Publication guideline TraumaRegister DGU®

Version: June 2016

for publication of results out of TraumaRegister DGU®

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This guideline was drawn up and passed by the Committee on Emergency Medicine, Intensive Care and Trauma Management (Sektion NIS)* of the German Trauma Society (Deutsche Gesellschaft für Unfallchirurgie, DGU) as the scientific responsible board and AUC – Academy for Trauma Surgery (AUC) as data owner together with the managing board of the DGU to ensure that
• the access to data out of TraumaRegister DGU® is an orderly process
• TraumaRegister DGU® is uniformly named in publications
• the publications’ quality will be standardised and the
• co-authorship is regulated clearly.

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Use of data

Own hospital data

After having entered data into TraumaRegister® each hospital keeps the right to access its own data (see below), that is to say it may fully use and publish its own data. The advice of members of the Working group TraumaRegister DGU® is not compulsory but recommended. This applies to all hospitals participating in TraumaRegister DGU®, irrespective of the document form used. If TraumaRegister DGU® is mentioned as co-author, the publication guideline must be fully applied.

Generally, no data sets will be released, that contain data from other than the inquiring hospital.

Data of the whole registry

Each hospital employee whose hospital has been participating in TraumaRegister DGU® by using the standard documentation form¹ for two years minimum, is entitled for data analysis out of the complete data set of TraumaRegister DGU®. Hereby the number of documented patients should exceed 75% of the average number of patients documented by the other hospitals of the same level of care. In case of changing from standard documentation form to QM documentation form² the permission for analysis out of the whole registry expires.

The applicant has to work as a physician for a hospital entitled for evaluation. If he is not a TraumaRegister hospital administrator for his hospital, a TraumaRegister hospital administrator of the respective hospital has to be named as co-applicant. The co-applicant has to sign the application as well.

If a physician, who keeps an application which is already approved and still valid (deadline not exceeded), changes from a hospital with entitlement for evaluation to a hospital with none, the permission for analysis will remain valid for another three years. If during this period, the hospital establishes the standard form and documents the number of patients required for the respective level of care (see above), the permission for analysis will continue.

Third party requests for data analysis (e.g. research institutes, industry) always need a separate approval by the steering group of TraumaRegister DGU® (see Review Board / Review process). After approval the usual review procedure has to be completed.

Cumulative data out of TraumaRegister DGU® annual reports are considered as published data. In case of using these data the source has to be mentioned as follows: “Annual report xxy TraumaRegister DGU®, www.traumaregister-dgu.de. See also Further exploitation of results and press releases on page 8.

¹ Standard documentation form: classical form with approx. 100 data per patient
² QM documentation form: reduced form for TraumaNetzwerk DGU® (approx. 40 data per patient)
Data analysis

Data of the own hospital may be requested at any time from the support of TraumaRegister DGU® at AUC Office Registries and Research Coordination (Email: support-tr@auc-online.de).

For data analysis out of the complete data set of TraumaRegister DGU® an application for data analysis (www.traumaregister-dgu.de, electronically fill in) has to be submitted to the support of TraumaRegister DGU® at AUC Office Registries and Research Coordination (Email: support-tr@auc-online.de).

Together with the Coordination Board of Working group TraumaRegister*, the AUC Office Registries and Research Coordination will judge the application’s conditions for evaluation and subsequently forward it to two reviewers of the TraumaRegister DGU® Review Board for checking the content (see Review Board / Review process).

The processing of the application will take about 6 weeks.

AUC Office Registries and Research Coordination will notify the applicant in writing of the Review Board’s decision. In this letter a timeline is given in which the data analysis has to be completed and a draft manuscript ready for journal submission has to be prepared. Each approved application receives a TraumaRegister DGU® project number (TR-DGU project ID) that has to be stated on all publications of results derived from this evaluation (see below).

The timeframe for the analysis and finalisation of the manuscript for the approved topic usually is 12 months after their first access to data (First appointment with the statistician), but no longer than 15 months after approval. This period can be extended once upon request (see second stage of reviewing under Review Board / Review process).

If the requested analysis comprises only a limited amount of descriptive data used for a lecture or talk, or for an actualization of already existing results, the Review Board is not engaged (the decision is made by the Coordination Board of Working group TraumaRegister*). Nevertheless, a request for analysis has to be made in such cases as well.

Review Board / Review process

The Review Board* of the TraumaRegister DGU® comprises the board members of DGU as well as members of Sektion NIS*, who already have experience in publishing results from the TraumaRegister DGU®.

The steering group comprises the following members:

- a member of the NIS board,
- a head of the Working group TraumaRegister,
- a member of the AUC management,
- a member of the DGU managing board,
- a member of AKUT,
- and the spokesman of the scientific council of DGU.
Assessment of the application (First stage of review process)

All applications received will be formally checked (Is the applicant permitted to apply? Does subjects overlap with other applications?) by the Coordination Board of Working group TraumaRegister and AUC Office Registries and Research Coordination. Then they are handed over to two reviewers (First stage review process). The reviewers decide on the approval of the issue. In the first stage of the review process the evaluation’s feasibility and general sense of purpose will be checked.

Appraisal of the manuscript (Second stage of review process)

When a manuscript is ready for publishing, prior to submission to the publisher, it has to be forwarded again to the Review Board via AUC Office Registries and Research Coordination by indicating the intended journal (Second stage review process). The reviewers decide on the approval of the manuscript. The following recommendations can be given:

- Approval without modification
- Approval with minor revision (e.g. TR-DGU project ID non-existent, discussion has to be adjusted, etc.)
- Major Revision: In case of major revisions, resubmission of the manuscript is demanded (additional data evaluation is necessary, methodological ambiguities, conclusions not supported by data etc.).

If after two revisions no agreement on approving the manuscript is reached, author or reviewers can forward the manuscript to the steering group of the TraumaRegister DGU® for final decision.

At the end of the internal review process, AUC Office Registries and Research Coordination forwards the publication-ready manuscript to the DGU managing board, which is represented by its General Secretary.

If the DGU managing board or previously the reviewers of the manuscript find questionable contents related to healthcare or professional policy, the steering group of TraumaRegister DGU® will again be engaged to clarify the facts.

Authorization for data analysis from TraumaRegister DGU®

Only the persons mentioned below are authorised to analyse the patient data from TraumaRegister DGU®:

- Employees of AUC and persons, who have been assigned for data analyses through a cooperation agreement with AUC.

Publications

Journal articles

All publications out of TraumaRegister DGU® have to be approved according to the procedure mentioned above (Chapter Data analysis or Review-Board / Review process).
Congress contributions

Results of approved and conducted analysis, which haven’t been published yet, are allowed to be submitted for poster presentations or lectures on scientific congresses, without having accomplished the second stage of the review process before. Here, the signed commitment to comply with the publication guideline must be already signed.

Accepted abstracts have to be reported to TraumaRegister DGU® via TraumaRegister DGU® support at the AUC Office Registries and Research Coordination (Email: support-tr@auc-online.de).

On the poster or respectively during the lecture the TR-DGU project ID has to be mentioned in the methods section. The TR-DGU project ID can be asked for via support of TraumaRegister DGU® at any time.

All results of analysis presented without completed review process (Second stage review), have to be provided always with the following indication:

<table>
<thead>
<tr>
<th>TR-DGU project ID: xxxx</th>
</tr>
</thead>
<tbody>
<tr>
<td>TraumaRegister DGU® has provided the data used.</td>
</tr>
<tr>
<td>The author is responsible for evaluation and interpretation. The final review process of TraumaRegister DGU® hasn’t been accomplished yet.</td>
</tr>
</tbody>
</table>

The text mentioned above can be downloaded as PowerPoint file from TraumaRegister DGU® website (www.traumaregister-dgu.de, text available in English and German).

Mandatory indications in publications

In the methods section of all kinds of publications with data from the TraumaRegister DGU® the following information has to be provided:

- TR-DGU project ID, which has been provided by approving the analysis
- Approval of the manuscript according to the publication guideline of the TraumaRegister DGU®
In each publication the following specifications have to be given in order to describe the data set used:

- Time period of the data set used (e.g. 2002 – 2012)
- Number of hospitals, whose data was used in the data set
- Usage of data from the standard documentation form or the QM documentation form
- Restrictions of the data set; inclusion criteria (e.g. age, injury severity, type of accident, etc.)
- In case of using the structural data collected by AKUT, an indication which data have been used

A description of the TraumaRegister DGU® for use in the methods section of publications can be found on the website (www.traumaregister-dgu.de) in English and German.

Citation and co-authorship

If members of the Sektion NIS are relevantly involved in the analysis and/or interpretation of TraumaRegister DGU® results, they are sufficiently designated as co-authors by mentioning TraumaRegister DGU as a co-author.

Example:

The outcome of severely injured patients ....

Lisa Mueller¹, MD, .... and the TraumaRegister DGU²

1 ... 2 Committee on Emergency Medicine, Intensive Care and Trauma Management (Sektion NIS) of the German Trauma Society (DGU)

Mentioned as a co-author, TraumaRegister DGU is written without the trademark symbol ®.

Co-authorship

If publishing TR-DGU results, co-authorships have to meet the rules of “Good scientific practice“, as published by the German Research Association (www.dfg.de), and the „Uniform requirements for manuscripts submitted to biomedical journals“ of the International Committee of Medical Journal Editors (www.icmje.org).
Spelling of the institutions

In publications all institutions have to be named as shown in the following table:

<table>
<thead>
<tr>
<th>German (Abbreviation in brackets)</th>
<th>English (Abbreviation in brackets)</th>
</tr>
</thead>
<tbody>
<tr>
<td>TraumaRegister DGU® (TR-DGU)</td>
<td>TraumaRegister DGU® (TR-DGU)</td>
</tr>
<tr>
<td>TraumaNetzwerk DGU® (TNW)</td>
<td>TraumaNetzwerk DGU® (TNW)</td>
</tr>
<tr>
<td>Deutsche Gesellschaft für Unfallchirurgie (DGU)</td>
<td>German Trauma Society (DGU)</td>
</tr>
<tr>
<td>AUC - Akademie der Unfallchirurgie GmbH (AUC)</td>
<td>AUC - Academy for Trauma Surgery (AUC)</td>
</tr>
<tr>
<td>Sektion Notfall-, Intensivmedizin und Schwerverletztenversorgung der DGU (Sektion NIS)</td>
<td>Committee on Emergency Medicine, Intensive Care and Trauma Management of the German Trauma Society (Sektion NIS)</td>
</tr>
</tbody>
</table>

Please note the correct spelling (capital letters within the whole names of TR-DGU and TNW) as well as the use of the trademark symbol.

Mentioning of participating hospitals

For mentioning those hospitals that have contributed data to the TraumaRegister DGU®, it is possible to refer to the TraumaRegister DGU® website (www.traumaregister-dgu.de), where the actual list of participating hospitals can be found in the menu option Registry structure under Participation.
Further exploitation of results and press releases

Additional statements on scientific work from TraumaRegister DGU® (and publications on results from the TraumaRegister DGU® annual report) as for example press releases or activities in other media, must be agreed with the DGU managing board. The coordination is done by the DGU General Secretary.

The draft of the statement must be submitted to the DGU office (Fax: 030 – 340 60 36 21; Email: office@dgu-online.de) with a lead time of three working days. The information will only be made available to the public after the DGU office has given its opinion.

Violation of the publication guideline

If applicants violate the rules specified above, the steering group of TraumaRegister DGU® is convened and the respective applicants and authors can be excluded from future analysis out of TraumaRegister DGU®.

Validity of this guideline

This publication guideline is valid from the 1 June 2016 until the notification of an updated version.

It applies from this date onwards

- to submitted applications for data evaluation
- to ongoing data analysis
- and to submitted manuscripts prior to acceptance by the Review Board of the TraumaRegister DGU®.

This shall also apply for the case that a previous version of the publication guideline has been already signed for an application or ongoing data analysis. In this case the applicant respectively the responsible author will be asked to sign the revised publication guideline.
Obligation to comply with
the publication guideline of the TraumaRegister DGU®

Version: June 2016

(Copy for applicant / first author)

The authors of a publication containing results of data from the TraumaRegister DGU® commit themselves with their signature to comply with the guideline expressed here.

In case of failure to observe the rules specified in the publication guideline of TraumaRegister DGU®, the steering group of TraumaRegister DGU® is convened and applicants and authors involved can be excluded from future analysis out of TraumaRegister DGU®.

Author(s) ___________________________________________________________

Topic _______________________________________________________________

TR-DGU project ID __________________________

Date, place ___________________________________________________________

Signature Applicant/first author _______________________________________

Signature TR-DGU statistics ______________________________________
Obligation to comply with
the publication guideline of the TraumaRegister DGU®

Version: June 2016
(Copy for AUC)

The authors of a publication containing results of data from the TraumaRegister DGU® commit themselves with their signature to comply with the guideline expressed here.

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Author(s) ____________________________________________________

Toic __________________________________________________________

TR-DGU project ID ________________________________

Date, place ___________________________________________________

Signature
Applicant/first author __________________________________________

Signature
TR-DGU statistics ______________________________________________
# Glossary

<table>
<thead>
<tr>
<th>Group</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>Committee on Emergency Medicine, Intensive Care and Trauma Management (Sektion NIS) of the German Trauma Society</td>
<td>A separate section within the German Trauma Society (Deutsche Gesellschaft für Unfallchirurgie, DGU)</td>
</tr>
<tr>
<td>Working group TraumaRegister DGU</td>
<td>A separate working group within DGU Sektion NIS, which aims to ensure the further development of TraumaRegister DGU®.</td>
</tr>
<tr>
<td>Coordination Board of Working group TraumaRegister</td>
<td>This board organises the review process.</td>
</tr>
<tr>
<td>Review Board of TraumaRegister DGU®</td>
<td>The Review Board has been established by Sektion NIS in order to control data analysis and ensure consistent methodological quality of the publications.</td>
</tr>
<tr>
<td>Steering group of TraumaRegister DGU®</td>
<td>This group takes a decision on controversial issues concerning the approval of the manuscripts</td>
</tr>
</tbody>
</table>