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Innovation in neurosurgery: Evaluation of neurosurgical innovation, related ethics, and solutions

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When time is critical, is informed consent less so? A discussion of patient autonomy in emergency neurosurgery

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Summary: *Neurosurgical interventions often take place in an emergency setting. In this setting, patients often have impaired consciousness or are severely threatened by spinal cord dysfunction and are therefore unable to express their values and wishes regarding their treatment. The limited time available for clinical decision making holds great ethical implications as the informed consent procedure may become compromised. The ethical situation may be further challenged by different views between the patient, relatives and the neurosurgeon; the presence of advance directives; innovative procedures; or if the procedure is part of a research project. In this moral opinion piece, we discuss the implications of time constraints and a lack of patient capacity for autonomous decision making in emergency neurosurgical situations. We also discuss potential solutions to these challenges that might help to improve ethical patient management in emergency settings.*

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Introduction

Time is of the essence for many neurosurgical procedures that often must be done on an emergent basis to mitigate the extent of patient morbidity and mortality.¹⁴ Emergency surgeries have been independently associated with increased post-operative morbidity and mortality when compared with non-emergent procedures.¹⁴ Patients may also have greater expected benefit from the procedure if it takes place sooner rather than later.¹⁹ Additionally, the need to operate as soon as possible creates ethical issues regarding patient autonomy and beneficence. Currently, no formal guidelines or statements exist that specifically describe how to obtain informed consent in an emergency setting for neurosurgery, but British physicians are allowed to act in the best interest of acutely incapacitated patients.^{6, 21} The statements of the American College of Surgeons and Association Of Surgeons Of Great Britain Ireland (ASGBI) on emergency surgery indicate that surgeons with appropriate training should be able to provide the necessary emergent care.^{2, 4} The ASGBI Good Clinical Practice Guideline does state that surgeons have a legal obligation to obtain informed consent in limited time.²⁶ While these statements on emergency surgery provide a general emphasis on good clinical practice and acting in the best interest of the patient, they unfortunately do not provide a template for striking a balance between respect for patient's autonomy and beneficence in an emergency scenario. A neurosurgeon is required to obtain adequate informed consent and make sure the patient undergoes the necessary procedure as soon as possible. This may be complicated and is frequently lacking, due to a relative lack of time and the rapidly evolving pathology that limits a patient's capacity to make an informed decision. During this complex process, neurosurgeons must balance the diverse views, choices, and actions of patients based on the patients' personal values and beliefs, that are often not expressed by the patients themselves at time of decision making, while ensuring that the care provided is of the highest standard. In this perspective piece, we discuss the ethical questions that might arise in an emergency neurosurgery related to respect for autonomy and propose methods to address them.

Respect for autonomy in an emergency setting

Respect for the autonomy of the patient during the informed consent process may be compromised during an emergency surgical scenario primarily for two reasons: a lack of time and questionable capacity.

Lack of time

In an emergency setting, patients are often unable to make an autonomous decision because of time constraints.^{3, 5} The limited time compromises the ability of the patient to weigh the benefits and risks, to appreciate the gravity of the situation, and to consider all treatment or non-treatment options and divergent outcomes. Patients and their proxies may also be frightened, misunderstand the proposed procedure, and feel pressured to consent in an emergency situation.¹ Therefore, autonomous decision making and informed consent may be compromised in an this acute setting.⁵ The lack of time also affects neurosurgeons as they have less time to perform a moral

deliberation and to prepare a surgical plan, and may be faced with increased emotional stress among the surgical team.¹⁷ Decisions to operate (or not) may also be influenced by a fear of malpractice lawsuits, especially when one would refrain from surgery.²⁸

Lack of capacity to make autonomous decisions

In addition to a lack of time for informed consent, acute neurosurgical diseases may limit the capacity of a patient to formulate or express an autonomous decision. Four scenarios may arise: 1) the patient has capacity to make an autonomous decision before surgery, 2) the patient lacks capacity to make an autonomous decision and relies on surrogate decision maker, 3) a patient lacks capacity to make an autonomous decision and has an advance directive for medical emergencies, or 4) the patient is comatose or tetraplegic and family members are unavailable (**Table 9.1**).

In the first scenario, communicating and providing informed consent efficiently given a relative lack of time is the main challenge in emergency surgery. This might for instance be the case for a trauma patient with a lower spinal cord injury, who is otherwise alert and orientated, but requires urgent stabilization or decompression. In the second -very common- scenario, a patient that requires emergency surgery has impaired level of consciousness and is no longer capable of autonomous decision making. Hence, decision making relies on a surrogate decision-maker (often a family member) if available. A patient may have previously expressed personal wishes or preferences in case of life-threatening scenarios which can guide decision-making by their representatives. This surrogate decision-maker should decide what the patient would have done with capacity in that scenario. This may aid the decision making-process, but their guidance does not necessarily equate what the patient would have preferred, as these cannot be known for each patient in any given emergency situation.

In the third scenario, the patient has an advance directive for medical emergencies. This can be a living-will that provides directions in specific circumstances and/or a durable power of attorney (DPA) in which the authority of the patient is carried over to another person through a legal document. Living wills offer a clear direction to take for the neurosurgeon, which respects the patient's autonomy. A clear and reasonable wish in a specific circumstance may seem "easy" for a neurosurgeon to follow (e.g. an elderly patient with a severe TBI and living will that states that no surgery should be pursued). However, multiple factors may cloud this decision. The living will may have been drafted at a time when the patient felt differently about their goals and personal views and post-operative outcome may be hard to predict. The neurosurgeon may personally disagree with a living will. Differing cultural and regional backgrounds of the neurosurgeon and patient further complicate the decision to operate due to widely varying expectations, values, and medical practices. For these and other reasons, living wills may have limited implications in neurosurgical emergency scenarios. One survey among neurosurgeons showed that only half of responding neurosurgeons would decline to operate on patients with an advance directive that limits post-operative life-supporting therapy.²⁵

A DPA may also provide guidance in the decision-making process for emergency

surgery. A DPA is been appointed by the patient and should be familiar the patient’s values and wishes. However, the DPA may be unavailable in an emergency situation and the patient’s wishes may have changed since the DPA was appointed. Therefore, the DPA still brings practical concerns and may not offer a solution in all scenarios.

Table 9.1: Four scenarios in emergency neurosurgery.

| Scenario | The patient is able to make autonomous decisions: | Other available parties or materials to guide decision-making. | Decision-maker. | Example. |
|----------|---|--|---|--|
| 1 | Yes | Not necessary. | The patient. | An adult patient with a traumatic vertebral fracture that needs urgent stabilization. |
| 2 | No | A surrogate decision-maker such as a family member. | The surrogate decision-maker. | A pediatric patient with an epidural hematoma that requires emergent evacuation. |
| 3 | | An advanced directive: DPA or living will. | The neurosurgeon, guided by the Advanced directive. | An elderly patient that has stated in a living will that no surgical procedure should be pursued but requires emergency evacuation of a subdural hematoma. |
| 4 | | Not available or enough time does not exist (e.g. patient with unilateral mydriasis and EDH) | The neurosurgeon. | A comatose patient with severe TBI that is brought in by emergency services whose name and family are unknown to the neurosurgeon. |

In the final scenario with a patient that is unable to make an autonomous decision and has no available surrogate decision maker or known living will, the neurosurgeon becomes the sole responsible person to make a decision that is in the patient’s best interest. This may also be the case when a patient cannot be expected to make a rational decision despite not being cognitively impaired, e.g. a tetraplegic patient. This requires the neurosurgeon to have some appreciation about what a favorable outcome would be for the patient based on their presumed culture and background.

Ethical challenges related to emergency neurosurgery

In emergency settings, lack of time and compromised capacity can challenge respect for autonomy. Here, we discuss how neurosurgeons may balance lack of time, compromised capacity of the patient and respect for autonomy and propose potential solutions to help guide management in these scenarios.

Balance between limited time, incapacitated patients, and respect for autonomy

In emergency situations, the neurosurgeon has to balance informed consent with minimal delay of the surgery. As a result, the formal informed consent procedure may be waived in acutely life-threatening scenarios like an evolving epidural hematoma causing uncal herniation. The ability to act fast maximizes beneficence to potentially incapacitated neurosurgical patients whose prognosis worsens with each minute of inaction. Most situations, however, will offer some – though limited – time to discuss treatment options but will still result in a compromised informed consent. All efforts should be made to obtain informed consent that is as complete as possible from the patient or surrogate decision-maker. Excellent communicational skills are of paramount importance for the neurosurgeon to provide a sufficient explanation in this limited time. The neurosurgical team should ideally try to elaborate on the expected outcome of the procedure including mortality, functional outcome, quality of life, and in particular the chance of survival with severe morbidity. However, this may be hard as most data is derived from large cohort studies that may not provide an accurate prediction of outcome for individual patients.

In the case of a patient that is incompetent to make an autonomous decision, the neurosurgeon should first consult the DPA or surrogate decision maker to guide decision-making. A living will may very well guide this process but should only aid decision-making if it provides a specified plan of action for the medical scenario. As indicated above, the decision to operate ultimately rests on the neurosurgeon's shoulders if no surrogate decision maker, DPA, or living will is available.

Disagreement between patient and neurosurgeon

We argue that neurosurgeons should in general regard the patient capable to make an autonomous decision when determining the patient's decision-making potential for emergent surgery. Only when the neurosurgeon has reasonable doubt regarding the patient's capacity to make autonomous decisions after discussion between multiple members of the neurosurgical team may operating without consent be ethically justified. Choosing to perform surgery without consent may be justified if the patient lacks capacity, has an unknown or unreachable health care proxy, has no living will or DPA prepared, and requires an urgent operation. A psychiatric evaluation could aid assessment of a patient's capacity to make an autonomous decision if time allows for it. This cautious management errs on the side of saving a life when it is not completely clear that a patient has capacity to make an autonomous decision. On the other hand, if a patient is capable to make an autonomous decision and does not change his or her mind over a reasonable amount of time, then the patient's decision should be respected despite potential detrimental outcomes. However, there may be no time to be sure that the patient is consistent in his or her reasoning over a longer period of time and the patient may also have chosen differently if the choice was not presented in an emergency scenario. Prioritizing beneficence over respect for autonomy may be ethically justified if respect or autonomy is viewed as a value or a relative right instead of an absolute right and thus beneficence (e.g. saving the patient's life) is highly likely to strongly outweigh respect for autonomy under the patient's own

value system.²⁷ In this situation, the neurosurgeon tries to act in the patient's best interest, which could be regarded as experience-based paternalism.⁸

This approach should be applied with caution. It may not be justifiable if there is no time available to further discuss treatment options with the patient or surrogate decision-makers. The neurosurgeon also risks incorrectly assuming the values and wishes of the patient due to social or cultural differences, which compromises the decision-making process. There may also be uncertainty to what constitutes a good outcome as seen with decompression for malignant middle cerebral artery infarction.^{11, 15} Some have argued that in addition to mortality, quality of life and functional outcomes are very valuable to patients and their families, even though early surgery may not result in improved outcomes for malignant middle cerebral artery infarction.^{10, 24} A neurosurgeon may also be inclined to operate due to reasons other than to provide optimal care, e.g. the fear of malpractice law suits.²⁸ An appreciation for a patient's legally protected preferences for end-of-life decision-making, such as living wills, should also be followed if they apply to the specific situation. The difficulty in weighing respect for autonomy and beneficence in complicated scenarios highlights the necessity for neurosurgeons to comply with the highest professional standards, be fully informed, and be sufficiently trained to avoid or take paternalistic positions as appropriate.

Conversely, respect for the autonomous decision to forgo surgery may outweigh the beneficence conferred by the surgery when the neurosurgeon wants to pursue surgery. This may be the case when there is a minor expected benefit, high risk of poor outcome, and great uncertainty regarding outcomes between surgery or conservative management.

A surgeon may also decide to refuse to offer surgery to the patient, while the patient or the surrogate want an operation. In this instance, the neurosurgeon prioritizes non-maleficence over respect for autonomy. This results in the neurosurgeon not performing a surgery and opt for conservative management even when the patient or surrogate decision-maker do not agree. Ethical justification for this practice requires reasonable certainty regarding the outcome and thorough explanation to the patient or surrogate decision makers. An example is a family demanding decompressive surgery for an elderly patient with a severe traumatic brain injury with expected poor outcome. A neurosurgeon (or the family) may consult a colleague for a second opinion if the patient or surrogate continues to insist on an operation. Furthermore, the neurosurgeon should always try to pursue a treatment plan that respects the values and follows the wishes of the patient as closely as possible whilst ensuring an optimal outcome for the patient.

Emergency neurosurgery in an innovative or research setting

Respect for autonomy in an emergency situation becomes even more challenging when the procedure is innovative or takes place in a research setting. The uniqueness of an emergency case may pressure the neurosurgeon to perform the relatively unproven or innovative procedure. There is no standard within surgery regarding the extent to which a neurosurgeon should discuss the innovative nature of the procedure, the evidence or lack thereof; the associated risks and benefits, unforeseeable

or unknown risks given the experimental and non-validated nature of the procedure, the operating surgeon's learning curve considering his or her experience with the procedure, and alternative treatment options.^{7, 29} Furthermore, given that innovative approaches arguable confer a more extensive consent process, the relative lack of time or patient incompetence to make an autonomous decision may result in a relative lack of understanding and voluntariness.

Currently, operative innovation is not subject to any form of oversight or regulation and is treated as regular care, which may result in a relative lack of disclosure from the neurosurgeon or a form of oversight.^{13, 29} This allows the neurosurgeon to innovate when this is deemed necessary to ensure an optimal outcome for a unique patient. However, neurosurgeons should realize that patients that are not able to provide consent in an emergency procedure might have refrained from surgery if they had known it to be innovative. This, therefore, requires a more extensive description of the procedure by the neurosurgeon postoperatively and a disclosure that the procedure was in fact innovative. This should, however, not result in neurosurgeons refraining from innovating in an emergency scenario when necessary.

Innovation may also take place in a research setting which requires specific informed consent. Informed consent in a research setting procedure requires understanding from the patient but also a voluntariness from the patient who will be exposed to potential unexpected outcomes. In some scenarios, e.g. where the patient is comatose, this understanding and voluntariness may be completely absent, and a surrogate decision-maker has to decide on the patient's behalf. One could, therefore, argue that these patients are not suitable research subjects. On the other hand, outcomes of future patients may only be improved through formal research and there may be no other ways investigate certain treatments. The Rescue ICP and RESCUE-ASDH trials demonstrate that formal research in incompetent patients in an emergency setting can be done safely and ethically.^{16, 18, 20, 23} In England, a legal representative is allowed to provide consent for an incapacitated patient to participate in a trial.²² Patients seem to be a survey showed that the vast majority of the public would find it acceptable if a surrogate or their next of kin provided consent for a trial in an emergency setting.⁹

Ethical care for emergency patients

We argue that greater awareness of the meaning and importance of autonomy as well as open communication between the patient and neurosurgeon will ensure that these scenarios are handled ethically. Here we outline several steps may be taken by all parties involved to achieve this involved in emergency neurosurgical care to achieve this in order of applicability.

A mandatory post-operative notification could be an additive to an incomplete informed consent procedure for an emergent case. The patient should be made aware of what the procedure entailed and what the reason was for choosing a particular procedure. This should ideally take place when the patient has recovered to a state that could be considered competent to make an autonomous decision. The representatives or family could be informed earlier if the patient remains cognitively impaired or needs extensive recovery. This encourages open communication between the patient

or the patient's family and the neurosurgeon after the procedure. The neurosurgeon should also explain why the informed consent procedure was completely or partially waived. We believe it is a professional obligation of the neurosurgeon to defend the course of action and discuss potential disagreement with the patient. Currently, it is customary for the neurosurgeon to talk to the patient and the family after surgery, especially if little time was available beforehand. Guidelines could help in this scenario by suggesting what should be communicated at a minimum.

Specific training for obtaining optimal informed consent in an emergency setting and communication with patients in emergency scenarios and afterwards could be included in the neurosurgical (ethics) curriculum. This training could focus not only on what to communicate, but also on how to honestly reflect expected outcomes, and how to encourage patients (and proxies) to express their wishes and values relevant to the decision-making process.

In addition, to create awareness and encourage advance directives, (potential) patients could be notified that the informed consent process may be partially or completely waived in an emergency situation. This could take the form of a notification in the emergency room or a brochure.¹² This notification could also state that the course of action will be explained to the patient afterwards. Such a notification has been implemented by the National Health Services (NHS) in the UK.²¹ A downside to this approach is that patients may ignore this notification or that patients will only notice this notification when requiring emergency surgery. There may also be differences between different hospitals, language barriers, and an impossibility to reach all patients such as comatose patients. However, we believe that greater awareness among patients may stimulate them to discuss values and wishes with family and other potential surrogate decision-makers or even provide advance directives. This could result in patients that are more involved in the decision-making process in advance and fasten the decision-making process in possible future emergency scenarios as a result. This knowledge of wishes and values of the patient could improve respect for autonomy in future emergency scenarios.

On a policy level, surgical societies could engage with patient advocates and hospitals to come up with guidelines, statements, or a form of oversight for emergency surgery. These guidelines could reflect the difficulties that may arise and how these may be handled by neurosurgeons. These guidelines could also require neurosurgeons to be trained how to communicate in emergency situations. Communication outside an emergency setting between all parties involved could ensure a more ethical handling of emergency neurosurgery and respect for patient's autonomy. We believe that these policies could improve awareness among patients and could increase the trust patients place in neurosurgeons when they seek emergency care.

Conclusion

Emergency neurosurgery challenges the respect of autonomy of the patient. The emergent nature compromises the respect for autonomy due to a lack of time, especially if the patient lacks capacity to make an autonomous decision. The neurosurgeon needs to possess robust knowledge of the inherent risks and benefits of various emergency scenarios, excellent communication skills to balance the time allotted and

informed consent, and prowess to ethically handle disagreement. The situation may be improved by a post-operative notification, specific training of the neurosurgical team, and greater awareness among patients.

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