Guide to completion

the data entry sheet of

TraumaRegister DGU®

Version 1.5 for V2020

30.06 2020
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<th>Changes</th>
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</thead>
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<tr>
<td>22.06.2017</td>
<td>Editorial changes in chapter “Box Outcome” (p 19)</td>
</tr>
</tbody>
</table>
| 20.02.2019 (version 1.4) | Change of content of sheet S "Anticoagulation":  
|                        |   • now a multiple selection is possible                              |
|                        | Change of content of sheet D "OPS code"                               |
|                        |   • OPS code specification has been removed and replaced by a list of  |
|                        |   possible surgeries (surgery groups).                                  |
|                        | Addition of Annex 1 (list of surgery groups)                           |
| June 2020 (Version 1.5)| Integration of changes for the 2020 sheet revision                     |
|                        |   (new and changed parameters are marked accordingly)                  |
|                        | Deleted parameters: pre-hospital: NACA index; ICU: ethanol (plasma),    |
|                        |   calcium administration                                               |
General comments

This guide explains how to complete the TraumaRegister DGU® data entry form in the version V2020, which has been published in July 2020. The online masks went live on 1 July 2020.

Inclusion criterion

All those patients have to be enclosed, who are admitted to hospital with living signs via emergency room with subsequent need of ICU care or die before admission to ICU. Within TraumaNetzwerk DGU®, all those patients have to be entered, who are transferred to a hospital of a higher level of care. For each patient who is entered, a declaration of consent must be available according to the current interpretation of the EU law (GDPR). A standardized information sheet is available for download in the TraumaRegister DGU® under "Information" -> "Patient information".

Data entry sheets

Standard sheet

The data entry sheet of TraumaRegister DGU® is available in two versions: The standard sheet 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 sheet, is existing (see below).

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

- Sheet S: Core Data
- Sheet A: Pre-hospital Data
- Sheet B: ER-/OR phase (Emergency and operation room)
- Sheet C: Intensive Care Unit
- Sheet D: Diagnoses and Outcome

QM sheet of TraumaNetzwerk DGU®

The data entry sheet available for TraumaNetzwerk DGU®, the so-called QM sheet, is a shortened version of the standard sheet (approx. 40 parameters). The QM sheet has the same number of pages as the standard sheet, but all parameters, which must not be recorded on the QM sheet, 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 sheet 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 sheet.

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

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

The layout of the data entry sheet’s paper version and the online masks has been adapted as far as possible.
Figure 1 Example of a single sheet: “Sheet” 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/index.php?id=1395&L=206%27A%3D0

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

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

Dataset revisions

The data set of the TraumaRegister DGU® is subject to a revision at regular intervals, the so-called dataset revision.

The dataset revisions are developed by the "Arbeitskreis TraumaRegister" (scientific board) of the Sektion NIS of the DGU together with the "AUC - Akademie der Unfallchirurgie GmbH" (operator).

These revisions are currently carried out every five years in parallel and in coordination with the "DIVI emergency admission protocol" („DIVI-Notaufnahmeprotokoll“, https://www.divi.de/forschung/ sektionsgruppen/notfallmedizin/notaufnahmeprotokoll). The parameters of the sheets S (master data), A (pre-hospital) and B (emergency room/OR phase) of the TraumaRegister DGU® are included in the "DIVI emergency medicine protocol".

The table below gives the name and validity of the last sheet revisions. The sheet revisions are named with a V (for version) and a year. The version number is indicated on the paper/PDF entry sheets in the upper right corner.

<table>
<thead>
<tr>
<th>Dataset revision</th>
<th>Validity</th>
</tr>
</thead>
<tbody>
<tr>
<td>V2009</td>
<td>08/2009 bis 01/2016</td>
</tr>
<tr>
<td>V2015</td>
<td>01/2016 bis 08/2019</td>
</tr>
<tr>
<td>V2015.1</td>
<td>08/2019 bis 06/2020</td>
</tr>
<tr>
<td>V2020</td>
<td>07/2020 bis 2025</td>
</tr>
</tbody>
</table>
Support/Hotline

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

Email: support-tr@auc-online.de

Phone: +49 221 888 239 – 10

Service times: Mon - Fri 9 to 12 h, 13 to 15 h
Sheet S – Core 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.
- New category from V2020:
  New category "divers" in adaptation to the change in the civil status law in Germany.

If female, pregnancy pre-existing?
- Pregnancy if female patient?

Box Mechanism of injury

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 Inter-hospital transfer

Inter-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).

<table>
<thead>
<tr>
<th>ASA PS Classification</th>
<th>Definition</th>
<th>Adult examples, including, but not limited to:</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASA I</td>
<td>A normal healthy patient</td>
<td>Healthy, non-smoking, no or minimal alcohol use</td>
</tr>
<tr>
<td>ASA II</td>
<td>A patient with mild systemic disease</td>
<td>Mild diseases only without substantive functional limitations. Examples include (but not limited to): current smoker, social alcohol drinker, pregnancy, obesity (30 &lt; BMI &lt; 40), well-controlled DM/HTN, mild lung disease</td>
</tr>
<tr>
<td>ASA III</td>
<td>A patient with severe systemic disease</td>
<td>Substantive functional limitations; One or more moderate to severe diseases. Examples include (but not limited to): poorly controlled DM or HTN, COPD, morbid obesity (BMI ≥40), active hepatitis, alcohol dependence or abuse, implanted pacemaker, moderate reduction of ejection fraction, ESRD undergoing regularly scheduled dialysis, premature infant PCA &lt; 60 weeks, history (&gt;3 months) of MI, CVA, TIA, or CAD/stents.</td>
</tr>
<tr>
<td>ASA IV</td>
<td>A patient with severe systemic disease that is a constant threat to life</td>
<td>Examples include (but not limited to): recent (&lt; 3 months) MI, CVA, TIA, or CAD/stents, ongoing cardiac ischemia or severe valve dysfunction, severe reduction of ejection fraction, sepsis, DIC, ARD or ESRD not undergoing regularly scheduled dialysis</td>
</tr>
<tr>
<td>ASA V</td>
<td>A moribund patient who is not expected to survive without the operation</td>
<td>Examples include (but not limited to): ruptured abdominal/thoracic aneurysm, massive trauma, intracranial bleed with mass effect, ischemic bowel in the face of significant cardiac pathology or multiple organ/system dysfunction</td>
</tr>
<tr>
<td>ASA VI</td>
<td>A declared brain-dead patient whose organs are being removed for donor purposes</td>
<td>-</td>
</tr>
</tbody>
</table>

Source: According to ASA Houses of Delegates, ASA physical classification system: https://www.asahq.org/standards-and-guidelines/asa-physical-status-classification-system (accessed 09/01/2020)
Anticoagulation

- Administration of anticoagulants before the accident?
- Multiple selection of drugs is possible (since 05/19)
- **New categories from V2020:**
  - The platelet aggregation inhibitors were divided into “Acetylsalicylic acid” and "other platelet aggregation inhibitors”.
  - The selection options “miscellaneous” and "unknown" were added.
- **Renamed categories from V2020:**
  - NOAC to DOAC [Direct-acting Oral Anticoagulants]
  - “Heparins and others” in “Heparinoids”

**Box Type of accident**

**New from V2020:** The selection options for the categories have been revised more comprehensively.

**Traffic**

**Car passenger**

- **New category from V2020!**
  - Now car passenger as a separate category (was previously combined as car/truck passenger).
  - A passenger car in this sense is a vehicle up to 7.5t.

**Lorry passenger**

- **New category from V2020!**
  - Now lorry passenger as an independent category (was previously combined as car/lorry passenger in one variable).
  - A lorry in this sense is a vehicle over 7.5t.

**Bus passenger**

- **New category from V2020!**
- Meant are persons in bus accidents (public transport, coach, etc.).

**Motorcyclist/socius**

- This refers to the motorcyclist himself or herself or a passenger (person in front of or behind the rider or sitting in a side-mounted pillion).

**Bicycle**

- This refers to all bicycles without an auxiliary motor.

**Supported bicycle**

- **New category from V2020!**
- This refers to all types of electrically assisted bicycles (E-Bike/(S-)Pedelec), regardless of the designation and status in the road traffic regulations of these bicycles in individual countries.

**E-Scooter**

- **New category from V2020!**
- Meant are all kinds of electric scooters (e-scooters).

**Pedestrians**

- This refers to pedestrians who have been hit by another road user.
Other road accident
- Traffic accidents other than those mentioned above can be entered here using a free text field.

Falls
High fall (>= 3 m)
- Means all falls from a height of more than three meters (lintel, tree, bridge, etc.).
- Falls from stairs belong to category "Fall from a height of fall < 3m"!

Low Fall (< 3 m)
- Means falling downstairs or falling out of bed.

Ground level fall
- New category from V2020!
- This refers to a fall from a standing position, e.g. over a carpet or kerb.

Other cause of accident
Hit by blunt object
- Hit by blunt object means any blunt impact, no matter whether it is caused by a person, object or other external impact (e.g. object, branch, etc.).

Gunshot
- Shot means any injury inflicted by a firearm, whether long gun, short gun, alarm pistol, air rifle, etc.

Stabbing
- Stabbing means any injury caused by a stabbing tool, whether knife, sword, any other blade, screwdriver, stick, etc., which leads to a perforation (i.e. to the loss of the protective function of the skin).

Explosion / Deflagration
- New category from V2020!
- Now as an independent category (could be entered before under "other accident types").
- This refers to thermodynamic combination injuries.

Spillage
- New category in V2020!
- This category includes all buried traumas (sand, stones, walls, snow, etc.).

Other type of accident
- Accident types other than those mentioned above can be entered here using a free text field.
- Please enter "Other" traffic accidents under "Other traffic accident"!
BG-/AUVA-Fall

- **New variable from V2020!**
  To be specified only by German (BG) and Austrian hospitals (AUVA).
- This refers to patients who suffer work-related accidents under their statutory accident insurance.

**Box Confirmation of patient consent**

Confirmation of patient consent (not shown on PDF data entry sheet)

- Patient consent is required for entering the data. When you create a case, the system queries whether this consent exists.
- Here you can change the data entered when creating the case, for example, if the patient later dies.

**Box Module des TR-DGU**

Module des TR-DGU (not shown on PDF data entry sheet)

- There are now several additional modules for the TR-DGU, which allow detailed documentation of the treatment for certain injury patterns. The modules in which the hospital participates are listed here. The modules run on the AUC register platform, for which separate access data are required.
- Please indicate for which module(s) further data should be entered. By saving this page, the patient code will be transferred to the module in the AUC register platform.

**Sheet A – Pre-hospital Data**

**Box Time of rescue**

First alarm (dispatcher)

- This refers to the first alarm at the dispatcher.

Arrival first rescue device at accident site

- Arrival time of the first arriving rescue device at the accident site.

Start of transport with patient

- Start (time) of transport of the patient from the accident site to the hospital.

EMS physician at scene

- **New variable from V2020!**
- Here it is to be indicated whether an emergency medical treatment took place at scene.

Transport

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

Additional claim for helicopter

- **New variable from V2020!**
- To distinguish whether the helicopter was primarily on scene or was requested by the rescue team on scene.
MCI
- **New variable from V2020!**
- The "mass casualty incident" (MCI) describes a situation where a large number of injured persons have to be treated.
- The definition is not uniform: Therefore, local regulation applies.

**Box Vital signs**
Please enter values unaffected by any therapy at the time of first rescue device arrival.

**New from V2020:**
The order of the measures was adapted to the order in the ATLS scheme!

**Capnometry performed**
- Capnometry performed on intubated patient?

**Glasgow Coma Scale**
- Please enter values unaffected by any therapy at the time of first rescue device 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 Injuries**

**New categories from V2020:**
- Addition of the two categories "closed" and "open" for type of injury.
- Adaptation to the "DIVI emergency medicine protocol" (version 5.1)

**Box Therapy**

**New from V2020:**
The order of the measures was adapted to the order in the ATLS scheme!

**Endotracheal tube**
- Changed variable from V2015:
  - The previous variable “intubation” has been divided in “endotracheal intubation” and “alternative airway management”.
- Here, only endotracheal intubation has to be documented.
Surgical airway
- **New variable from V2020!**
- Here, every airway that is surgically induced (tracheotomy, cricotomy) should be recorded.

Alternative airway management
- **Changed variable from V2015:**
  The previous variable “intubation” has been divided in "endotracheal intubation" and "alternative airway management".
- Please indicate if there was no endotracheal intubation, but airway protection by larynx mask or similar.

Cervical spine immobilization
- **New variable from V2020!**
- The cervical spine immobilization is to be recorded by means of stiff neck, neck collar, head blocks, in the sense of a permanent manual in-line stabilization.

Needle decompression
- **New variable from V2020!**
- Means the needle decompression of the thorax to eliminate a tension component in pneumothorax.

Chest tube
- **Changed variable from V2020!**
  - Includes any form of pleural relief except needle decompression (see above).
  - These include Bülau-drain, Monaldi-drain or finger thoracostomy (without thoracotomies).

Pelvic binder
- Pre-hospitaly attached pelvic binder?

Tourniquet
- **New variable from V2020!**
- This refers to the application of a tourniquet (or similar, e.g. belt/elastic band) to interrupt the blood supply and thus stop the bleeding in the extremities.

Intraosseous access
- **New variable from V2020!**
- This refers to an intraosseous access for the infusion of fluid.

Cardio-pulmonary resuscitation
- Was a cardio-pulmonary resuscitation performed pre-hospital?

Pre-hospital thoracotomy
- **New variable from V2020!**
- Has a thoracotomy (e.g. clamshell thoracotomy, unilateral thoracotomy) been performed pre-hospital?
Tranexamic acid
- Has tranexamic acid (for haemostasis) been administered pre-hospital?

Catecholamines
- Were catecholamines administered pre-hospital?

Analgosedation
- Includes analgesics, sedative and narcotics.

Sheet B – Emergency room and OR phase

Box Admission
The time of admission of the patient to the hospital / emergency room applies. Documentation upon entry into the emergency room/delivery by emergency services.

New from V2020:
In addition to the date, the time is now also a mandatory field.

Box COVID-19
Was a COVID-19 smear test (PCR test) performed on the patient on admission to detect the SARS-CoV-2 virus? If so, what was the result of the test.

Box Vital signs
The first vital signs measured at admission to the emergency room.

New from V2020:
The order of the measures was adapted to the order in the ATLS scheme!

Already ventilated at admission?
- Was patient ventilated at admission?
- All patients are considered as "ventilated" if with "Therapy" on Sheet A either "Endotracheal tube", “Surgical airway” or "Alternative airway management" has been indicated.

FiO₂
- For this variable two units are available: [%] or [decimal value]!
  Example: 21 % corresponds to 0.21.
- Please check proper selection of the unit. The requested unit can be selected by the TR hospital administrator under the menu item "set units".

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 at admission to the emergency room.
- 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 at admission to the emergency room.
- For this variable two units are available: [cell count/nl] 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".

PT (Quick)
- First value after admission to the emergency room.

PTT
- First value after admission to the emergency room.

INR
- First value after admission to the emergency room.

Base Excess (-/+)
- First value after admission to the emergency room.
- The base excess can be measured arterially and venously.
- Please enter the plus/minus sign properly!

Ca (ionised)
- Calcium (ionised) titre at time of first blood collection in the emergency room.
- 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)
- 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
- First value after admission to the emergency room.
- 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 Diagnostic
Please indicate the aforementioned diagnostics including starting time (start image recording).

FAST / eFAST
- New from V2020:
  - "FAST" renamed to "FAST / eFAST"
  - This refers to the sonographic FAST examination of the abdomen, if necessary, with extended imaging of both lungs (eFAST)

Free liquid in FAST?
- Did FAST / eFast clearly indicate free intra-abdominal fluid?

Selective CT
New from V2020:
- Differentiated presentation of selective CT diagnostics, should no whole body CT have been performed. Multiple selection is possible.

Head
- Selective CT of the head (cCT).

Cervical spine
- New variable from V2020!
- Selective CT of the cervical spine.

Chest / thoracic spine
- New variable from V2020!
- Selective CT of the thorax and/or the thoracic spine.

Abdomen / lumbar spine / pelvis
- New variable from V2020!
- Selective CT of the abdomen, lumbar spine and pelvis.

Extremities
- New variable from V2020!
- Selective CT of the extremities.
MRI
- Magnetic resonance imaging (MRI) during initial diagnosis?

ROTEM®
- Please indicate values only if ROTEM® is used (no TEG® because different data were collected there!).
- For the time of ROTEM, the time of blood collection must be indicated.

EXTEM-CT
- Clotting time in EXTEM test (clotting activated by thromboplastin).

EXTEM-MCF
- Maximum blood clot density EXTEM test (clotting activated by thromboplastin)

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

Teleradiology used?
- Parameter for German and Swiss hospitals only!

Box Volume administration
All data refer to the period between emergency room and ICU, possibly comprising surgery. The prehospital phase will not be considered.

New from V2020:
Volume administration can now be entered separately for the emergency room phase and the surgery phase. If the surgery is to be performed in the emergency room, the volume entered then still counts as part of the surgery phase. The time of the skin incision counts.

Box Therapy Emergency Room
New from V2020:
The order of the measures was adapted to the order in the ATLS scheme!

Endotracheal intubation
- Endotracheal intubation at admission?

Surgical airway
- New variable from V2020!
- Here, every airway that is surgically induced (tracheotomy, cricotomy) should be recorded.

Chest Tube
- Chest tube includes any form of pleural relief.
Cardio-pulmonary resuscitation
  - Was a cardio-pulmonary resuscitation performed in the emergency room?

Pericardiocentesis
  - **New variable from V2020!**
  - Means the percutaneous puncture of the pericardium:
    - With or without sonographic control.
    - Regardless of whether a drain is left or not.

Pelvic binder
  - Was a pelvic binder put on in the emergency room?
  - This refers to all non-invasive tools for stabilizing the pelvis.

Catecholamines (first / cont.)
  - Were catecholamines administered in the emergency room?

**Box Emergency surgeries prior to ICU admission**
Here, all listed surgeries (only these eleven) shall be recorded, if they have been performed in the emergency room 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.

Decompressive Craniectomy
  - Decompressive Craniectomy means craniotomy or ICP probe.

Laminectomy
  - Resection of one or more vertebral arches to relieve the spinal cord.

Thoracotomy
  - Without chest tube and mini-thoracotomy.

Laparotomy
  - Surgical opening of the abdominal cavity to perform abdominal surgery.

Revascularization
  - Restoration of blood circulation through vascular anastomoses, stenting or similar.

Embolization
  - (Interventional) haemostasis by embolization.

REBOA
  - **New variable from V2020!**
  - Use of the REBOA (Resuscitative Endovascular Balloon Occlusion of the Aorta) technique.
External pelvic stabilization

- Stabilization of the pelvis using osteosynthetic procedures (e.g. fixator, pelvic clamp, ISG screw connection, etc.).

External extremity stabilization

- Osteosynthetic stabilization of the extremities.

Escharotomy

- **New variable from V2020!**
- Creation of relief cuts of the skin in case of burns.

Dermatofasciotomy

- **New variable from V2020!**
- This refers to the dermatofasciotomy of the extremities to correct a compartment syndrome.

**Box Haemostasis Treatment**

All data refer to the period between emergency room and ICU, possibly comprising surgery. The pre-hospital phase will not be considered.

**New from V2020:**
Quantity specifications for haemostasis therapy can now be entered separately for the emergency room and OR phases. If the surgery is performed in the emergency room, the haemostasis therapy then performed is still considered part of the surgery phase.

Packed red blood cells (RBCs) administration: Time of first RBCs

- Time of first administration of PRBCs in the emergency room respectively during OR 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 (1 unit = 1 bag, 2.4x1011 platelets).
- 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 the emergency room and ICU, possibly comprising surgery. The pre-hospital phase will not be considered.
Tranexamic acid
- Renamed variable since V2015: Variable formerly called "antifibrinolytics".
- Administration of tranexamic acid for medical haemostasis?
- **New from V2020:**
  - Specification of the time of first administration.
  - Until V2015.1 the time of the first administration of one of the mentioned drugs was queried.

Fibrinogen
- Administration of Fibrinogen for medical haemostasis?
- **New from V2020:**
  - Specification of the time of first administration.
  - Until V2015.1 the time of the first administration of one of the mentioned drugs was queried.

PCC
- Administration of PCC for medical haemostasis?

Calcium
- Renamed variable since V2015: Variable formerly called "Other haemostatic medications".
- Administration of Calcium for medical haemostasis?

Factor XIII
- Administration of Factor VIII for medical haemostasis?

DOAC antidote
- **New variable from V2020!**
- Examples (currently approved in D):
  - Idarucizumab (for Dabigatran),
  - Andexanet alfa (for Apixaban, Rivaroxaban).

**Box Management**

**Further clinical course Time**
- Completion time of SR respectively OR phase.
Sheet 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 since V2015.
- 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 since V2015.
- 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 since V2015.
- Clotting time in EXTEM test (clotting activated by thromboplastin).

EXTEM-MCF
- New variable since V2015.
- Maximum blood clot density in EXTEM test (clotting activated by thromboplastin).

FIBTEM-A10
- New variable since V2015.
- Blood clot density after 10 min. running the test: Fibrin polymerisation after blocking platelet aggregation (Evaluation fibrin polymerisation).
Box Haemostasis 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“.

**Platelets**
- **New variable from V2020**!
- Please indicate only the administration in the first 48 hours on ICU.
- For this variable two units are available: [units] or [ml]!
- Volume equivalent: 1 unit TK mostly 250 ml (1 unit = 1 bag, 2.4x10¹¹ platelets)
- 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

Given medication for coagulation therapy in the first 48 hours AFTER admission on ICU.

**Tranexamic acid**
- Please indicate medication within the first 48 h on ICU.

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

**Factor XIII**
- 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 24 hours IMC is classified as ICU.
- If stay on ICU was interrupted, please indicate cumulative length of stay (individual days are to be counted together).
- 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 since V2015.
- 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: \( \text{PaO}_2/\text{FiO}_2 \leq 200 \text{ mmHg} \) instead of ventilation.
- Coagulation: Platelets < 50,000\( \mu l \) respectively 50 gpt/l.
- Hepatic: Bilirubin \( \geq 6.0 \text{ mg/dl} \).
- Cardio-vascular: Catecholamine dose dopamine > 5 \( \mu g/kg \text{ min} \) OR administration of any adrenalin / noradrenalin.
- CNS: Glasgow Coma Scala (GCS) \( \leq 9 \) points.
- Renal: Creatinine \( \geq 3.5 \text{ mg/dl} \) or clearance per day < 500 ml/day.

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

Sepsis
- **New definition from V2020!**
- New definition: Sepsis is a life-threatening (multi-)organ failure caused by a misdirected immune response of the host to an infection.
  - Calculation via SOFA-Score: \( \text{PaO}_2/\text{FiO}_2 \), Glasgow Coma Scale, mean arterial blood pressure (MAP) or use of vasopressors, bilirubin, platelets, creatinine
  - Source: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4968574/ (freely available publication)

- **Old definition (until V2015.1):**
  Sepsis was defined as SIRS plus one positive blood culture:
  - SIRS = 2 or more of the following criteria are fulfilled:
    - temperature \( \geq 38.0 \text{ °C} \) or \( \leq 36.0 \text{ °C} \),
    - pulse: Tachycardia with heart rate \( \geq 90/\text{min} \),
    - respiratory rate: < 20/\text{min} or \( \text{PaCO}_2 < 4.3 \text{ kPa} \) respectively 33 mmHg,
    - leukocytes: \( \geq 20,000/\text{mm}^3 \) or \( \leq 4,000/\text{mm}^3 \).
If Sepsis yes: Focus?

- New variable since V2015.
- Single selection!
- Please select the most probable focus.
- In case of several septic phases the first one.
- In case of indeterminate focus please indicate “other”.

Sheet 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.

Box Diagnosis

AIS code

- The Abbreviated Injury Scale (AIS code) published by the “Association for the Advancement of Automotive Medicine” (AAAM) in the USA is used to describe the injury pattern.
  - For the TR-DGU, the original manual with about 2000 codes was reduced to about 500 trauma-relevant codes for the "TR-DGU - AIS Short Version AIS 2005".
  - The currently used version of the AIS code is the version "AIS 2005 Update 2008" (in use since V2009).
  - A list of the used codes as PDF can be found in the TraumaPortal: TraumaRegister DGU® > Information > Summary AIS 2005.
  - For further information on the AIS code see the homepage of the publisher: https://www.aaam.org/abbreviated-injury-scale-ais/.
- At least one diagnosis (AIS code) must be specified (mandatory field).
  - All traumatic injuries should be recorded.
  - Injuries that occur as a result of other injuries, such as compartment syndrome, are not listed and cannot be entered.

Description injury / diagnosis

- When a diagnosis (AIS code) is selected, this field is automatically filled with the description text for the selected AIS code.
- This assigned text can be replaced by an individual text by the person entering the data.

Diagnosis identified after ICU admission?

- Here it can be specified whether the diagnosis for the diagnosis (AIS code) was made after admission to the intensive care unit.

Box 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.
Surgery treatment

- Changed variable since V2015.1.
- 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 31)

Description of the procedure

- Here you can enter further information about the procedure.
- If "other" was selected in "Surgery measures", please enter the surgery performed here.

Box Fracture

Degree of soft tissue injury (I-V)

- 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.

Box Initial surgical strategy

- First surgical intervention according to damage control?

Sheet D – Outcome

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 Discharge/relocation/death

In the case of “death”

- Changed variable from V2020!
  (was in V2015/2015.1 "Patient's volition")

Reason for end-of-life-decision:

- **palliative**: A medium/long-term survival is not possible due to the severity of the injury according to the current state of knowledge in medicine.
- **presumed will of patient**: In the absence of a patient’s volition, this will can be determined from the patient's previous statements and values, e.g. in the context of interdisciplinary case and/or ethics conferences together with the patient’s relatives/caregivers.
- **written willingness of the patient**: Presence of an individual written patient’s volition or similar documents in which the will of the patient is clearly formulated.

Box Condition at discharge/relocation

Condition at discharge/relocation

- Changed and renamed variable from V2020!
- For V2015/2015.1, the variable had been renamed from "Glasgow Outcome Scale (GOS)" to "Outcome", since the GOS is by definition limited to TBI patients. The renaming should make it clear that the variable applies generally to all patients.
- Renamed again for V2020 to "Condition at discharge/relocation" to emphasize that the condition at the moment of discharge/relocation is meant.
- The category "Death" has been removed from the entry sheet to simplify the entry (if "Dead" is entered for "Discharge/Relocation/Death", this entry is automatically transferred to the database for "Status at Discharge/Relocation" also when saving the case).
- The following definitions apply to the individual categories:
  - **good recovery**: Good recovery.
  - **moderate disability**: Moderate disability (handicapped but independent).
  - **severe disability**: Severe disability (conscious but handicapped and dependent on help).
  - **vegetative state**: Permanent vegetative state.
  - **death**: Death.

Box Cause of death

Cause of death

- New variable since V2015.
- Death-causing organ system that is trauma-associated as the cause of death.
- The following definitions apply to the individual categories:
  - **Traumatic brain injury**: The traumatic brain injury leads directly to death or therapy was discontinued due to the severity of the traumatic brain injury.
  - **Haemorrhage**: Death due to trauma-associated bleeding. Multiorgan failure due to prologue shock is to be classified as "Organ failure". Bleeding that occurs independently of trauma, e.g. gastrointestinal bleeding, is to be classified as "Other" cause of death.
  - **Organ failure**: Death due to progredient organ failure (multi-organ failure). This can be caused by sepsis, as a result of a bleeding shock, etc. Acute myocardial infarction or pulmonary embolism is not meant. Select "Other" here.
  - **Other**: Death not due to traumatic brain injury, haemorrhage, or organ failure. In this case, for example, pulmonary embolism, myocardial infarction, tension pneumothorax, quadriplegia or similar would be considered.
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 Sheet D – Diagnoses on page 28).

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
Dermatofasciectomy
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