

Outcomes: NINDS CDE Project

Working group: Outcomes

Completed by: Mark Luciano, John Heiss

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The development of the Common Data Elements (CDEs) for the Chiari I malformation Outcomes Subgroup followed the same general process as for the other subgroups. In short, a subgroup draft was supplemented and edited in serial workshops, which included 15 to 40 persons. Drafts of the CDE files were also released to the entire Chiari and Syringomyelia Foundation Advisory Board and internationally to participating Chiari-interested caregivers, researchers and industry representatives. Elements were chosen based on 3 major classifications: anatomical outcome, functional outcomes and complications. Outcomes were expressed as both end-state and as post-treatment change when possible. Variable choice was based on the anatomical and presentation measures described in the literature and in the respective CDE listings. Instrument/tool choice was based on general established functional tools related to quality of life (QOL), pain, and neurological function, factors most frequently affected by Chiari I malformation. Quality of life instruments include those measuring overall QOL, such as the SF-36 and others that assess the effect of neurological impairment on QOL, such as ambulation difficulty evaluated by the European Quality of Life 5 Dimension Questionnaire. The Brief Pain Inventory (BPI), which represents 15 distinct CDEs, is included to capture the effects of treatment on pain. The Chiari Symptom Profile is a Chiari-specific instrument that could be used to assess outcome if performed before and after treatment. The Chicago Chiari Outcome Score is another Chiari-specific outcome instrument included to measure change in function from pre-treatment. It should be noted that while the anatomical and complication outcome CDEs apply to both pediatric and adult populations, the instruments listed are specific to a population as listed.