VIEWPOINT

Issues with Consent in Stroke Patients

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ABSTRACT

Background: *Consent in stroke management may be required for either treatment, intervention or for research reasons. Consent capacity is an integral element of informed consent to treatment which requires that a patient's consent be voluntary, informed and competent. Without proper informed consent, medical treatment provided to a patient is a legal and ethical minefield, even if the treatment is benign and intended to benefit the patient.*

Results: *Recent advances have enabled dramatic recovery in some stroke victims, transforming the previously generally negative outcomes of stroke care, whereas others face varying levels of disability. Explaining and sharing such details with patients and their families is essential. If this is not possible then there are other options such as emergency consent which may be justified in specific scenarios. Stroke may affect various areas of the brain and this may also include the prefrontal cortex which is involved in decision-making. There have been observations that individuals with damage to the ventro-medial prefrontal cortex may be prone to impulsive decision-making in real life and these patients are impaired on laboratory decision-making tasks that require balancing rewards, punishments and risk. This may therefore have an impact on consent decisions made by the patient.*

Conclusion: *Ethical clinical research requires balancing several ethical requirements, including the requirement for scientific validity and the requirement to respect individuals by treating them as autonomous agents through the process of informed consent. Opportunities to improve on public awareness about stroke are essential to change the perception of this potentially devastating disorder.*

Keywords: Clinical research, consent, ethics, stroke

Problemas con el Consentimiento de los Pacientes con Accidente Cerebrovascular

RESUMEN

Antecedentes: *El consentimiento en el manejo del accidente cerebrovascular puede requerirse para el tratamiento, la intervención, o por razones de investigación. La capacidad de consentimiento es un elemento integral del consentimiento informado en los tratamientos que requieren que el consentimiento del paciente sea voluntario, informado y competente. Sin el consentimiento informado adecuado, el tratamiento médico dado a un paciente es un campo minado de dificultades legales y éticas, incluso si el tratamiento es benigno y encaminado a beneficiar al paciente.*

Resultados: *Avances recientes han transformado los resultados clínicos de la atención al accidente vascular, con anterioridad generalmente negativos, permitiendo la recuperación dramática de algunas de las víctimas, mientras que otros enfrentan distintos grados de discapacidad. Es imprescindible explicar y compartir dicha información con los pacientes y sus familias. Si esto no es posible, entonces hay otras opciones, tales como el consentimiento de emergencia, que puede justificarse en escenarios específicos. El accidente cerebrovascular puede afectar varias áreas del cerebro, incluyendo la corteza prefrontal que participa en la toma de decisiones. Ha habido observaciones que indican que las personas con daños en la corteza prefrontal ventromedial pueden estar propensas a tomar decisiones*

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impulsivas en la vida real. Los pacientes con tales daños experimentan una disminución en su capacidad a la hora de realizar tareas de toma de decisión en el laboratorio, para las que se requiere equilibrar recompensas, castigos y riesgos. Por consiguiente, esto puede tener un impacto sobre las decisiones de consentimiento por el paciente.

Conclusión: *La investigación clínica ética requiere equilibrar varios requerimientos éticos, incluyendo el requisito de la validez científica y la obligación de respetar a los individuos, tratándolos como agentes autónomos a través del proceso de consentimiento informado. Oportunidades de mejorar la conciencia pública acerca del accidente cerebrovascular son esenciales para cambiar la percepción de este trastorno potencialmente devastador.*

Palabras claves: Investigación clínica, consentimiento, ética, accidente cerebrovascular

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INTRODUCTION

Stroke is defined as a condition with "rapidly developing clinical signs of focal loss of cerebral function, with symptoms lasting more than 24 hours or leading to death, with no apparent cause other than that of vascular origin" (1). Stroke is a major killer and is the cause of much disability (2).

Despite meagre research investment, important progress has been made and this is reflected in various guideline initiatives. There is now a great deal of research into the mechanisms of stroke aetiology, prevention, acute and chronic management as well as post-event rehabilitation. Early assessment after stroke will enable the identification of those who need help to increase independence. In the long-term, about 40–50% of stroke survivors will be left with some physical disability and about 5–10% will need long-term institutional care. Reducing the burden which results from stroke requires optimizing stroke prevention and improving acute care, but rehabilitation is equally essential (3, 4).

The family/friends of a patient diagnosed with a stroke will undergo numerous emotions such as anger, loss, guilt, frustration and confusion; the intensity of which depends upon the nature of their relationship with the patient (5). Coping with a patient's disability may prove harder for the family/friends than coping with the patient's death. As any friends or family members are an essential aspect of the rehabilitation process, it is also a part of the rehabilitation team's role to be aware of their problems and needs (6, 7).

Consent in stroke management may be required for either treatment or intervention-related or even for research reasons. The capacity to consent is important as patients and their families must make complex decisions about medical care and also whether to be involved in a research project or not. Consent capacity is an integral element of informed consent to treatment which requires that a patient's consent be voluntary, informed and competent. Without proper informed consent, medical treatment provided to a patient is a legal and ethical minefield, even if the treatment is benign and intended to benefit the patient. This is equally true of research participation. Thus, potential impairments in the consent capacity of patients have important medical, legal and ethical implications for healthcare providers (8).

The ethics of informed consent are fundamental to research protocols. Institutional review boards require that all staff involved in human subject research receive ethics training and successfully complete a competency examination before any work can be initiated with participants. In order to consent for research participation, three conditions must be met: participant capacity, voluntariness and disclosure (9).

The process of informed consent is an integral component in the daily practice of medicine. This is a universally recognized doctrine designed to protect the patient. This has become a great enough issue that certain healthcare providers are now documenting "informed refusal" (10).

Discussions of risk, benefits and alternatives have culminated in informed consent documents reaching twenty pages in length, which create its own problems in patient-doctor communication. There are ongoing public debates as to whether consent should be required in emergency research; however, the public interest in this subject, which may be of direct future interest to them, is minimal. Researchers have also been reluctant to scrutinize the effect of informed consent for fear that this may jeopardize ongoing trial recruitment. Inspection of informed consent may provide certain observations and raise new questions which may have negative effects on their study design. Informed consent is particularly complex in acute stroke as public knowledge of stroke is not believed to be adequate at this moment in time. Due to this lack of knowledge, doctors are required to focus their efforts on the education of recognition of basic stroke warning signs and symptoms. As most of the general public is unaware that stroke occurs in the brain, stroke specialists advise a "just get here" message to encourage admission to the nearest emergency room as soon as possible.

This lack of in-depth knowledge means that explaining the pathophysiology to patients and families under time

pressure, when even some medical specialists may not truly comprehend, is a complex yet worrying problem. Patients and their families may opt for aggressive strategies to restore independence in those originally destined to die, yet others may trade death for marked disability. Family members may also wish to exchange disability for withdrawal of care and death, citing the patient's longstanding wishes. 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 provisions to be addressed with a signature at the bottom of the printed document to allow for yet another trial enrolment. Recent advances have enabled dramatic recovery in some stroke victims, transforming the previously generally negative outcomes of stroke care, whereas others face varying levels of disability. Explaining and sharing such details with patients and their families is essential. In the event that this is not possible, then there are other options such as emergency consent which may be justified in specific scenarios (10).

A majority of stroke patients believe in the importance of treatment development and many are receptive to being involved in research relating to this (11). The motivation to participate in such research extends beyond hope for personal benefit and altruistic concerns. Some participants in past research have expressed concern about the use of investigational interventions without informed consent, which may support the widespread emphasis on the importance of informed consent and cautions about the use of the exemption in emergency research (12). Surrogate consent may be one solution to this and, although concern has been voiced regarding accuracy and selection, studies have shown that most patients believe that family members should provide consent on their behalf although further research would be needed to define which family member patients would regard as the ideal surrogate (13, 14). Patients also clearly expressed the appropriateness of the treating physician as a surrogate. Most believed that if the patient or family were not able to consent, then the treating physician would be the appropriate person to make the decision, showing great trust in the healthcare professionals treating the individual (11). Chen *et al* demonstrated in another study that stroke severity and subtype differ between those with and without the capacity to provide informed consent which may indicate the need for further research into the need for surrogates or proxies for potentially life-saving treatment (15).

To protect against possible exploitation, studies proposing to enrol adults who lack the capacity to provide informed consent for research must at least satisfy the "necessity requirement", to show that enrolment of such individuals is scientifically necessary (16). Studies which can obtain scientifically valid results with participants who can provide informed consent should not enrol persons who lack capacity. Some studies, however, may be able to obtain valid results only by including individuals who lack the capacity to provide informed consent. Allowing their enrolment with appropriate safeguards may be important for the study to provide generalizable knowledge. Such safeguards are delineated by regulatory authorities. Adults requiring treatment are safeguarded by the Mental Capacity Act of 2005, where people who lack the capacity to give consent have assigned proxies to make the decisions for them (17). This is not yet available for research consent (15).

The results by Chen *et al* supported the "necessity requirement" for ethical enrolment of "decisionally-impaired" individuals in ischaemic stroke research (15). Enrolment by surrogate decision-makers and limiting permissible research to acceptable risk levels provide important safeguards for these individuals. Excluding individuals unable to provide informed consent may diminish the investigators' ability to conduct exhaustive research which may lead to decisional impairment and limit external validity. It is well established that in epidemiological research, there is the potential for survival bias in general and in stroke research specifically (18). In many ways, survival bias can be considered as an extreme version of consent bias. Bias which negatively affects capacity to provide informed consent for research may suggest that there is an ethical necessity to consider allowing surrogate enrolment in research studies (15).

Stroke may affect various areas of the brain and this may also include the prefrontal cortex which is involved in decision-making. There have been observations that individuals with damage to the ventro-medial prefrontal cortex may be prone to impulsive decision-making in real life and these patients are impaired on laboratory decision-making tasks that require balancing rewards, punishments and risk. This may therefore have an impact on consent decisions made by the patient (19).

CONCLUSION

Ethical clinical research requires balancing several ethical requirements, including the requirement for scientific validity and the requirement to respect individuals by treating them as autonomous agents through the process of informed consent. Opportunities must be taken to increase public knowledge about stroke in general and change the perception of this potentially devastating, yet preventable disorder (10).

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