Informed Consent in Acute Stroke

To the Editor:

The process of informed consent is an integral component in the daily practice of medicine. Ongoing debate reflecting varying societal issues across wide geographical locales, medicolegal sophistication and evolving regulations have shaped this process. Increasingly complex medical decisions are formulated through this interaction between patients and doctors, opting for established surgical procedures, concocting medication regimens for off-label use, or choosing investigational approaches. Although a dedicated document may not be used in every scenario, the process embodies a universal doctrine designed to protect the patient. Elaborate algorithms or language considerations are often devoted to protect specific populations, yet this process also protects the doctor by noting patient consent. When consent is not established, many providers now document informed refusal.1 Discussions of risks, benefits, and alternatives have culminated in informed consent or refusal documents spanning up to 20 pages. Such documentation may not be feasible and the process may be entirely waived under specific emergency circumstances. The US Food and Drug Administration recently held public hearings to update stipulations for waiver of consent in emergency research. Clinical trialists have actively engaged in these forums, yet paradoxically, public interest and participation in these discussions that may decisively influence their future health care may be only minimal. Trialists have also been reluctant to scrutinize the impact of informed consent until enrollment has been completed in most studies, lest they jeopardize ongoing trial recruitment because of unexpected flaws in the process. Introspection and research on informed consent may provide striking observations and raise new questions.

The nuances of informed consent are particularly complex in acute stroke. Public knowledge of stroke is so abysmal that doctors focus their efforts to educate others only about recognition of the most basic stroke warning signs and symptoms. Much of the public is even unaware that stroke occurs in the brain. Stroke specialists often advise to “just get here” in order to encourage others to come to the nearest emergency room as soon as possible. Ironically, much of the stroke research community has failed to understand ischemic pathophysiology and successfully translate investigational approaches leading to effective stroke therapy. Much information may be provided regarding the presumed effects of a drug, device, or procedure, yet many of the actual details remain unclear. Can the pathophysiology be succinctly explained to patients and families under time pressure when even other medical specialists may not truly comprehend? Even when the presumed effect is exceedingly simple, such as restoring arterial patency in an occluded vessel, we must explain that technical efficacy does not necessarily equate to improved clinical outcome and long-term benefit. Mechanical thrombectomy may reopen arteries and recombinant factor VIIa may limit hematoma expansion, yet neither is proven to improve clinical outcome in randomized studies.2,3 As a result of these shortcomings, obtaining informed consent is likely heavily dependent on what and how things are conveyed. Recent breakthroughs in stroke may add further complexity as arterial recanalization may

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Figure. Baseline (A) diffusion-weighted MRI, angiography after failed mechanical thrombectomy (B) and day 5 diffusion-weighted MRI (C) showing infarct evolution in a case of left MCA stroke where disability was ultimately exchanged with death when comfort care measures were elected by the family. Baseline noncontrast CT (D), frontal skull x-ray (E), and follow-up noncontrast CT (F) after decompressive hemicraniectomy for malignant right middle cerebral artery stroke where death was averted in exchange for disability.
induce a Lazarus effect in some, yet predicting in advance who will be saved from death or years of disability may be impossible at present. Patients and their families often opt to pursue aggressive strategies to restore independence to those originally destined to die, yet many patients inadvertently trade death for marked disability as a result. Not so infrequently, family members may also later wish to exchange such severe disability for withdrawal of care and death, citing the patient’s longstanding wishes. Such designer stroke care to match individual preferences may be inconceivable to reconcile within minutes of discussion in an emergency room hallway. Unfortunately, the idealized binary outcome of death versus non-disabling results that many espouse is unrealistic when dealing with stroke, the leading cause of disability.

Informed consent of patients and their legal representatives will fuel participation in clinical research studies to develop and advance therapeutic strategies for acute stroke. Such informed consent does not solely amount to a simple checklist of legal provisos to be addressed with a signature at the bottom of the printed document to allow for yet another trial enrollment. The process is particularly complex in stroke because of our limited knowledge of relevant pathophysiology, logistic hurdles of time pressure in an emotionally chaotic situation where relatives may share decision responsibility, and the extensive variability in clinical outcomes where death and disability may be readily exchanged (Figure). Recent advances have enabled us to achieve dramatic recovery in some stroke victims, transforming the previously nihilistic milieu of stroke care, yet others face years of disability. Explaining and sharing such details with our patients and their families is essential when feasible. Emergency consent is not ideal and waiver of consent may also be justified in specific scenarios. These issues should ideally be discussed before stroke onset in public forums where individuals of a particular community may express, debate, and thoughtfully evaluate their values and wishes. Although this exact format may be required for attaining waiver of consent for emergency research in a given community, one may argue that this process should be used on a broader scale to educate the public about stroke before the burden of consent is imposed in an emotionally tumultuous environment where minutes count. Informed consent is an incredibly important public issue, not simply a logistic hurdle for stroke trialists. Further study and discussion of informed consent in stroke will undoubtedly be productive because these activities may be the best avenue to address public education on stroke. Such opportunities may be used to increase public knowledge about stroke in general and change perception of this potentially devastating, yet preventable disorder.

**Disclosures**

None.

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