Trauma Surgery & Acute Care Open

Launch of the National Trauma Research Repository coincides with new data sharing requirements

Michelle A Price,[1] Pam J Bixby,[1] Monica J Phillips,[1] Gregory J Beilman,[2] Eileen M Bulger,[3] Michael R Davis,[4] Matthew J McAuliffe,[5] Todd E Rasmussen,[6] Jose Salinas,[7] Sharon L Smith,[1] Mary Ann Spott,[8] Leonard J Weireter,[9] Donald H Jenkins[10]

[1]National Trauma Institute, San Antonio, Texas, USA
[2]Department of Surgery, University of Minnesota, Minneapolis, Minnesota, USA
[3]Department of Surgery, University of Washington, Seattle, Washington, USA
[4]US Combat Casualty Care Research Program, US Army Medical Research and Materiel Command, Ft Detrick, Maryland, USA
[5]Center for Information Technology, National Institutes of Health, Bethesda, Maryland, USA
[6]F Edward Hébert School of Medicine, Uniformed Services University of the Health Sciences, Bethesda, Maryland, USA
[7]Clinical Decision Support and Automation Research, US Army Institute of Surgical Research, JBSA Fort Sam Houston, San Antonio, Texas, USA
[8]Joint Trauma System, JBSA Fort Sam Houston, San Antonio, Texas, USA
[9]Department of Surgery, Eastern Virginia Medical School, Norfolk, Virginia, USA
[10]Department of Surgery, University of Texas Health – San Antonio, San Antonio, Texas, USA

Correspondence to
Dr Michelle A Price; Michelle@NatTrauma.org

Received 1 June 2018
Accepted 7 June 2018

© Author(s) (or their employer(s)) 2018. Re-use permitted under CC BY-NC. No commercial re-use. See rights and permissions. Published by BMJ.

To cite: Price MA, Bixby PJ, Phillips MJ, *et al*. *Trauma Surg Acute Care Open* 2018;**3**:e000193.

NTRR IS LAUNCHING

Previous analyses of research data have shown that many trauma studies cannot be replicated or validated due to a variety of factors, including lack of access to study data, lack of access to protocol information, and inability to replicate procedures used in the study. New data sharing rules for federally funded studies have been put in place to address factors associated with this issue.

To address these new data sharing requirements, beginning this month, investigators conducting research on trauma and critical care will be able to maximize the utility of the data they produce with the launch of the National Trauma Research Repository (NTRR). The system was developed as a resource to support new and emerging data sharing needs within the trauma research community and is envisioned to be a key piece of the national trauma research infrastructure. It is funded by the Department of Defense (DoD) and developed by the National Trauma Institute (NTI) to promote collaboration, accelerate research, and advance knowledge on the treatment of trauma. When it becomes fully functional, the NTRR will be a comprehensive repository offering thousands of data points from hundreds of studies, enabling investigators to query across studies for their own research objectives.

The NTRR was developed by trauma researchers for trauma researchers. A national committee was convened of civilian and military trauma researchers and stakeholder organizations to define the functional requirements of the repository that would best serve investigators.[1] The NTRR allows users to peruse available data elements, study data sets, and supporting documentation (eg, protocols, consent forms, data dictionaries). Investigators contributing data to the NTRR can upload completed data sets and supporting documents at the completion of a study or as the study is being conducted. All studies will submit core data elements and study metadata (information about the study). Use of common data elements (CDEs) is encouraged to improve data harmonization and opportunities for comparison and combination of data from multiple studies. The system also allows researchers to use unique data elements, or UDEs, if a CDE for that variable is not available. When the data set is complete and validated, it will receive a digital object identifier (DOI) to allow contributing researchers to be acknowledged in publications resulting from secondary analyses.

The NTRR is organized in four modules representing the entire patient care trajectory: prehospital care, inpatient care, rehabilitation, and long-term outcomes/quality of life issues. Access to the system is through a web-based interface developed by the National Institutes of Health (NIH) – Center for Information Technology and enhanced by the NTI. Hosted in a secure Amazon Web Services cloud environment, the repository conforms to standards set forth in the Federal Information Security Management Act, which provides a standardized approach for assessing, monitoring, securing, and authorizing cloud computing products. Specific security controls in place for the NTRR include firewalls, application monitoring software and integrated cloud tools for operating system scanning, SSL (Secure Sockets Layer), antivirus and password encryption technology, and security audits and inspections.

Uploading trauma research data into the NTRR will fulfill both funder and publisher obligations to share and help to create a rich resource to support trauma investigations over time. Although it will take years to build out the repository and for it to be used at full capacity, the NTRR holds great promise for the responsible stewardship of data, respecting the contributions of study participants, the efforts of trialists, and the sources of public funding whose ultimate goal is to improve patient outcomes and minimize death and disability.

NTRR ENTERS AN EMERGING DATA SHARING LANDSCAPE

Over the past 15 years, the concept of data sharing has grown from a few disease-specific efforts such as traumatic brain injury and Parkinson's disease to almost universal expectations by research funding entities and journal editors. Those requiring various degrees of sharing include academic journal publishers and a wide variety of funding agencies, from government entities like the DoD and the NIH to private philanthropies like the Bill & Melinda Gates Foundation and Wellcome Trust, to corporate entities like Medtronic and GlaxoSmithKline.[2 3]

Perhaps the earliest funder to recognize the benefits of data sharing, the NIH initially published its Statement on Sharing Research Data in 2003.

Trauma Surg Acute Care Open: first published as 10.1136/tsaco-2018-000193 on 27 June 2018. Downloaded from http://tsaco.bmj.com/ on April 23, 2024 by guest. Protected by copyright.

Declaring that "data sharing is essential for expedited translation of research results into knowledge, products, and procedures to improve human health," the NIH requires applicants seeking $500 000 or more in grant funding to include a plan for data sharing in their proposals.[4] Likewise, since 2011, the National Science Foundation (NSF) has required funding proposals to include a data management plan describing how they will conform to the NSF policy on the dissemination and sharing of research results.[5] Such plans are expected to address the types of data and other materials to be produced during the study, the data and metadata standards to be used, policies for access and sharing, policies for reuse, and plans for archiving and preserving access to data and other research products.

In 2013, the White House Office of Science and Technology Policy (OSTP) asserted that federal agencies will work to develop policies to make the results of federally funded research freely available to the public and for requiring researchers to better account for and manage the digital data resulting from federally funded research.[6] After OSTP's mandate, the DoD issued its guidance in 2015, with a "Plan to Establish Public Access to the Results of Federally Funded Research." The plan provides a framework for increasing public access to both scholarly publications and the scientific data that underlie them—for the research and programs funded in part or wholly by the DoD. "Having DoD components work together within this proposed framework will yield synergies and innovations no single component can achieve alone," explained its authors (p2).[7] According to the plan, those submitting research proposals must include a data management plan that largely follows what is required by the NSF, and must upload research outputs—including peer-reviewed scholarly publications and data sets—to an online repository maintained by the Defense Technical Information Center.[7]

In 2014, *The Public Library of Science* (*PLOS*) was one of the first publishers to make data sharing a requirement for those investigators whose articles are accepted for publication in its journals.[8 9] *British Medical Journals*, *Springer Nature*, and many other publishers now have data policies requiring or recommending data statements and data sharing.[8 10] In 2017, the International Committee of Medical Journal Editors (ICMJE) revised its *Uniform Requirements for Manuscripts* (renamed *Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals*) to include a mandate that the results of clinical trials must contain a data sharing statement beginning in July 2018, and that clinical trials that begin enrolling participants on or after 1 January 2019 must include a data sharing plan in the trials' registration (table 1).[11–13] The ICMJE—a small working group of general medical editors including the *British Medical Journals*, *Journal of the American Medical Association*, *New England Journal of Medicine*, *PLOS Medicine*, and the *US National Library of Medicine*—has a great deal of clout. Most medical journal editors follow the ICMJE's recommendations. Trauma clinical trials researchers will recall that the ICMJE's recommendation requiring trial registration (eg, www.clinicaltrials.gov) was quickly adopted by nearly all medical journals. An informal survey of editors of the journals in which trauma investigators often publish revealed that they are aware of ICMJE's mandate and are developing their own data sharing policies.

Therefore, researchers who have had little incentive to share data now find that there is no choice but to do so, as more members of the research community recognize that data resulting from publicly funded clinical trials are a public good, to be made openly available with as few restrictions as possible.[14] The NTRR is the mechanism that trauma researchers can now use to meet such funder and publisher requirements.

Table 1 Examples of data sharing statements that fulfill the ICMJE requirements

	Example 1	Example 2	Example 3	Example 4
Will individual participant data be available (including data dictionaries)?	Yes.	Yes.	Yes.	No.
What data in particular will be shared?	All of the individual participant data collected during the trial, after deidentification.	Individual participant data that underlie the results reported in this article after deidentification (text, tables, figures, and appendices).	Individual participant data that underlie the results reported in this article after deidentification (text, tables, figures, and appendices).	Not available.
What other documents will be available?	Study protocol, statistical analysis plan, informed consent form, clinical study report, analytic code.	Study protocol, statistical analysis plan, analytic code.	Study protocol.	Not available.
When will data be available (start and end dates)?	Immediately after publication—no end date.	Beginning 3 months and ending 5 years after article publication.	Beginning 9 months and ending 36 months after article publication.	Not applicable.
With whom will the data be shared?	Anyone who wishes to access the data.	Researchers who provide a methodologically sound proposal.	Investigators whose proposed use of the data has been approved by an independent review committee (learned intermediary) identified for this purpose.	Not applicable.
What types of analyses are authorized to be conducted?	Any purpose.	To achieve aims in the approved proposal.	For individual participant data meta-analysis.	Not applicable.
By what mechanism will data be made available?	Data are available indefinitely at (include link).	Proposals should be directed to xxx@yyy. To gain access, data requesters will need to sign a data access agreement. Data are available for 5 years at (include link).	Proposals may be submitted up to 36 months after article publication. After 36 months the data will be available in our university's data warehouse but without investigator support other than deposited metadata. Information regarding submitting proposals and accessing data is at (include link).	

ICMJE, International Committee of Medical Journal Editors.
[a]Reprinted with permission from the Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals at http://www.icmje.org/icmje-recommendations.pdf.[13]

Trauma Surg Acute Care Open: first published as 10.1136/tsaco-2018-000193 on 27 June 2018. Downloaded from http://tsaco.bmj.com/ on April 23, 2024 by guest. Protected by copyright.

DATA SHARING BRINGS BOTH BENEFITS AND CHALLENGES

The purpose of data sharing is to make research data available for reuse, validation, meta-analysis, and replication.[15] The purported benefits of data sharing include replication of previous findings, comparisons with independent data sets, testing of additional hypotheses, teaching, and improving patient safety.[16] Evidence has shown that data sharing practices may also help correct for publication bias (the publication or non-publication of research findings depending on the nature and direction of the results) and outcome reporting bias (the selective reporting of some outcomes but not others).[17] Individual researchers benefit from data sharing via increased visibility, improved output connections, and reduced inefficiencies. The research community benefits from advances in reproducibility, improved long-term data archiving, and a reduction in unnecessary studies. Society benefits from data sharing by increased innovation, easier access to research, and scientifically informed policy making.[18] Of course, the ultimate goal of responsible sharing of clinical trial data is to increase scientific knowledge that leads to better therapies for patients.[19]

As with any new paradigm, difficulties and weaknesses become apparent in the first attempts to meet new expectations and goals—the higher the expectations, the greater the likelihood there will be challenges in meeting them. The challenges associated with data sharing are real. Researchers are concerned about the barriers to data sharing, even as the benefits are well documented and requirements for doing so come due.[8] Still at issue are the resources required to prepare data for sharing, the potential for other users to misinterpret data, and the possibility that the original researchers—the ones who did all the work to design and conduct the trials—may not be able to publish as many articles using the data as they might otherwise have.[14] In a recent survey of more than 7700 researchers, *Springer Nature* reported that among the medical sciences researchers surveyed (2683 respondents), 39% shared data neither through supplements nor repositories.[8] These respondents identified the following barriers to data sharing:

- "Unsure about copyright and licensing" (44%).
- "Organizing data in a presentable and useful way" (40%).
- "Not knowing what repository to use" (37%).
- "Lack of time to deposit data" (25%).
- "Costs of data sharing" (21%).[8]

Risks, burdens, and challenges also include protecting the privacy of trial subjects, safeguarding intellectual property and proprietary information, checking invalid secondary analyses that could harm public health, providing enough time for researchers to analyze their own data and receive recognition before sharing, and addressing the costs.[19]

The NTRR is working to overcome such challenges and will continue to refine its policies and processes as new issues arise. To address the concern researchers may have that their ability to produce publications will be compromised, the NTRR holds to a 1 year embargo from the time of the first study publication before making data available for sharing. Further, the NTRR will limit access to data by requiring researcher credentials and institutional endorsement. Requesting investigators will be required to have institutional review board approval for their planned secondary analyses. They will be encouraged to collaborate with the contributing investigator and required to cite the original data source (via DOI). Shared data will either be deidentified or be limited data sets with appropriate institutional data use agreements. With these safeguards in place, the NTRR administrators expect to minimize the potential for misinterpreting or misusing the data.

IT'S YOUR NATIONAL TRAUMA RESEARCH REPOSITORY: HELP TO BUILD THIS RESOURCE AND IMPROVE PATIENT OUTCOMES

Data sharing platforms encourage transfer of research data and knowledge between civilian and military researchers, reduce redundancy, and maximize limited research funding.[1] Optimizing the research life cycle now involves responsible data stewardship, as opposed to ownership. The old paradigm—in which individual investigators maintain indefinite ownership of the data resulting from their publicly funded work—results in now unacceptable research waste, including hidden data and irreproducible findings.[20] Single-instance use of research data and the inability to access data resulting from studies limit the impact of trauma research funding. Especially in fields such as trauma, where research funding has never been free-flowing and in the past decade has become even more difficult to come by, it is imperative to make every research dollar count. As the trauma research community seeks to maximize available research funds, the NTRR makes data available for enduring use and will effectively allow for more data analysis and knowledge translation, which can result in improved patient care.

Still in its infancy, the NTRR needs trauma investigators' participation to realize the vision of advancing the field of trauma research to achieve improved outcomes for injured patients. Become a data steward and help build YOUR National Trauma Research Repository. You can find additional information and detailed implementation guidance on the NTRR website (www.ntrr-nti.org).

Contributors MAP and PJB conducted the literature search and contributed to the planning, writing, and critical revision of the article. All authors contributed to the writing and critical revision of the article.

Funding This work was sponsored by the Department of the Army, Prime Award #W81XWH-15.2.0089. The US Army Medical Research Acquisition Activity (820 Chandler Street, Fort Detrick, MD 21702-5014) is the awarding and administering acquisition office. The opinions or assertions contained herein are the private views of the authors and are not to be construed as official or as reflecting the view of the Department of the Army or the Department of Defense.

Competing interests None declared.

Patient consent Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement There are no data to share.

Open access This is an Open access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited, appropriate credit is given, any changes made indicated, and the use is non-commercial. See: http://creativecommons.org/licenses/by-nc/4.0/.

REFERENCES

1. Smith SL, Price MA, Fabian TC, Jurkovich GJ, Pruitt BA, Stewart RM, Jenkins DH. The National Trauma Research Repository: Ushering in a New ERA of trauma research (Commentary). *Shock* 2016;46(3 Suppl 1):37–41.
2. Ross JS, Krumholz HM. Ushering in a new era of open science through data sharing: the wall must come down. *JAMA* 2013;309:1355–6.
3. Krumholz HM, Terry SF, Waldstreicher J. Data Acquisition, Curation, and Use for a Continuously Learning Health System. *JAMA* 2016;316:1669–70.
4. National Institutes of Health Office of Extramural Research. NIH Data sharing policy and implementation guidance. 2003. https://grants.nih.gov/grants/policy/data_sharing/ ([updated August 30, 2006; accessed May 29, 2018).
5. National Science Foundation. NSF Data sharing policy. 2017. https://www.nsf.gov/bfa/dias/policy/dmp.jsp (accessed May 29, 2018).
6. Office of Science and Technology Policy. *Memorandum for the heads of executive departments and agencies*. Washington, DC: Executive Office of the President, Office of Management and Budget, 2013.
7. Department of Defense. Plan to establish public access to the results of federally funded research. 2015.

Trauma Surg Acute Care Open: first published as 10.1136/tsaco-2018-000193 on 27 June 2018. Downloaded from http://tsaco.bmj.com/ on April 23, 2024 by guest. Protected by copyright.

8. David S, Grace B, Iain H. Whitepaper: Practical challenges for researchers in data sharing. 2018.
9. PLOS One. PLOS One Data Policy. 2014. http://journals.plos.org/plosone/s/data-availability (accessed May 29, 2018).
10. BMJ Publishing Group Ltd. BMJ Open Science. 2018. http://openscience.bmj.com/pages/policies/#OData (accessed May 28, 2018).
11. Taichman DB, Backus J, Baethge C, Bauchner H, de Leeuw PW, Drazen JM, Fletcher J, Frizelle FA, Groves T, Haileamlak A, *et al*. Sharing Clinical Trial Data--A Proposal from the International Committee of Medical Journal Editors. *N Engl J Med* 2016;374:384–6.
12. Taichman DB, Sahni P, Pinborg A, Peiperl L, Laine C, James A, Hong ST, Haileamlak A, Gollogly L, Godlee F, *et al*. Data Sharing Statements for Clinical Trials: A Requirement of the International Committee of Medical Journal Editors. *JAMA* 2017;317:2491–2.
13. International Committee of medical Journal Editors. Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals. 2017. http://www.icmje.org/icmje-recommendations.pdf (accessed 21 May 2018).
14. Ohmann C, Banzi R, Canham S, Battaglia S, Matei M, Ariyo C, Becnel L, Bierer B, Bowers S, Clivio L, *et al*. Sharing and reuse of individual participant data from clinical trials: principles and recommendations. *BMJ Open* 2017;7:e018647.
15. Van Tuyl S, Whitmire AL. Water, Water, Everywhere: Defining and Assessing Data Sharing in Academia. *PLoS One* 2016;11:e0147942.
16. Hrynaszkiewicz I, Norton ML, Vickers AJ, Altman DG. Preparing raw clinical data for publication: guidance for journal editors, authors, and peer reviewers. *BMJ* 2010;340:c181.
17. McGauran N, Wieseler B, Kreis J, Schüler YB, Kölsch H, Kaiser T. Reporting bias in medical research - a narrative review. *Trials* 2010;11:37.
18. Data S, Mathias A. Benefits of Open Research Data Infographic. 2017.
19. *Institute of Medicine (IOM). Sharing clinical trial data: Maximizing benefits, minimizing risk*. Washington, DC: The National Academies Press, 2015.
20. Rowhani-Farid A, Allen M, Barnett AG. What incentives increase data sharing in health and medical research? A systematic review. *Res Integr Peer Rev* 2017;2:4.

Trauma Surg Acute Care Open: first published as 10.1136/tsaco-2018-000193 on 27 June 2018. Downloaded from http://tsaco.bmj.com/ on April 23, 2024 by guest. Protected by copyright.