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

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General discussion

The various parts of this thesis show that innovation in neurosurgery generally does not occur systematically and often only becomes apparent in hindsight. This lack of systematic innovation is unethical as patients face unjustifiable risks due to a lack of informed consent, outcome evaluation, and oversight. These unjustifiable risks highlight the need for a more systematic approach to neurosurgical innovation that has the interests of patients close at heart. This approach should involve methodologically sound research, evaluation of outcomes, informed patients, and adequate oversight. Some have proposed frameworks such as the Idea, Development, Exploration, Assessment, Long-term study (IDEAL)[8] Framework and learning health systems (LHS)[1] that aim to provide guidance in innovative surgery and encourage learning from every patient, respectively. Still, these frameworks are not adjusted to neurosurgery, introduce new ethical concerns, and require tremendous efforts to realize. Here, a system is proposed that aims to ethically improve neurosurgical innovation. This system is based on the IDEAL Framework[8] and LHS[1] and envisions the collection of large-scale, high-quality data, methodologically sound research, and proper valuation of systematic ethical neurosurgical innovation.

Data collection

Currently, high-quality data is only obtainable through expensive studies, such as RCTs and prospective cohort studies. Although these studies may provide valuable answers for neurosurgeons, many answers still come with several limitations. These issues may be related to inclusion criteria, treatment variation, and a lack of follow-up. Improved data collection may be beneficial by providing more granular data based on a greater variety of patients followed for longer periods.

One possibility may be the automatic collection of prospective high-quality data on patients through the modification of current electronic medical record (EMR) systems. The EMR systems that neurosurgeons currently use are primarily designed for monitoring the medical status of a patient (in written form), billing, and providing legal security, but, critically, not research.[4,7,10] An EMR system that also provides well-sorted data on patients and outcomes will be more convenient to analyze. Neurosurgeons can also use these newly generated data to compare outcomes in different clinical settings and interventions. Large-scale systematic data collection will also allow neurosurgeons to obtain more data from patients suffering from diseases that require neurosurgical intervention, especially when the disease is rare. For instance, well-sorted data on cognitive outcomes of subarachnoid hemorrhage patients treated with novel medical devices may provide key insights regarding effectiveness, practice variation, and long-term outcomes. Such a system currently does not exist and will require tremendous efforts to construct and maintain. There are currently no incentives or demands for such a system to be created. Ideally, these EMR systems would be introduced on a national level to increase the availability of data further. Such an EMR system will aid research on neurosurgical patients as most treated diseases are rare and hard to study on a large scale. Parts of the data gathered may also be shared with researchers outside the healthcare system in a de-identified manner, perhaps similar to the UK Biobank[3], to increase the amount and quality of publicly available data. These data sets will also be crucial to train artificial intelligence (AI) algorithms, perform large-scale (genetic) research, and study the effects of practice variations, among many other topics.

All relevant parties need to be involved to introduce an EMR with these capabilities effectively and aware of ethical challenges that may arise. Ethical issues may, for instance, arise due to compromised patient autonomy, compromised privacy, and vulnerable patient populations. These challenges may be comparable to challenges that come with an LHS which is why the framework suggested by Faden et al. may offer solutions through obligations for all parties involved.[5] Every patient needs to be adequately informed about the data that will be collected and provide consent for how much data is collected, the duration of data storage, and the use of the data to uphold the ethical obligation to respect the rights and dignities of patients. This consent process should be a simple and straightforward procedure to make it easy for well-informed patients to join. The neurosurgical community needs to actively encourage patients to participate and educate them on what active participation entails and how this will help neurosurgeons improve future care. Naturally, patients have the right to decline participation but also have the ethical obligation to "contribute to the common purpose of improving the quality and value of clinical care and health care systems".[5] Still, even marginal changes in the number of participating patients can significantly improve the amount of available data on a national scale. The creation of an EMR with such capabilities also introduces privacy-related ethical risks due to the potential of data theft. The neurosurgical community has the obligation to avoid posing non-clinical risks and burdens on patients. All parties involved, therefore, need to put all possible security measures in place to prevent sensitive data from reaching external parties. Data that are automatically collected for innovation when neurosurgical patients are vulnerable (e.g., incapacitated patients due to neurotrauma) need to be carefully stored and removed when asked by the patient at a later timepoint. Neurosurgeons should also make sure that otherwise vulnerable patient populations, such as ethnic minorities, understand the implications of an EMR with the aforementioned capabilities.

An EMR with enhanced research capabilities that is implemented whilst all parties accept their respective obligations will enable the neurosurgical community to fulfill its ethical obligation to provide optimal care that is based on continuous learning to each patient.

Research quality

Research that follows the highest ethical and methodological standards will provide more clinically relevant answers. Neurosurgeons could improve the quality of the research in neurosurgery in several ways.

First, education on ethically and methodologically sound research should be a core part of neurosurgical training programs. Second, studies that follow the highest possible standards will ensure relevant answers based on fair comparisons that allow for adequate appraisal. Standardization and registration of protocols, trials, and publications will help achieve these goals. All parties involved should avoid an unacceptable increase in bureaucracy and should be on board when increasing regulation through registration.

Third, the neurosurgical community could also be thought about the value of soft skills to improve ethical research (e.g., communication, conflict resolution, and creative thinking). Although many of these soft skills are being taught during residency and are applied by neurosurgeons every day, a greater focus and more dedicated training could further improve innovative neurosurgical care. Developed soft skills will enhance teamwork, patient communication, disclosure of COIs, and teaching skills, which are an absolute necessity for ethical innovation in neurosurgery. These practice improvements and abilities will ensure continued respect for patient autonomy and patient involvement.

The neurosurgical community also needs to allocate adequate resources, setup dedicated innovation teams, and collaborate with other innovation teams and people with different expertise (epidemiology, AI, imaging, among others). Patients should also be made part of innovations teams and may come up with initiatives. External parties such as governmental organizations and health insurers may also be involved to gain more support and provide valuable input on achievability, funding strategies, and scalability. External recognition (e.g., through rankings), increased compensation, and greater appreciation by patients may stimulate neurosurgical teams to conduct ethically and methodologically sound research and thereby accelerate meaningful innovation.

Valuation of innovation

Traditionally, value in health care is defined as outcomes relative to their cost.[9] Innovation that is conducted and implemented ethically and effectively may result in more value than the current standard of care. The amount of created additional value over the current standard of care can be used as a metric to evaluate the quality, quantity, efficacy, and efficiency of neurosurgical innovation. The IDEAL collaboration regards innovative techniques and devices that differ from the gold standard because they are altogether new, are applied to a new anatomical location, or are applied to a new patient group as a surgical innovation.[6] Innovation in neurosurgical care that does not meet this definition can still result in value creation for patients through for instance quality improvement and comparative effectiveness research. For instance, waste reduction in the neurosurgical operation room can create value by cost reduction.[2] Therefore, the following definition of neurosurgical care innovation is proposed: *The creation of more value than the current (gold) standard of neurosurgical care*. The amount of created value will depend on the magnitude and the scale of the innovation. The potential to create substantial additional amounts of value over the current standard may stimulate neurosurgical departments to learn from every patient. Even a minor innovation may result in a small yet meaningful amount value when implemented at scale. This will allow all parties of all sizes to conduct neurosurgical care innovation and create value.

Ethical neurosurgical care innovation will require adequate evaluation, reporting, implementation, oversight, and financial compensation. Neurosurgical innovation teams, improved education of the neurosurgical community, and aforementioned EMR could ensure adequate evaluation, reporting, and implementation of neurosurgical care innovations. The created value needs to be carefully evaluated and reported on to avoid pseudo value creation. The measurement of created additional value will be challenging and will depend on the magnitude and scale of the innovation. Outcomes may be measured in for instance survival, complication rates, readmission rates, Quality-Adjusted Life Years (QALYs), and Disability-Adjusted Life Years (DALYs) in relation to their respective costs. It will be hard to determine the ideal metric for each innovation. It will require an external party formed by neurosurgeons, patients, and hospital managers, among others, that determines which metric(s) are appropriate. This external party can also determine whether the innovation has genuinely resulted in additional value over current care. This external party could also be made responsible for providing adequate oversight, the amount of which should be determined by the magnitude of the anticipated ethical risk that comes with the innovation. Guidelines on methodological standards put forward by the external party could help innovation teams meet these standard during the innovation process.

The creation of value through ethical neurosurgical care innovation must be adequately financially compensated to provide incentives to all parties involved. Hospitals and neurosurgical departments should be paid for value creation as well as for sharing the innovation as an innovation that results in value creation should never be monopolized. Alongside grant mechanisms, a certain amount of created value should result in a predefined amount of financial reimbursement. The compensation needs to be substantial to motivate all parties involved. Patient advocacy groups, neurosurgical societies, the governmental agencies, and health care insurers could provide necessary funds and may prioritize specific patient populations, determine relevant value metrics, and select particular procedures. This compensation mechanism will result in a more focused and productive innovation that all parties support as well as an additional revenue source for neurosurgical departments. This new form of reimbursement requires adequate oversight to make sure that risks patients are limited, will result in both improvement of care and cost reduction, and ensures that generated knowledge is actively shared. This new reimbursement system may also provide an alternative to traditional forms of competition in innovation and thereby stimulate innovation. This competition, however, should never compromise outcomes for patients and should be a continuous focus of oversight. Naturally, not all attempts at neurosurgical care innovation will result in increased value and compensation. A minimum amount of compensation could be made available to innovation groups that adhere to the highest ethical standards but fail to create additional value to avoid pseudo value creation and stimulate unbiased analysis and reporting of results.

Ethical neurosurgical care innovation as described above is an innovation itself as it is a deviation from the current manner of neurosurgical care improvement. The introduction of ethical neurosurgical care innovation, therefore, needs to be carefully planned, systematically introduced, continuously evaluated, and adjusted where necessary. The probability of success of ethical neurosurgical care innovation depends on dedication and motivation from all parties involved, sufficient funding, and the willingness of patients to participate. Improved education, a greater focus on soft skills, improved collaboration, and efficient communications may further increase the probability of improved patients outcomes through ethical neurosurgical care innovation.

In conclusion, ethical neurosurgical care innovation may increase and accelerate value creation over the current standard of care in neurosurgery. Ethical neurosurgical care innovation needs to be carefully introduced, financial compensated, guided by external parties, and subjected to adequate oversight. This will, hopefully, improve outcomes for neurosurgical patients in the most efficient manner.

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