

NATO STANDARD

AMedP–8.16

NATO TRAUMA REGISTRY SYSTEM

Edition A Version 1

AUGUST 2019



NORTH ATLANTIC TREATY ORGANIZATION

ALLIED MEDICAL PUBLICATION

**Published by the
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NATO LETTER OF PROMULGATION

21 August 2019

1. The enclosed Allied Medical Publication AMedP-8.16, Edition A, Version 1, NATO TRAUMA REGISTRY SYSTEM, which has been approved by the nations in the Military Committee Medical Standardization Board, is promulgated herewith. The agreement of nations to use this publication is recorded in STANAG 6516.
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4. This publication shall be handled in accordance with C-M(2002)60.



Zoltán GULYÁS
Brigadier General, HUNAF
Director, NATO Standardization Office

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RECORD OF SPECIFIC RESERVATIONS

[nation]	[detail of reservation]
BEL	BEL will manage the medical record following national privacy laws.
CAN	CAN will reserve the right to decide whether our citizen or soldier personal information is shared, subject to compliance with national requirements, in all cases.
DEU	DEU reserves the right to participate only in trauma registration-related databases which are authorized/allowed under the EU-Datenschutzgrundverordnung (EU General Data Protection Regulation), the DEU Bundesdatenschutzgesetz (Federal Data Protection Act) and the national laws and regulations regarding the observance of medical confidentiality.
FRA	The information systems security (SSI) certification process and, above all, the procedures for the registration of a personal medical database with the relevant national authorities (CNIL) still have to be consolidated and are subject to reservation.
<p>Note: The reservations listed on this page include only those that were recorded at time of promulgation and may not be complete. Refer to the NATO Standardization Document Database for the complete list of existing reservations.</p>	

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CHAPTER 1 BACKGROUND

1.1 Introduction

1. Intent

The intent of this standard is to standardize the administrative structures and processes supporting the NATO Trauma Registry (NTR). The following guidelines are established to ensure the NTR has an ethical, legal, accurate and complete governance structure. The following administrative topics covered by this standard include:

- a. Data and Database Requirements
 - (1). Identifiable and De-identifiable data
 - (2) Data Accuracy and Completion and Data Submission
 - (3) Data Submission Responsibilities
 - (4) Data Fields – “Required” and “Non-required” fields
 - (5) Data Security
 - (6) Data Ownership
 - (7) Dataset Request and Release of Datasets
 - (8) Pre-publication Review
- b. Governance Bodies
 - (1) NTR Approval Board (NAB)
 - (2) NTR Development Board (NDB)
- c. Process Issues
 - (1) Dataset Release processes
 - (2) Software Updates

This document is limited to administrative functions required to provide integrated and consistent management of the NTR.

1.2 Definitions

1. Trauma Registry

Trauma Registries (TR) are standardized medical data sets consisting of data points related to trauma outcome. The principal goals of TRs are to support the creation of strategies to prevent or mitigate trauma, and to identify best practices through the entire continuum of care of traumatic events and to inform Improvement processes using statistical analysis methods. The NATO TR (NTR) is created to provide, an Alliance wide TR where data from all patients treated in a Medical Treatment Facility during Alliance missions and exercises can be pooled for increased statistical strength. Additionally, the TR may be used for the collection of civilian trauma data. To ensure that knowledge generated

using the NTR is valid, it is required that submitted data be complete and accurate. National data will be collected in accordance with national standards. The use of the pooled data must meet legal and ethical requirements for medical research and will be outlined in the Terms of Reference (TOR). Additionally, there must be mechanisms in place to review research requests, provide appropriate datasets for approved research and to monitor the state of knowledge concerning all aspects of trauma and trauma care in order to update the NTR as advances in trauma care occur.

2. Data Collection, National Areas and Central Data Repository (CDR)

The Data Collection consists of all the data that is uploaded into the NTR. The data collection will be housed within the Server farm, managed and maintained by NATO Communication and Information Agency (NCIA) who is responsible for ensuring security for the information. The Data Collection is to be partitioned into two separate areas. One, the collection of National Areas, will house complete (identifiable) data which is only accessible by nationally identified administrators or by system administrators with the agreement of national administrators. The second area is the Central Data Repository (CDR) which houses data, with individually identifiable patient information removed, aggregated following the push of data from the National Areas. For nations wishing to use their own, separate TRs, they will have the option to push data directly to the CDR. Access to the CDR is strictly controlled by the NTR Approval Board (NAB) to ensure the use of the information agrees with established medical ethics and to ensure confidentiality of the contained data. (see 2.1 1. for definitions and further discussion).

3. NTR Team (NTRT)

To ensure the continued oversight of the NTR and the related processes, the NTR Team (NTRT) has been created, under the auspices of the COMEDS Military Healthcare Working Group (MHCWG). The primary responsibility for the NTRT is to monitor and steer the development, implementation of the NTR in its entirety. The membership of the NTR Team will change based on the needs of the registry and will always include a representative from Allied Command Operations, the Emergency Medicine Panel, Medical Health Care Working Group (MHCWG), and the Military Medicine Centre of Excellence.

4. Participating Nation (PN)

A Nation is identified as a Participating Nation if it has officially been granted permission to use the NTR. Usually this will include submission of data to the NTR CDR however it is possible that a nation will have no members who have experienced trauma. If the nation has prepared for data submission, that nation is still considered a PN.

5. Contributing Nation (CN)

A Contributing Nation is a nation who has one or more patient's medical data included within the CDR dataset. In general, any individual's record in the CDR

will be included in the released dataset however, a nation can elect to remove all its members from a dataset for a given Research Request. This unlikely occurrence would result when a nation has determined that they are not in agreement with the decision to release a dataset for a specific research request. This would allow the research to continue, albeit with a smaller, and potentially skewed, dataset.

6. Nationally Assigned Medical Representative (NAMR)

Each PN/CN will formally assign a single person (with nationally determined number of secondary assignees) who is the single POC for Research Requests originating within their Nation.

7. NTR Approval Board (NAB)

An administrative Board established to review research proposals to determine if the research is in accordance with established medical ethics, is statistically robust, and that the CDR has the required data. The board receives Requests for Data (RFD) from an NAMR after the research protocol has been reviewed and approved by a national or institutional research review process. Roles and responsibilities are defined in 2.2.1.a.

8. NTR Development Board (NDB)

An administrative body that is tasked to review changes in trauma management and trauma registry design and recommend modifications to the NTR. These recommendations will be forwarded to MHCWG and the software developer acting under NCI Agency. Roles and responsibilities are defined in 2.2.1.b.

9. Dataset

A dataset is a subset of the CDR that is to be provided to fulfil a Request for Data (RFD). It includes the records required to address the question(s) presented within an approved RFD.

10. Request For Data (RFD)

A Request for Data (RFD) is the term for the process whereby a researcher submits a request for a dataset from the NTR through the NAMR based on the principles in this document.

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CHAPTER 2 GUIDELINES

2.1 Data and Database Requirements

1. Identifiable and De-identifiable data

To protect the privacy of individuals who have information entered into the NTR, the Data Collection will consist of two components; 1) a collection of multiple areas under national control that can store identifiable data and 2) an area for pooled, de-identified data.

a. National Areas

The first component is the collection where National Areas are established for each PN. The intent of this area is to provide a national trauma registry that is accessible by nationally designated registrars who retain the ability to modify the data without the requirement to seek NAB approval for these administrative processes. The entries will be indexed using the NTR system generated identification number and it is the responsibility of the nation to develop a reference table to allow them to link the national (identifiable) ID number to the NTR entry. This link is critical to allow updating of data on a given individual and to support the elimination of duplicate entries on the same individual. National system administrators will be able to access the National Area as will NCI Agency system administrators in order to perform normal tasks related to the upkeep and functioning of the NTR. The access by NCI Agency system administrators will require the awareness and agreement of national administrators.

Each nation is required to establish national processes to control access to these areas that is consistent with their policies on the protection of medical information. A component of this process must include the ability to link an identifiable individual's data to the de-identified data within the Central Data Repository.

b. Central Data Repository

The second area is the Central Data Repository (CDR) which houses the pooled data from across the Alliance. The information within the CDR consists of data downloaded (pushed) from the National Area and is de-identified. Specifically, the CDR will not have the ability to store individually identifiable information or national identifying number. The system generated identification number will only link back to the national ID number via the nationally developed, and controlled, reference table.

For nations with small numbers of individuals entered into the NTR it may be possible, from included (required) demographics, to identify a specific individual. To satisfy de-identification requirements, especially for those

CNs with smaller database contributions, the following table outlines the agreed upon standards for creating de-identified records.

National Field	De-identified Field within Central Data Repository
Name	Field not available
National ID number	System generated ID number*
Date of birth	Age ranges (5 year increments)
Rank	Rank range (OR 1-4, OR 5-9, OF 1-3, OF 4,5, OF 6-9)

* This number will be pushed back to National Representatives and it is a national responsibility to link this number to the correct individual's record.

2. Data Accuracy and Completion and Data Submission

Data accuracy and completeness are the most important requirements for the ability of the NTR to provide scientifically valid datasets. Incomplete or erroneous data or duplicate records can result in invalid conclusions which may result in increased morbidity or mortality. Removal of data that has been uploaded into the CDR for reasons other than to correct erroneous submissions, will negatively impact the validity of any conclusions reached using the CDR data. It will have especially negative impacts on the ability to compare results from research on related topics that occur over time.

Contributing nations are responsible for accuracy and completeness of data submissions. Internal consistency checks are included within the software (for example surgery cannot occur prior to an injury) which will result in error reduction, however accurate and complete extraction of data from clinical and administrative records is required. Accurate Date-Time Groups are particularly critical to prevent errors in data submission.

Nations will establish national processes for certifying that an individual is trained and qualified to extract information from a medical record (Data extraction) and that same or different individuals are trained to enter the data within their National Area of the NTR.

Submission to the CDR is through two mechanisms. First, national data is entered into the National Area and then pushed to the CDR. Second, data can be submitted from a standalone TR using the option push capability of the NTR software.

To limit the accidental corruption of data within the CDR, the NTR software does not have the capability to modify data that has been uploaded. Instead, any data that is identified as being incorrect will be returned to the originator for correction and resubmission. To correct erroneous data, the CN will need to correct the entry within their National Area and resubmit that record. Once the pushed data is received, the CDR will overwrite the existing record with this new, corrected data and notification of the modification.

3. Data Fields – Minimum Data Set and Non-required

The NTR consists of numerous data fields which allow entry of information concerning a trauma experienced by an individual and the medical interventions and their outcomes. Some of these data fields have been designated as required and constitute the Minimum Data Set. A required data element is one that has been certified by the NTRT as one that must be entered for the system to record (store) the information. Without completion of all required fields, the user will receive an error message indicating which fields must be completed and the information will not be uploaded.

Non-required fields include information that may not pertain to every patient or fields included within some but not all national systems. For example, having a traumatic injury somewhere would be a required field, but having data entered into the “injury to the right leg” field is non-required since many patients won’t have an injury in that specific location.

National systems may collect data in addition to the minimal dataset.

Mechanisms are included in the software to allow CNs the ability to select other NON-REQUIRED fields to withhold from upload to the CDR in order to comply with National legal requirements. For example, the CDR will have non-required fields available to record the type of personal protection used by an injured member. National regulations may preclude releasing that information. Each nation will be able to block transmission of those nationally chosen fields from the National Area to the CDR.

4. Data Security

Security of the data provided to the NTR is the responsibility of NCIA. Limited access to the data within the NTR is crucial to maintaining data integrity. Two entities will have access to National Areas – the specific nation’s assigned personnel (Data entry and system administrators for example) and NCIA system administrators to perform normal tasks related to the upkeep and functioning of the NTR. This access will require the awareness and concurrence of national administrators.

Participating Nations will have the ability to assign access (read and edit rights) to the data provided for their personnel within the National Area. Access to the CDR will also be controlled and data will be released after NAB approval.

5. Data Ownership

Data will remain the property of the nation.

Nations retain the right to exclude all of their national data for a given research proposal but they cannot pick and choose individual records to exclude – this choice is “All data for a nation is included or none”. If a nation chooses to exclude

its data from a research project, the data remains in the CDR and but is excluded from the released dataset.

6. Dataset Request and Release of Datasets

Formalized processes for the release of Datasets are established and include:

a. Dataset Nomenclature

“Primary Data” consists of data that is uploaded into the CDR by a CN. “Secondary Data” consists of the datasets provided BY the NTR for research using the RFD and established processes. Secondary datasets are loaned to the researcher for specific questions (as outlined within the RFD). That data is not to be used for further, unapproved research or “data exploration” and is to be destroyed by the researcher at the conclusion of the research.

b. Standardized Request For Data (RFD)

Datasets from the CDR are to be requested using a standard Request for Data (RFD) form. The form is to be completed in its entirety with the assistance of the NAMR.

c. Entities eligible to request datasets

All PN are eligible to submit an RFD to the NAB through their Nationally Assigned Medical Representative (NAMR).

For RFDs originating from International Military Staff (IMS), Allied Command Operations (ACO) and Allied Command Transformation (ACT) the respective Medical Advisor (MEDAD) will act in the role of the NAMR for the respective organization.

For data requests originating from other NATO entities, the RFD will be sent via the MEDAD of IMS, ACO or ACT.

Regardless of the origin of the RFD, the NAMR (or equivalent (i.e. MEDAD)) is expected to advocate for the RFD and all studies that will be conducted using the CDR data will comply with minimum established human research ethical standards.

7. Pre-publication Review

In order for nations to be able to prepare press releases and talking points, the NAMR from each nation whose data has been included in the released dataset for a given research question will be able to review, prior to publication, any manuscripts generated from that research which have been accepted for publication. It is explicitly stated that nations have no power to stop publication of a manuscript nor do nations have the right or authority to review a manuscript prior to its being submitted or accepted for publication. This pre-publication

review is solely to provide an opportunity for a nation to prepare timely and proactive communication concerning research findings.

2.2 Governance Bodies Roles and Responsibilities

1. General

There are two governance bodies that are required to maintain the utility of the NTR and to ensure scientific oversight of dataset requests. A board set up to review research requests, and a board in place to ensure the database is kept current.

a. NTR Approval Board (NAB)

The NTR Approval Board (NAB) will review Requests for Data (RFD) and approve (or disapprove) the release of datasets. Membership of the board will include a chairman from STO-HFM and a core team of eight (8) members who are suitably qualified and experienced in medical research requirements. These members will be appointed by the Committee of the Chiefs of Military Medical Services (COMEDS) and will serve five year terms. Additional members may be added as needed at the core team's discretion. The NAB will be responsible for ensuring the data requested will meet the study's requirements. The decision to release data will be based on majority vote. The NAB will notify all CN on the pending data release allowing them the opportunity to withdraw their data from the study. If data is withdrawn The NAB will review the remaining data to ensure it still meets the study requirements. The NAB will be responsible for development of a RFD form that meets their needs.

b. NTR Development Board (NDB)

The NTR Development Board (NDB) is responsible for recommending updates.

2.3 Process Issues

1. Dataset Release Process

The release of datasets must follow strict guidelines to ensure control of the released data and that the use of the data is in accordance with ethical standards.

- a. An NAMR must ensure that any RFD forwarded to the NAB has gone through an Institutional Review Board process that meets or exceeds national and international requirements for ethics in medical research.

- b. The RFD will be presented to the NAB by the NAMR for discussion.
- c. Once a RFD has been approved, the NAB will release the data.

2. Software Updates

Software updates are the responsibility of the Software developer and are to be handled in accordance with processes established by the NCI Agency.

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