Trading death and disability in malignant stroke

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Investigating introspective aspects of informed consent in a contemporary stroke trial

The process of informed consent is considerably complex in acute stroke.

In this issue of *J Neurol Neurosurg Psychiatry*, Hofmeijer and colleagues¹ examined informed consent for hemicraniectomy in malignant stroke, a particularly difficult clinical scenario that underscores the uncertainty, limited evidence and complexity that clinicians must convey to patients and families regarding stroke, and seemingly heroic measures that have recently allowed for positive outcomes in select cases (*see page 1124*). Hemicraniectomy or decompressive surgery for malignant stroke superimposes further complexity. Such a surgical option is entertained only when the perceived risk of neurological injury due to expanding oedema is so excessive that death from impending herniation is inevitable. Considerable neurological deficits are already established with little hope of reversing those impairments. It is critical for clinicians to explain that such intervention averts death but does not treat stroke itself. These cases underscore the valuations made under emergency situations where gambles are made in attempts to trade death and disability. Young patients may be most vulnerable to life threatening oedema, yet decompression may lead to decades of subsequent residual disability. During these precarious hours when cerebral oedema

develops, decompression may be entertained requiring discussion with family members as most patients may have compromised ability to interact.

Hofmeijer and colleagues¹ investigated family members' recall of the informed consent procedure approximately 1 year after enrolment in the Hemicraniectomy After Middle cerebral artery infarction with Life-threatening Edema Trial (HAMLET).^{1,2} They compared these results with similar data extracted from another acute stroke trial focused on the use of acetaminophen.³ Relatives of HAMLET participants remembered considerable detail of the informed consent obtained prior to hemicraniectomy within 96 h of stroke onset. The authors suggest that the dramatic, yet conceptually straightforward, nature of the procedure enhanced recall. Unlike informed consent for the trial of acetaminophen, a substantial proportion of relatives (30%) harboured negative feelings about the informed consent process. The majority attributed such negative feelings to the acute and emotional turmoil during consent. Relatives remembered what was done, but not the presumed effects of treatment. Many consenting parties in the analysed trials stated that they did not actually read the informed consent document. In HAMLET, 39% of consenting relatives would have also preferred

that the doctor decided the treatment choice. Failure to include similar recall data from relatives that refused trial participation may have biased the study, yet informed refusal may be even more difficult to study.

Despite the limitations in the design of their study, Hofmeijer and colleagues¹ should be applauded for investigating introspective aspects of informed consent in a contemporary stroke trial. Recall of informed consent, as assessed by Hofmeijer *et al* however, should not be used in itself as a criterion to validate or dispute effectiveness of the informed consent process. What will we do if recall differs substantially? Perhaps such insight will be used to enhance the way we tackle medical decisions in concert with our patients. Further research on the process and impact of informed consent will only serve to enhance the way we practice medicine.

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REFERENCES

- 1 Hofmeijer J, Amelink GJ, den Hertog HM, *et al*, on behalf of the HAMLET and PAIS investigators. Appreciation of the informed consent procedure in a randomised trial of decompressive surgery for space occupying hemispheric infarction. *J Neurol Neurosurg Psychiatry* 2007;**78**:1124–8.
- 2 Hofmeijer J, Amelink GJ, Algra A, *et al*. Hemicraniectomy After Middle cerebral artery infarction with Life-threatening Edema Trial (HAMLET). Protocol for a randomised controlled trial of decompressive surgery in space occupying hemispheric infarction. *Trials* 2006;**7**:29.
- 3 van Breda EJ, van der Worp HB, van Gemert HM, *et al*. PAIS investigators. PAIS: paracetamol (acetaminophen) in stroke; protocol for a randomized, double blind clinical trial (ISCRN 74418480). *BMC Cardiovasc Disord* 2005;**5**:24.