



Universiteit
Leiden
The Netherlands

Defining innovation in neurosurgery: results from an international survey

Zaki, M.M.; Cote, D.J.; Muskens, I.S.; Smith, T.R.; Broekman, M.L.

Citation

Zaki, M. M., Cote, D. J., Muskens, I. S., Smith, T. R., & Broekman, M. L. (2018). Defining innovation in neurosurgery: results from an international survey. *World Neurosurgery*, 114, E1038-E1048. doi:10.1016/j.wneu.2018.03.142

Version: Publisher's Version

License: [Licensed under Article 25fa Copyright Act/Law \(Amendment Taverne\)](#)

Downloaded from: <https://hdl.handle.net/1887/4303129>

Note: To cite this publication please use the final published version (if applicable).



Defining Innovation in Neurosurgery: Results from an International Survey

Mark M. Zaki¹, David J. Cote¹, Ivo S. Muskens², Timothy R. Smith¹, Marike L. Broekman²

■ BACKGROUND: Innovation is a part of the daily practice of neurosurgery. However, a clear definition of what constitutes innovation is lacking and opinions vary from continent to continent, from hospital to hospital, and from surgeon to surgeon.

■ METHODS: In this study, we distributed an online survey to neurosurgeons from multiple countries to investigate what neurosurgeons consider innovative, by gathering opinions on several hypothetical cases. The anonymous survey consisted of 52 questions and took approximately 10 minutes to complete.

■ RESULTS: A total of 355 neurosurgeons across all continents excluding Antarctica completed the survey. Neurosurgeons achieved consensus (>75%) in considering specific cases to be innovative, including laser resection of meningioma, focused ultrasonography for tumor, oncolytic virus, deep brain stimulation for addiction, and photodynamic therapy for tumor. Although the new dura substitute case was not considered innovative, there was consensus among neurosurgeons indicating that institutional review board approval was still necessary to maintain ethical standards. Furthermore, although 90% of neurosurgeons considered an oncolytic virus for glioblastoma multiforme to be innovative, only 78% believed that institutional review board approval was necessary before treatment.

■ CONCLUSIONS: Our results indicate that innovation is a heterogeneous concept among neurosurgeons that necessitates standardization to ensure appropriate patient safety without stifling progress. We discuss both the ethical drawbacks of not having a clear definition of innovation

and the challenges in achieving a unified understanding of innovation in neurosurgery and offer suggestions for uniting the field.

INTRODUCTION

Innovation is at the heart of neurosurgery. In a continually evolving field, neurosurgeons must constantly assess and reassess the most appropriate and effective treatments for each patient. Innovation is conducted by neurosurgeons investigating novel treatments for brain tumors in major academic institutions, as well as those performing creative surgeries in low-resource settings across the world.^{1,2} Yet, something so ubiquitous among neurosurgeons remains difficult to define with consensus. Great heterogeneity exists in what surgeons consider innovative.^{3,4} Various interpretations of what constitutes innovation lead to a lack of standardization of assessing innovation across surgeons, departments, institutions, and nations. In addition, proof of the innovative nature of a project is often a key component of securing grant funding; therefore, efforts to standardize what should be considered innovative could be beneficial to funding agencies.

Attempts to standardize the definition of innovation have been made. The Society of University Surgeons has proposed discerning between variations, innovations, and research.⁵ Some have suggested splitting innovations by type, such as minor modifications of standard procedures, major modifications of standard procedures, and innovations that are new to the institution but have been validated elsewhere.⁶ Others have suggested a rating of surgical innovations directly related to the amount of oversight deemed necessary.⁷ Despite these attempts, along with many other suggestions for appropriate oversight in surgery,⁸⁻¹⁶ a clear answer does not exist.

Key words

- Ethics
- Innovation
- International
- Neurosurgery
- Survey

Abbreviations and Acronyms

IRB: Institutional review board

MSIIT: Macquarie Surgical Innovation Identification Checklist

SIC: Surgical innovation committee

From the ¹Cushing Neurosurgery Outcomes Center, Department of Neurosurgery, Brigham and Women's Hospital, Harvard Medical School, Boston, Massachusetts, USA; and ²Department of Neurosurgery, University Medical Center, Utrecht, The Netherlands

To whom correspondence should be addressed: Marike L. Broekman, M.D., Ph.D., J.D.
[E-mail: M.L.D.Broekman-4@umcutrecht.nl]

Citation: *World Neurosurg.* (2018) 114:e1038-e1048.
<https://doi.org/10.1016/j.wneu.2018.03.142>

Journal homepage: www.WORLDNEUROSURGERY.org

Available online: www.sciencedirect.com

1878-8750/\$ - see front matter © 2018 Elsevier Inc. All rights reserved.

Lack of consistency in the general surgical literature warrants an investigation of what neurosurgeons themselves consider innovative. To this point, the definition of innovation has yet to be evaluated specifically among neurosurgeons. Using a survey consisting of hypothetical cases, the aim of this study is to describe what neurosurgeons consider innovative. There is also discussion of how the definition of innovation affects aspects of patient care, influences appropriate oversight, and promotes effective collaboration in neurosurgery.

METHODS

Survey Development

An online survey was developed to identify trends in the opinions of neurosurgeons on the definition of innovation. The anonymous survey consisted of 52 questions and took approximately 10 minutes to complete. Respondents could exit the survey at any point.

Demographic data were collected from each respondent, including sex, annual case volume, lifetime case volume, years of experience, type of practice, subspecialty, group size, and continent of practice.

Eleven hypothetical cases were written highlighting past and contemporary advances in neurosurgical instrumentation, methodology, or both. For each case, respondents were asked to select their opinion via Likert scale assessment (strongly disagree, disagree, neither disagree nor agree, agree, or strongly agree) on the following statements: 1) This case is an example of innovation in neurosurgery; 2) By not having obtained some sort of approval from the institutional review board or an innovation committee for this case, the neurosurgeon violated ethical standard in this case; 3) Advancing the field of neurosurgery was valued more than individual patient care. Respondents were asked what type of innovation they considered each case: none, minor modification of a standard procedure, major modification of a standard

Table 1. Case Descriptions

Case Number	Topic	Description
1	Dura substitute	A patient undergoes a craniotomy for a convexity meningioma. When closing, the neurosurgeon uses a dura substitute that has never been used in patients, and the only safety and efficacy data available are from animal studies
2	Supramaximal resection	A patient with recurrent high-grade glioma presents for surgery. The surgeon uses a supramaximal technique for resection, removing all of the contrast-enhancing tissue as well as some surrounding tissue, with the hope of delaying or preventing recurrence or tumor progression
3	New vascular balloon device	A patient presents with carotid stenosis and a family history of stroke. Instead of undergoing a carotid endarterectomy, the patient is treated with balloon angioplasty. This is the first time this device will be used in patients
4	Endoscopic third ventriculostomy	A patient requires endoscopic third ventriculostomy. During the case, the surgeon employs the use of a new catheter to create the opening in the floor of the third ventricle. This catheter has been used for other indications
5	Laser resection of meningioma	A surgically-accessible meningioma is resected using a thulium laser instead of traditional resection. The laser has been used for other indications in humans, however not for this purpose
6	Focused ultrasonography	A patient presents with a skull-base meningioma. Rather than attempting traditional resection, the surgeon employs focused ultrasonography therapy
7	Virus for GBM	A patient with glioblastoma multiforme (GBM) undergoes surgical resection. Following resection, the tumor cavity is injected with modified adenovirus in an attempt to stimulate the host immune system against any remaining GBM cells
8	DBS for addiction	A patient with a 10-year history of opioid addiction presents for therapy. The surgeon decides to use DBS to stimulate the nucleus accumbens, in the hope of alleviating the patient's addiction
9	New pedicle screws	A patient requires lumbar laminectomy and fusion. The surgeon uses new pedicle screws that are claimed to reduce post-operative pain
10	Photodynamic therapy	A patient presents with an irresectable malignant glioma. A biopsy using 5-ALA is performed. Upon biopsy, the surgeon leaves a light source in place for a few days with the aim to kill remaining tumor cells
11	New high-speed drill	A patient requires a transsphenoidal approach for resection of a pituitary adenoma. During the opening of the sella, the surgeon uses a new drill whose manufacturers claim it reduces the risk of lesioning the surrounding structures

GBM, glioblastoma multiforme; DBS, deep brain stimulation; 5-ALA, 5-aminolevulinic acid.

Table 2. Respondent Demographics and Practice Characteristics

	%
Sex	
Male	85
Female	15
Annual volume	
<50	6
51–100	14
101–200	26
201–300	28
301–400	11
401–500	5
>500	10
Lifetime volume	
<500	11
501–1000	15
1001–2000	20
2001–3000	13
3001–4000	10
4001–5000	10
5001–10,000	14
>10,000	8
Experience	
In residency	22
<5 years out	26
6–10 years out	18
11–20 years out	19
21–30 years out	9
>30 years out	7
Practice type	
Academic	68
Private practice	12
Neither	20
Specialty	
Pediatrics	6
Functional	3
Cerebrovascular	12
Tumor	22
Spine	17
Trauma	3
General (none)	38
Continues	

Table 2. Continued

	%
Practice size	
1 or 2 neurosurgeons	11
3–5 neurosurgeons	21
6–10 neurosurgeons	35
11–15 neurosurgeons	19
>15 neurosurgeons	14
Continent	
North America	4
South America	2
Europe	75
Africa	7
Asia	12
Australia	0.3

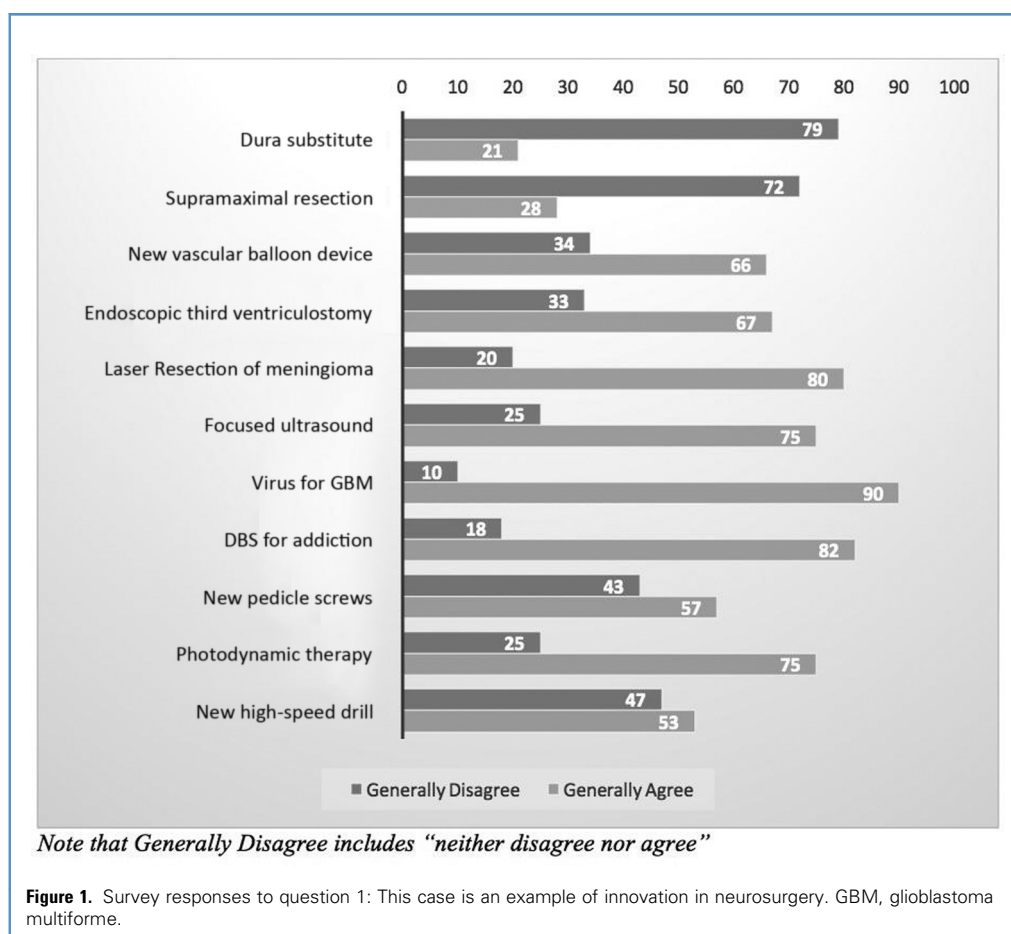
procedure, or a radical innovation. Likert scales, rather than open-ended answers, were chosen to help foster a sense of consensus among a heterogeneous population. The 11 cases were chosen based on themes identified in recent neurosurgical literature, including technical and technological advances that were considered by the authors to include relatively minor to more radical advancements. These cases are listed in [Table 1](#).

Survey Distribution

The survey was sent to members of the Committee on Ethics and Legal Affairs of the World Federation of Neurosurgical Societies and the Ethico-Legal Committee of the European Association of Neurosurgical Societies. Members were encouraged to distribute the survey within the departments of their respective home institutions. The survey was subsequently distributed to all individual members of the European Association of Neurosurgical Societies. Most responses were collected in the first week of distribution. A reminder was sent at 2 weeks after initial distribution. After several days without incoming responses, the survey was then closed. Responses were collected from November 21, 2016 to December 30, 2016.

Data Analysis

Survey data were collected and analyzed in SPSS version 22 (IBM Corp., Armonk, New York, USA). Nominal variables, including basic respondent demographics and Likert scale responses, were summarized using counts and percentages. Subsequent dichotomization of Likert scale responses was performed, such that 1 category ranged from strongly disagree to neither disagree nor agree and another category included agree to strongly agree. In determining whether there was consensus of opinion, an a priori set value of $\geq 75\%$ of respondents falling in either category was used as a cutoff for all questions in this study.



RESULTS

Respondent Demographics

A total of 355 of approximately 1500 neurosurgeons (~23.7%) completed the survey, an expected response rate for this kind of questionnaire¹⁷; 85% were male, with respondents from all continents excluding Antarctica. Demographics and practice characteristics are summarized in [Table 2](#). No significant demographic variables (including sex, annual or lifetime volume, experience, practice type, subspecialty, practice size, or continent of origin) were determined to influence how participants responded to the following questions (data not shown).

Question 1: This Case is an Example of Innovation in Neurosurgery

Initial Likert scale responses to question 1 and subsequent dichotomization are shown in [Supplementary Table 1](#) and [Figure 1](#), respectively. Cases 5, 6, 7, 8, and 10 were considered more innovative by neurosurgeons ($\geq 75\%$ indicated agree or strongly agree). These cases corresponded to laser resection of a meningioma, focused ultrasonography for meningioma, viral injection into a tumor cavity, deep brain stimulation treatment for addiction, and photodynamic therapy for an irresectable glioma, respectively. Conversely, case 1 was rarely considered

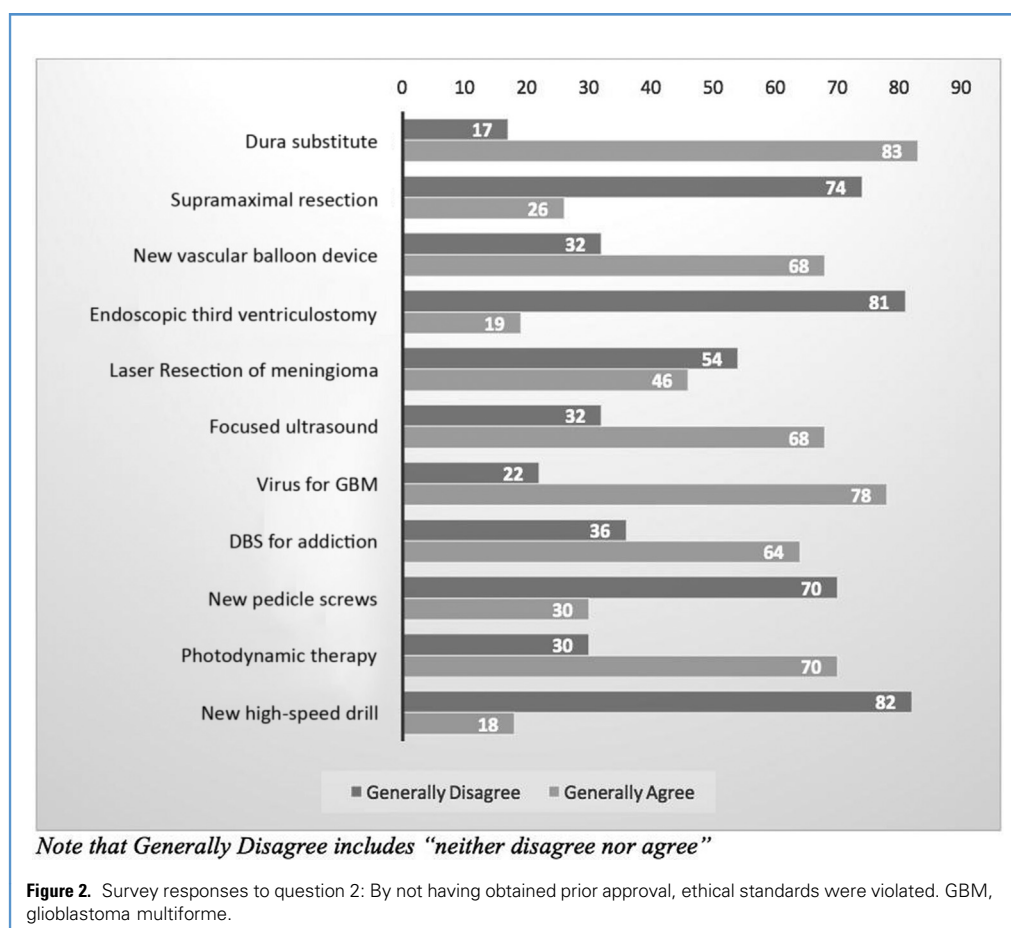
innovative ($\leq 25\%$ indicated agree or strongly agree). This case corresponded to the dura substitute.

Question 2: By Not Having Obtained Prior Approval, Ethical Standards Were Violated

Likert scale responses to question 2 are shown in [Supplementary Table 2](#). Neurosurgeons generally responded that the virus for glioblastoma multiforme in case 7 violated ethical standards without previous approval from an institutional review board (IRB) or innovation committee. Although the dura substitute in case 1 was not considered innovative ([Supplementary Table 1](#), [Figure 1](#)), most neurosurgeons believed that ethical standards were violated by not seeking prior approval from the IRB or an innovation committee ([Supplementary Table 2](#), [Figure 2](#)). Neurosurgeons predominantly ($\geq 75\%$) did not believe that any ethical standards were breached in the endoscopic third ventriculostomy in case 4 or using the new high-speed drill in case 11.

Question 3: Advancing the Field of Neurosurgery Was Valued More Than Individual Patient Care

The survey responses for question 3 are presented in [Supplementary Table 3](#) and [Figure 3](#). Neurosurgeons showed a



consensus ($\geq 75\%$) that advancing neurosurgery was not valued more than individual patient care in cases 4, 9, and 11, but these were just over the set threshold of 75%. These cases were the endoscopic third ventriculostomy, laser resection of meningioma, and the new high-speed drill, respectively. Before dichotomization, neither disagree nor agree was a common (20%–30%) answer for almost every case.

Question 4: What Type of Innovation Is This?

The results for question 4 are presented in [Supplementary Table 4](#) and [Figure 4](#). Considering consensus at 75%, cases 1, 2, 4, 9, and 11 were generally considered less innovative, whereas case 7 was generally considered more innovative. Cases 3, 5, 6, 8, and 10 showed less consensus.

DISCUSSION

These findings indicate that, similar to other fields of surgery,^{18–20} neurosurgery lacks a clear consensus about what constitutes innovation. The varied responses shown here are likely a reflection of the complexity and lack of consensus in defining innovation and determining appropriate oversight for innovative procedures. For example, only 10% of respondents did not consider an oncolytic virus to be innovative, yet more than double this number

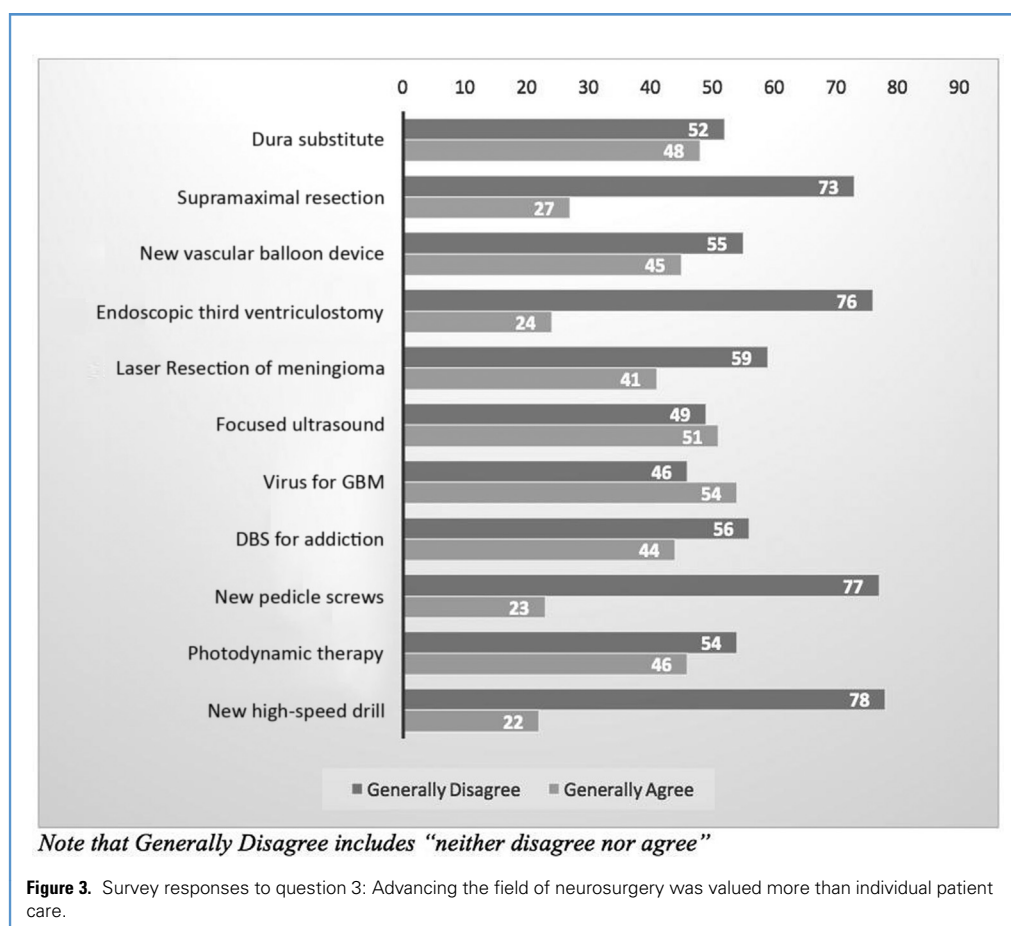
at 22% of respondents did not believe an IRB or equivalent was necessary. Because this scenario is still considered experimental therapy, our findings may indicate a lack of consistency in educating neurosurgeons on ethical standards in investigative research across the globe.

The absence of finding demographic variables that significantly predicted responses could be influenced by insufficient power in this study. Nevertheless, having an unclear definition poses serious ethical and practical issues that warrant further discussion.

The Need for Standardizing a Definition

Ethically, physicians are called to do no harm. Rapid application before proper evaluation has historically led to compromising patient safety; for example, the ubiquitous use of frontal lobotomy before it was properly evaluated led to numerous undesired consequences.²¹ Being able to a priori define what constitutes innovation would thus ensure appropriate evaluation of patient safety and ethical care before implementing an innovation into practice.

Often, the person introducing the innovation is the surgeon using the novel technique or device. In scenarios in which the surgeon is the one who strongly believes in the promise of the innovation, innovator bias may prevent the surgeon from thoroughly evaluating



the potential harms associated with the new intervention.²² Such lack of perceived clinical equipoise, as well as other personal conflicts of interests, are therefore just as important to be aware of as financial conflicts of interests.²³ Nonbiased evaluation may help to limit the effect of such conflicts of interest in cases in which a new idea is clearly defined as an innovation.

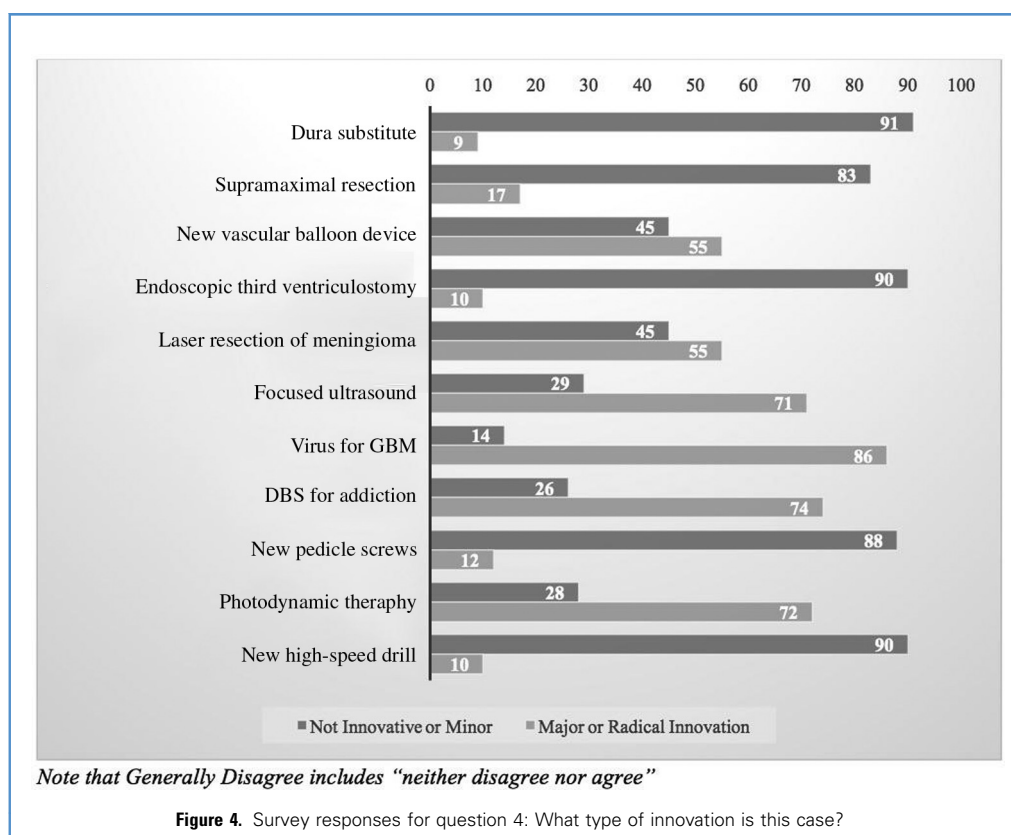
Furthermore, the principle of patient autonomy is contingent on informed consent,²⁴ and it is controversial whether or not the consent patients provide in new surgeries is truly informed.²⁵ A key component of informed consent is that the relevant risks and benefits are disclosed to the patient, as well as the details of the procedure itself. If an innovation is being implemented, in which the risks are unknown, the patient may not be truly informed to offer appropriate consent.²⁶ Even if certain patients tend to put full trust in their surgeon without knowing all the details of the procedure,²⁷ it is important that all relevant information be available to the patient and the surgeon to make an informed decision plan. Again, knowing when to critically evaluate a novel innovation and when to simply use a new type of suture depends on how innovation is defined.

The principle of justice can also be explored, both regarding overenrolling vulnerable patient populations as well as underenrolling patients from disadvantaged backgrounds. Because severely ill neurosurgical patients may not have the cognitive

ability to adjudicate risks and benefits, as well as having a strong emotional drive to attempt any option feasible, these patients are susceptible to being easily persuaded into a novel treatment.²⁸ Regarding underaccess, minority and low-income neuro-oncology patients have worse access to surgical care than do white patients or those who have higher incomes, respectively.²⁹ Because many innovations tend to be costly, low-income patients may not be able to access the latest and potentially most effective treatments.³⁰ Conversely, dangerous innovations may be forced on to minority populations, as has occurred in Tuskegee.³¹ Without a proper framework of innovation or appropriate oversight, these injustices are prone to exacerbation. Potentially compromising these core ethical principles thus necessitates a standard definition of innovation to promote ethical and practical patient safety.

The Difficulty in Defining Innovation in Neurosurgery

Innovations are not unique to neurosurgery. They occur in numerous medical specialties as well as in every industry outside medicine. In the business literature, innovations can broadly be categorized into sustaining and disruptive innovations.³² Sustaining innovations improve an existing product and maintain the incumbent firm. One example can be the latest version of an existing smartphone. Disruptive innovations



introduce a new firm that radically disturbs an existing industry, such as the effect of Uber on the taxi industry.³³ Businesses can predict the type of innovation something will be, because they use consumer reports and market predictions to guide the development and marketing of their products. However, surgery is not driven primarily by consumer requests and other market forces. It is guided by surgeon preference, patient outcomes, and peer review.³⁴

In addition to differences between business and medicine, innovation in surgery specifically varies from other fields of medicine.²⁷ Medical innovations, such as devices or new drugs, undergo a rigorous and thorough evaluation before they are approved for the clinical market. Once they are introduced, these innovations are believed to be safe and effective in achieving the desired effect. Thus, there is a clear border between research and clinical care in medicine. Surgery is more complicated. Because the U.S. Food and Drug Administration or an equivalent organization does not typically review the safety and efficacy of new surgical procedures,³⁵ research and clinical care are not mutually exclusive in surgical hypothesis testing. Surgical innovation in both the research and the clinical paradigm may contain untested novel ideas,⁷ but innovation in research is aimed at generating generalizable knowledge,^{36,37} whereas innovation in clinical care is aimed at improving the outcome of the individual patient.³⁶ When new surgical procedures are implemented in patients, generating universal knowledge thus coincides with the aim of ameliorating the

suffering of the individual patient. Such overlap, along with the lack of oversight, have obfuscated a clear definition of innovation in the surgical field.

One recent attempt to quantify innovation in neurosurgery was accomplished by measuring the number of neurosurgical patents between 1960 and 2010.³⁸ One limitation of this approach is that it may severely underestimate the extent of innovation in neurosurgery by focusing only on patents, most of which relate to solely technological innovations without including technical innovations or off-label use of existing patent technology.³⁹ Off-label use in particular helps delineate what may be considered innovative from what is considered research. For example, innovation can occur without an IRB or ethical board review when a clear and documented discussion between the physician and patient leads to informed consent of off-label use. Varying legislature allows these practices to occur in certain countries, and only when this off-label use is retrospectively analyzed and presented is it considered research. Another difficulty in defining innovation is its temporal nature. When a new procedure or technology is introduced, its novelty can only diminish. This progression is not linear but rather goes through branching phases, from initially being studied to community-wide acceptance and subsequent refinement (a process termed progressive scholarly acceptance).⁴⁰

Lack of Definition: Implications for Oversight

As indicated, these results show that neurosurgeons do not agree on what constitutes innovation, and achieving a definition would

allow appropriate regulation. Some fear that oversight may stifle innovation and the continual advancement of surgery⁴¹; however, appropriate oversight that balances patient safety and the surgeon's autonomy is the goal. Many proposals have been suggested for achieving appropriate oversight in cases in which deviations from the norm take place, whether they be technical or technological deviations. We have previously reviewed⁶ the proposals for various types of innovations, including those that suggest national regulation for major modifications or radical innovations⁴² as well as those that suggest an institutional surgical innovation committee (SIC).^{22,43,44}

The first step in determining appropriate oversight for an innovative surgery is to determine which operations require an evaluation. On one extreme, every operation may be considered a deviation from the norm as surgeons tailor their operations to the uniqueness of each presentation.³⁴ However, it would be impractical and inefficient to evaluate every deviation from the norm. The Macquarie Surgical Innovation Identification Checklist (MSIIT) has been introduced as a simple checklist that is being tested in its ability to identify when a procedure qualifies as innovative.⁴⁵ It suggests that scenarios in which the techniques, instruments, and/or devices used are new to the hospital or new to the surgeon should acquire further information regarding necessary training, patient communication, and an evaluation of past use of the novelty elsewhere. If a technique, instrument, and/or device is being used for a new indication, in a sex or age in which such differences or comorbidities are relevant, the MSIIT suggests that further information should be acquired regarding potential consequences of the innovation, whether such outcomes are reportable, and whether special preparations should be put in place to accommodate the innovation. The value of the MSIIT is not that it seeks to create stringent criteria for what constitutes innovation but rather that it aims to identify which surgical procedures warrant further information and oversight when necessary. Another noteworthy endeavor is the IDEAL (Idea, Development, Exploration, Assessment, Long-term follow-up) collaboration,⁴⁶ which seeks to discuss appropriate oversight at all stages of innovation. It includes suggestions such as a negative database of failed ideas, mandating detailed technical descriptions of novel approaches, exploring the learning curve of innovations, expanding and assessing the innovation in multicenter trials, and monitoring long-term outcomes. Recent review of 2 neurosurgical procedures, namely the endoscopic endonasal approach for skull-base meningiomas and the WovenEndobridge for endovascular treatment of intracranial aneurysm, suggest that the process of innovation does not follow the path outlined in the IDEAL framework,⁴⁷ emphasizing the need for more appropriate oversight.

After identifying which procedures warrant further oversight, the regulation that is deemed appropriate could be determined by an SIC. An SIC may comprise experienced surgeons, ethicists, engineers, and other relevant stakeholders. When a new technique or device is being introduced, the SIC can critically evaluate the scientific validity of the proposal, ensure that the patient is truly informed about all known risks and the novelty of the procedure,

and confirm that the necessary adaptations to the novel procedure are made available to the surgeon. When an innovation has been proved effective, there will be a learning curve that must be overcome before other colleagues are able to effectively incorporate it into common practice.^{48,49} SICs can serve as facilitators that connect experienced surgeons with similar ideas and experiences to foster educational dialogue between colleagues.

Overall, surgical innovation is a ubiquitous phenomenon that remains poorly defined. Without a proper definition, patient safety and ethical care are at risk. Despite the difficulties in producing an exact definition of surgical innovation, programs that facilitate critical feedback and opportunities for experienced surgeons to share their knowledge⁵⁰ would promote an environment conducive to collaborative learning and appropriate patient safety.

Strengths and Limitations

This is the first survey of its kind to acquire the opinions of hundreds of neurosurgeons from numerous continents. It shows that neurosurgery, like many other fields of surgery, does not have a universal definition of innovation. In this article, the ethical and practical concerns associated with not having a unified definition are discussed and suggestions are offered to overcome barriers in place.

Although these results were created based on response from 355 respondents, 75% of the respondents are based in Europe. Further surveys should involve larger numbers of respondents from other continents to determine if opinions vary based on respective continental and national regulations. In addition, 68% of respondents are from academic institutions and thus may have underlying user bias in assessing what constitutes innovation. Another limitation is that first-hand experience with innovation was not directly inquired about in the respondent demographics, which may have also showed bias in the responses. Furthermore, the cases present a limited spectrum of innovation because these cases can be considered possible extensions of current surgical practices rather than genuinely novel approaches or treatments. Although this study discusses the necessity for a unified definition of innovation in neurosurgery, it does not present a clear-cut algorithm that can be applied to determine if a new idea qualifies a surgical innovation. Further studies could elicit possible definitions from neurosurgeons first-hand, how common innovation is seen in their respective practices, and the factors involved in surgeons deciding to adopt innovative practices.

CONCLUSIONS

This study indicates that neurosurgeons lack a clear definition of innovation. This lack of consensus poses practical and ethical concerns relevant to appropriate oversight of innovative procedures. Surgeons should actively seek critical feedback on new ideas from peers and relevant stakeholders in a collaborative environment. In the future, appropriate steps should be taken to define innovation in neurosurgery so that neurosurgeons can use innovation to advance neurosurgery without the risk of compromising patient safety.

REFERENCES

- Ravindra VM, Kraus KL, Riva-Cambrin JK, Kestle JR. The need for cost-effective neurosurgical innovation—A Global Surgery Initiative. *World Neurosurg.* 2015;84:1458-1461.
- Bean JR. Neurosurgical innovation in the developing world: where will it come from? *World Neurosurg.* 2015;84:1522-1524.
- Rogers WA, Lotz M, Hutchison K, Pourmoslemi A, Evers A. Identifying surgical innovation: a qualitative study of surgeons' views. *Ann Surg.* 2014;259:273-278.
- Reitsma AM, Moreno JD. Ethics of innovative surgery: US surgeons' definitions, knowledge, and attitudes. *J Am Coll Surg.* 2005;200:103-110.
- Biffi WL, Spain DA, Reitsma AM, Minter RM, Upperman J, Wilson M, et al. Responsible development and application of surgical innovations: a position statement of the Society of University Surgeons. *J Am Coll Surg.* 2008;206:1204-1209.
- Broekman ML, Carriere ME, Bredenoord AL. Surgical innovation: the ethical agenda: a systematic review. *Medicine (Baltimore).* 2016;95:e3790.
- Bernstein M, Bampoe J. Surgical innovation or surgical evolution: an ethical and practical guide to handling novel neurosurgical procedures. *J Neurosurg.* 2004;100:2-7.
- Awad IA. Innovation through minimalism: assessing emerging technology in neurosurgery. *Clin Neurosurg.* 1996;43:303-316.
- Beech R, Morgan M. Constraints on innovative practice: the case of day surgery in the NHS. *Int J Health Plann Manage.* 1992;7:133-148.
- Bunker JP, Hinkley D, McDermott WV. Surgical innovation and its evaluation. *Science.* 1978;200:937-941.
- Frader JE, Flanagan-Klygis E. Innovation and research in pediatric surgery. *Semin Pediatr Surg.* 2001;10:198-203.
- Gillett G. Ethics of surgical innovation. *Br J Surg.* 2001;88:897-898.
- Haines SJ. Randomized clinical trials in the evaluation of surgical innovation. *J Neurosurg.* 1979;51:5-11.
- McKneally MF. Ethical problems in surgery: innovation leading to unforeseen complications. *World J Surg.* 1999;23:786-788.
- Ergina PL, Cook JA, Blazeby JM, Boutron I, Clavien PA, Reeves BC, et al. Challenges in evaluating surgical innovation. *Lancet.* 2009;374:1097-1104.
- Schwartz JA. Innovation in pediatric surgery: the surgical innovation continuum and the ETHICAL model. *J Pediatr Surg.* 2014;49:639-645.
- Kelley K, Clark B, Brown V, Sitzia J. Good practice in the conduct and reporting of survey research. *Int J Qual Health Care.* 2003;15:261-266.
- ACOG Committee on Ethics. ACOG Committee Opinion No. 352: innovative practice: ethical guidelines. *Obstet Gynecol.* 2006;108:1589-1595.
- Lieberman JR, Wenger N. New technology and the orthopaedic surgeon: are you protecting your patients? *Clin Orthop Relat Res.* 2004;338-341.
- Wang Y, Kotsis SV, Chung KC. Applying the concepts of innovation strategies to plastic surgery. *Plast Reconstr Surg.* 2013;132:483-490.
- Agarwal P, Sarris CE, Herschman Y, Agarwal N, Mammis A. Schizophrenia and neurosurgery: a dark past with hope of a brighter future. *J Clin Neurosci.* 2016;34:53-58.
- Morreim H, Mack MJ, Sade RM. Surgical innovation: too risky to remain unregulated? *Ann Thorac Surg.* 2006;82:1957-1965.
- Minter RM, Angelos P, Coimbra R, Dale P, de Vera ME, Hardacre J, et al. Ethical management of conflict of interest: proposed standards for academic surgical societies. *J Am Coll Surg.* 2011;213:677-682.
- Hall DE, Prochazka AV, Fink AS. Informed consent for clinical treatment. *CMAJ.* 2012;184:533-540.
- Falagas ME, Korbila IP, Giannopoulou KP, Kondilis BK, Peppas G. Informed consent: how much and what do patients understand? *Am J Surg.* 2009;198:420-435.
- Geiger JD, Hirschl RB. Innovation in surgical technology and techniques: challenges and ethical issues. *Semin Pediatr Surg.* 2015;24:115-121.
- Angelos P. Surgical ethics and the challenge of surgical innovation. *Am J Surg.* 2014;208:881-885.
- Ford PJ. Vulnerable brains: research ethics and neurosurgical patients. *J Law Med Ethics.* 2009;37:73-82.
- Mukherjee D, Zaidi HA, Kosztowski T, Chaichana KL, Brem H, Chang DC, et al. Disparities in access to neuro-oncologic care in the United States. *Arch Surg.* 2010;145:247-253.
- Hutchison K, Johnson J, Carter D. Justice and surgical innovation: the case of robotic prostatectomy. *Bioethics.* 2016;30:536-546.
- Howell J. Race and U.S. medical experimentation: the case of Tuskegee. *Cad Saude Publica.* 2017;33(suppl 1):e00168016.
- Hwang J, Christensen CM. Disruptive innovation in health care delivery: a framework for business-model innovation. *Health Aff (Millwood).* 2008;27:1329-1335.
- Schneider H. *Creative Destruction and the Sharing Economy: Uber as Disruptive Innovation.* Cheltenham, UK: Edward Elgar Publishing; 2017.
- Riskin DJ, Longaker MT, Gertner M, Krummel TM. Innovation in surgery: a historical perspective. *Ann Surg.* 2006;244:686-693.
- Spodick DH. Numerators without denominators. There is no FDA for the surgeon. *JAMA.* 1975;232:35-36.
- U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research.* Bethesda, MD. Washington: The Commission; 1978.
- World Medical Association. *World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects.* JAMA. 2013;310:2191-2194.
- Marcus HJ, Hughes-Hallett A, Kwasnicki RM, Darzi A, Yang GZ, Nandi D. Technological innovation in neurosurgery: a quantitative study. *J Neurosurg.* 2015;123:174-181.
- Muskens IS, Gupta S, Hulsbergen A, Moojen WA, Broekman MLD. Introduction of novel medical devices in surgery: ethical challenges of current oversight and regulation. *J Am Coll Surg.* 2017;225:558-565.
- Schnurman Z, Kondziolka D. Evaluating innovation. Part 1: the concept of progressive scholarly acceptance. *J Neurosurg.* 2016;124:207-211.
- Moojen WA, Bredenoord AL, Viergever RF, Peul WC. Scientific evaluation of spinal implants: an ethical necessity. *Spine (Phila Pa 1976).* 2014;39:2115-2118.
- Qualms about innovative surgery. *Lancet.* 1985;1:149.
- Georgeson K. Surgical innovation and quality assurance: can we have both? *Semin Pediatr Surg.* 2015;24:112-114.
- McKneally MF, Daar AS. Introducing new technologies: protecting subjects of surgical innovation and research. *World J Surg.* 2003;27:930-934 [discussion: 934-935].
- Blakely B, Selwood A, Rogers WA, Clay-Williams R. Macquarie Surgical Innovation Identification Tool (MSIIT): a study protocol for a usability and pilot test. *BMJ Open.* 2016;6:e013704.
- Hirst A, Agha RA, Rosin D, McCulloch P. How can we improve surgical research and innovation?: the IDEAL framework for action. *Int J Surg.* 2013;11:1038-1042.
- Muskens IS, Diederer SJH, Senders JT, Zamanipoor Najafabadi AH, van Furth WR, May AM, et al. Innovation in neurosurgery: less than IDEAL? A systematic review. *Acta Neurochir (Wien).* 2017;159:1957-1966.
- Mayer E, Darzi A. Innovation and surgical clinical trials. *Lancet.* 2016;388:1027-1028.
- Cook JA. The challenges faced in the design, conduct and analysis of surgical randomised controlled trials. *Trials.* 2009;10:9.
- Healey P, Samanta J. When does the 'learning curve' of innovative interventions become questionable practice? *Eur J Vasc Endovasc Surg.* 2008;36:253-257.

Conflict of interest statement: National Institutes of Health (NIH) Training Grant T32 CA 009001 (D.J.C.). All other authors have nothing to disclose and report no conflicts of interest.

Received 31 December 2017; accepted 20 March 2018

Citation: *World Neurosurg.* (2018) 114:e1038-e1048.

<https://doi.org/10.1016/j.wneu.2018.03.142>

Journal homepage: www.WORLDNEUROSURGERY.org

Available online: www.sciencedirect.com

1878-8750/\$ - see front matter © 2018 Elsevier Inc. All rights reserved.

APPENDIX

Supplementary Table 1. “This Case is an Example of Innovation in Neurosurgery”

	Strongly Disagree	Disagree	Neither Disagree nor Agree	Agree	Strongly Agree
Dura substitute	28	38	13	19	2
Supramaximal resection	11	42	19	22	6
New vascular balloon device	7	16	11	52	14
Endoscopic third ventriculostomy	4	14	15	59	8
Laser resection of meningioma	3	8	9	66	14
Focused ultrasonography	7	10	8	54	21
Virus for glioblastoma multiforme	1	4	5	45	45
Deep brain stimulation for addiction	1	4	13	58	24
New pedicle screws	5	18	20	50	7
Photodynamic therapy	2	12	11	51	24
New high-speed drill	4	22	21	47	6
Value are % of total responses.					

Supplementary Table 2. “By Not Having Obtained Some Sort of Approval From the IRB or Innovation Committee for This Case, the Neurosurgeon Violated Ethical Standards”

	Strongly Disagree	Disagree	Neither Disagree nor Agree	Agree	Strongly Agree
Dura substitute	2	6	9	43	40
Supramaximal resection	12	44	18	18	8
New vascular balloon device	2	12	18	42	26
Endoscopic third ventriculostomy	8	49	24	16	3
Laser resection of meningioma	3	27	24	35	11
Focused ultrasonography	3	16	13	41	27
Virus for glioblastoma multiforme	3	8	11	29	49
Deep brain stimulation for addiction	1	12	23	35	29
New pedicle screws	7	42	21	23	7
Photodynamic therapy	1	13	16	41	29
New high-speed drill	14	47	21	15	3
Values are % of total responses.					

Supplementary Table 3. "Advancing the Field of Neurosurgery Was Valued More Than Individual Patient Care"

	Strongly Disagree	Disagree	Neither Disagree nor Agree	Agree	Strongly Agree
Dura substitute	9	21	22	36	12
Supramaximal resection	13	37	23	22	5
New vascular balloon device	5	24	26	34	11
Endoscopic third ventriculostomy	7	37	32	22	2
Laser resection of meningioma	7	25	27	35	6
Focused ultrasonography	5	22	22	38	13
Virus for glioblastoma multiforme	5	22	19	33	21
Deep brain stimulation for addiction	4	21	31	32	12
New pedicle screws	9	37	31	19	4
Photodynamic therapy	4	24	26	33	13
New high-speed drill	11	39	28	19	3
Values are % of total responses.					

Supplementary Table 4. "What Type of Innovation is This?"

	Not a Type of Innovation	Minor Modification	Major Modification	Radical Innovation
Dura substitute	47	44	7	2
Supramaximal resection	43	40	15	2
New vascular balloon device	20	25	37	18
Endoscopic third ventriculostomy	15	75	10	0
Laser resection of meningioma	10	35	39	16
Focused ultrasonography	15	14	26	45
Virus for glioblastoma multiforme	5	9	29	57
Deep brain stimulation for addiction	7	19	35	39
New pedicle screws	22	66	9	3
Photodynamic therapy	14	14	33	39
New high-speed drill	31	59	8	2
Values are % of total responses.				