus please indicate "other”.

Form D – Diagnoses

All injuries have to be entered. Only **direct trauma diagnoses** are relevant, but no individual trauma sequelae (e.g. shock, compartment syndrome) or pre-existing conditions. One **AIS code** is obligatory for each diagnosis.

Surgery

- Under 1. and 2. the two most important surgeries related to the diagnosis should be listed (e.g. 1. external fixator, 2. plate osteosynthesis).
- All further surgeries related to this diagnosis can be enumerated without specification.
- Please enter as OPS or free text with date

Surgery measures

- Formerly "OPS 301" (up to 3/2019)
- After selecting a diagnosis (AIS code), a list of diagnosis-typical surgical measures is available here.
- If the surgery carried out is not listed, it should be mentioned under "Description of surgery”
- For a list of possible measures see **Annex 1** (page 19)
Initial surgical strategy

- First surgical intervention according to damage control?

Fracture open?

- Closed fractures:
  - **Grade 0**: No or minimal soft tissue injury, indirect trauma, simple fracture
  - **Grade I**: Superficial abrasion or contusion, contusion by fragment pressure from within, simple to moderate fracture pattern
  - **Grade II**: Deep contaminated abrasions, contusion from direct trauma, impending compartment syndrome, moderate to severe fracture pattern
  - **Grade III**: Extensive skin contusion or muscle destruction, subcutaneous avulsion, manifest compartment syndrome, major vessel injury.

- Open fractures
  - **Grade I**: Skin perforation, negligible contamination, simple fracture
  - **Grade II**: Skin laceration, circumferential skin- and soft-tissue contusion, moderate contamination, variable fracture patterns
  - **Grade III**: Extensive soft-tissue damage, often arterial and neural injuries, heavy contamination, extensive bone damage
  - **Grade IV**: Subtotal amputation with less than a quarter of the soft tissue mantle being intact and extensive neural and arterial injuries.

Form D – Completion

**Box Date of discharge/death**

- In case of transfer within 48 h or death additionally to the date the time has to be entered.

**Box Cause of death**

Cause of death

- **New variable from 2015!**

**Box Discharge**

Patient’s volition

- **New variable from 2015!**
- To be indicate only in case of death!

**Box Outcome**

Outcome

- **Changed variable from 2015!**
- Previously indicated as Glasgow Outcome Scale (GOS) (by definition confined to patients with TBI).
- Now generally for all patients
- The following definitions apply to the individual categories:
  - **Death**: Death
  - **Vegetative state**: Permanent vegetative state
o **Severe disability**: Severe disability (conscious but handicapped and dependent on help)
o **Moderate disability**: Moderate disability (handicapped but independent)
o **Good recovery**: Good recovery

**Annex 1**

**Surgery groups for specifying the surgeries performed**

Until 2018, the TraumaRegister DGU® recorded the respective OPS code for the surgeries. At the beginning of 2019, this field was removed from the data set and replaced by a list of possible surgical measures for the respective diagnosis.

For this purpose, surgical measures that can be performed for a specific injury pattern were combined in a common "surgery group". Each diagnosis (AIS code) was then assigned to one of these “surgery groups”. After selecting a diagnosis (AIS code), up to two of these procedures can be selected in the input screens for "surgical measures" (see also Form D – Diagnoses / Surgery measures on page 17).

Some surgical measures occur in several groups of surgical measures.

**Surgical group 0**
(no surgery performed)

**Surgery group 1**
(Injuries to the brain, including penetrating injuries with brain involvement)
Decompressive Craniectomy
Craniotomy
Intraparenchymal pressure probe
External ventricular drainage (EVD)

**Surgery group 2**
(Skull base fracture, nose, teeth)
Cerclage wire / tension band wire
Flap (rotation, fasciocutaneous, muscle)
Plate osteosynthesis
Frontobasal reconstruction
Replantation
Reduction, closed
Screw osteosynthesis

**Surgery group 3**
(Penetrating injuries (without brain involvement), soft tissue injuries, electricity accident)
Surgical bleeding control
Escharotomy
Foreign body removal
Dermatofasciotomy
Flap (rotation, fasciocutaneous, muscle)
Suture / reconstruction incl. debridement
Temporary coverage incl. debridement (VAC, Epigard,...)

**Surgery group 4**

(Vascular injuries)
Balloon occlusion
Bypass / shunt
Surgical occlusion (ligature, ...)
Interposition graft (incl. prosthesis)
Interventional occlusion (coiling, ...)
Reconstruction (direct suture / patch)
Stent graft

**Surgery group 5**

(Nerve and spinal cord injuries)
Interpositional nerve grafting
Laminectomy
Suture (coaptation)
Neurolysis / decompression

**Surgery group 6**

(Retroperitoneal hematoma; internal organs; injuries to neck organs, oral cavity, and ear)
Balloon occlusion
Discontinuity closure
Surgical bleeding control
Drainage
Exploration
Enterostomy
Interventional bleeding control
Suture / reconstruction (prim. /sec.)
Resection
Stent graft
Partial resection
Tracheostoma / cricothyroidotomy

**Surgery group 7**

(Bony injuries to the thorax and extremities)
Amputation / stump debridement
Arthrodesis
Cerclage wire / tension band wire
External stabilization (FixEx, ...)
Intramedullary fixation
Flap (rotation, fasciocutaneous, muscle)
Nail osteosynthesis
Plate osteosynthesis
Prosthesis / joint (partly) replacement
Replantation
Reduction, closed
Resection arthroplasty
Screw osteosynthesis

**Surgery group 8**
(Pelvic injuries)
Amputation / stump debridement
Arthrodesis
Balloon occlusion
Surgical bleeding control
External stabilization (FixEx, ...)
Interventional bleeding control
Flap (rotation, fasciocutaneous, muscle)
Plate osteosynthesis
Prosthesis / joint (partly) replacement
Replantation
Reduction, closed
Resection arthroplasty
Screw osteosynthesis

**Surgery group 9**
(Bony / ligamentous spine (without spinal cord injury); intervertebral discs)
Posterior stabilization
Halo fixator
Laminectomy / decompression
Anterior stabilization