# NEUROWORSENING

**NeuWors = Neuroworsening**

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| **1. CDE Variable** | NeuWors = Neuroworsening |
| **2. CDE Definition** | Neuroworsening is considered present when one or more of the following symptoms occur:<br>1. a spontaneous decrease in the GCS motor score of 2 points or more compared with the previous examination<br>2. a new loss of pupillary reactivity, development of pupillary asymmetry ≥ 2mm<br>3. deterioration in neurological or CT status sufficient to warrant immediate medical or surgical intervention |
| **3. Recommended instrument for assessment** | Predefined criteria as summarized under CDE definition (2). |
| **4. Description of measure** | Presence of neuroworsening: binary.<br>Symptoms and action taken: categorical; multiple entries permitted. Add date tag. |
| **5. Permissible values** | Neuroworsening: no/yes/unknown.<br><br>**Intermediate/advanced**<br>***If yes:***<br>Symptoms of neuroworsening:<br>- decrease in motor score ≥ 2 points<br>- development of new pupillary abnormalities<br>- other neurological and/or CT deterioration<br><br>Action taken if yes:<br>- none<br>- unscheduled CT scan<br>- change in medical therapy<br>- surgical intervention |
| **6. Classification: Basic/Intermediate/Advanced** | Basic: presence of neuroworsening<br>Intermediate/advanced: symptoms and action taken. |
| **7. Procedure** | Record information prospectively or obtain information from review of medical charts. |
| **8. Comments/Special instructions:**<br>The element neuroworsening can be assessed at various time periods as mandated per protocol. As a minimum we recommend assessment over the entire clinical observation period, or on day 14, whichever comes first. In the intermediate and advanced versions we recommend assessment on a daily basis for the first week and on day 14. Assessment at fixed time periods is preferred over for example the clinical course which is a variable time period.<br>Neuroworsening should only be scored present if the symptoms are not considered to be caused by effects of sedation and/or neuromuscular blockade. | |
| **9. Rationale/justification:**<br>The occurrence of neuroworsening is considered a symptom of progressive brain damage and has been suggested as early endpoint for clinical trials in TBI. Its definitive value as early endpoint has however not been fully established. | |
| **10. References:**<br>*Morris GF, Juul N, Marshall SB, et al*. Neurological deterioration as a potential alternative | |

endpoint in human clinical trials of experimental pharmacological agents for treatment of severe traumatic brain injuries. Executive Committee of the International Selfotel Trial. *Neurosurgery*. Dec 1998;43(6):1369-74

**Recommended time for assessment:**
Basic: over the clinical observation period or at day 14, whichever comes first.
Intermediate/advanced: daily and day 14.