

EDITORIALS



The Importance — and the Complexities — of Data Sharing

Jeffrey M. Drazen, M.D., Stephen Morrissey, Ph.D., Debra Malina, Ph.D.,
Mary Beth Hamel, M.D., and Edward W. Campion, M.D.

We at the *Journal* are committed to making the sharing of clinical trial data an effective, efficient, and sustainable part of biomedical research. This issue of the *Journal* includes three Perspective articles on the topic of data sharing. Grossman et al. describe the Genomic Data Commons, which will initially house raw genomic data and diagnostic, histologic, and clinical outcome data from National Cancer Institute–funded projects.¹ Lo and DeMets recommend steps for addressing clinical trialists' primary reservations about sharing their data.² And Rockhold et al. consider progress to date and a path forward that could avert the creation of a fragmented data-sharing landscape.³ In August 2016, we published four Perspective articles on the same topic — two by experts who favored rapid open access to clinical trial data and two by other experts who were more reserved in their enthusiasm, focusing on the hurdles to be overcome.⁴⁻⁷ With these articles, and with others to come, our goal is to bring to the table a wide variety of opinions about the value, risks, unknowns, and rewards that accompany data sharing in the context of clinical trials. We firmly believe that complex issues are best clarified through open discussion and the airing of various viewpoints. Only by seeing the issue through many sets of eyes can we achieve the clarity we need to move forward. We hope that you will read each of these pieces with this idea in mind. Our enemy is disease and the human toll it takes. We need to use every means possible to come closer to vanquishing the real foe.

One of the best ways to make an idea a reality is to demonstrate its application. To that end, the *Journal* is sponsoring, with the help of the Na-

tional Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health, a contest to show how clinical trial data can be used to identify additional advances in human health that can be derived from a given data set. In November 2015, we published the primary outcome of the NHLBI Systolic Blood Pressure Intervention Trial (SPRINT) on the intensive treatment of hypertension.⁸ We now challenge clinical trialists, data analysts, and any other interested party to reanalyze the published SPRINT data, either alone or in combination with other publicly available data, to derive new insights or ideas. The SPRINT data will be made available on the NHLBI's BioLINCC website on November 1, 2016. We encourage you to use these data to generate new findings with the potential to improve our understanding of disease or patient care by participating in the NEJM SPRINT Data Analysis Challenge (<http://challenge.nejm.org>). The winners of the Challenge will be awarded prizes and will present their work at a live event at which researchers and patients will explore ways to align incentives for all toward the responsible and effective sharing of clinical trial data.

As we work through these complex issues, we want to make it clear that the *Journal* is committed to making data sharing part of our everyday business. Just as we introduced the inclusion of clinical trial protocols with the publication of all clinical trial research reports, we are working, in the same spirit of transparency, toward the goal of making data sharing a reality. We urge you to engage in the conversation by commenting on our published pieces at nejm.org but more important by taking up the SPRINT Challenge.

Disclosure forms provided by the authors are available with the full text of this editorial at NEJM.org.

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Intracranial Pressure Rescued by Decompressive Surgery after Traumatic Brain Injury

Lori A. Shutter, M.D., and Shelly D. Timmons, M.D., Ph.D.

Hutchinson et al.¹ report in the *Journal* the results of the Randomised Evaluation of Surgery with Craniectomy for Uncontrollable Elevation of Intracranial Pressure (RESCUEicp) trial, which compared decompressive craniectomy with continued medical management for refractory elevation of intracranial pressure after severe traumatic brain injury. Urgent treatment of patients with such an injury focuses on minimizing secondary brain injury, particularly from increased intracranial pressure. When common medical interventions fail to control intracranial pressure, decompressive craniectomy to prevent herniation may be considered. This surgery addresses a physiological problem (refractory elevation of intracranial pressure) and has a proven benefit in the management of malignant cerebral edema after ischemic stroke.² Craniectomy may be performed in isolation for intracranial-pressure control or with the simultaneous evacuation of acute intracranial mass lesions. In the RESCUEicp trial, craniectomy was performed specifically for the purpose of lowering the intracranial pressure, although patients could be enrolled if refractory intracranial-pressure elevation had developed after a preceding surgery to evacuate an intracranial hematoma during which the bone flap had been replaced.

Guidelines for the management of traumatic brain injury are based on limited evidence,³ and trials in the past several years have caused con-

troversy.⁴⁻⁶ In 2011, the Decompressive Craniectomy in Diffuse Traumatic Brain Injury (DECRA) study, the results of which appeared in the *Journal*, showed that there was no benefit from bifrontal surgical decompressive craniectomy to reduce intracranial pressure, although the restrictive entry criteria of that trial raised questions regarding the generalizability of the negative results, and the definition of refractory intracranial pressure was called into question.^{6,7} The RESCUEicp trial addressed these concerns by including more commonly encountered types of patients with traumatic intracranial mass lesions and by refining the definition of refractory intracranial-pressure elevation (>25 mm Hg for 1 to 12 hours, as compared with >20 mm Hg for 15 minutes within a 1-hour period in the DECRA study).⁶

Patients in the surgical group of the RESCUEicp trial underwent either unilateral hemicraniectomy or bifrontal craniectomy on the basis of computed tomographic imaging and at the discretion of the surgeon. Patients in the medical group received continued medical therapy with the optional addition of barbiturate therapy to reduce intracranial pressure; patients could undergo delayed decompression if further deterioration occurred. The primary-outcome measure was the 6-month Extended Glasgow Outcome Scale (GOS-E) rating (on an 8-point scale, ranging from death to upper good recovery [no injury-related problems]). The trial showed better intra-