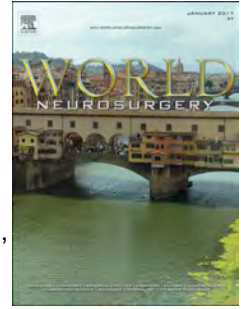


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Defining Innovation in Neurosurgery: Results from an International Survey

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23 **Key words**

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47 **Abstract**

48 **Background:**

49 Innovation is a part of the daily practice of neurosurgery. A clear definition of what
50 constitutes innovation is currently lacking, however, and opinions vary from continent to
51 continent, from hospital to hospital, and from surgeon to surgeon.

52

53 **Methods:**

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

58

59 **Results:**

60 A total of 355 neurosurgeons across all continents excluding Antarctica completed the
61 survey. Neurosurgeons achieved consensus (>75%) in considering specific cases to be
62 innovative, including laser resection of meningioma, focused ultrasound for tumor,
63 oncolytic virus, DBS for addiction, and photodynamic therapy for tumor. Although the
64 new dura substitute case was not considered innovative, there was consensus among
65 neurosurgeons indicating that IRB approval was still necessary to maintain ethical
66 standards. Furthermore, although 90% of neurosurgeons considered an oncolytic virus for
67 GBM to be innovative, only 78% believed that IRB approval was necessary prior to
68 treatment.

69

70 **Conclusions:**

71 Our results indicate that innovation is a heterogeneous concept among neurosurgeons that
72 necessitates standardization to ensure appropriate patient safety without stifling progress.
73 We discuss the ethical drawbacks of not having a clear definition of innovation, the
74 current challenges in achieving a unified understanding of innovation in neurosurgery,
75 and offer suggestions for uniting the field going forward.

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93 **Introduction**

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

106
107 Attempts to standardize the definition of innovation have been presented. The Society of
108 University Surgeons has proposed discerning between variations, innovations, and
109 research.⁵ Some have suggested splitting innovations by type, such as minor
110 modifications of standard procedures, major modifications of standard procedures, and
111 innovations that are new to the institution but have been validated elsewhere.⁶ Others
112 have suggested a rating of surgical innovations directly related to the amount of oversight
113 deemed necessary.⁷ Despite these attempts, along with many other suggestions for
114 appropriate oversight in surgery^{8, 9-16}, a clear answer does not exist.

115
116 Lack of consistency in the general surgical literature warrants an investigation of what
117 neurosurgeons themselves consider innovative. To this point, the definition of innovation
118 has yet to be evaluated specifically among neurosurgeons. Using a survey consisting of
119 hypothetical cases, this study aims to describe what neurosurgeons consider innovative.
120 This study also discusses how the definition of innovation impacts aspects of patient care,
121 influences appropriate oversight, and promotes effective collaboration in the field of
122 neurosurgery.

123

124

125 **Methods**

126 *Survey Development*

127 An online survey was developed to identify trends in the opinions of neurosurgeons on
128 the definition of innovation in the field. In total, the anonymous survey consisted of 52
129 questions, and took approximately 10 minutes to complete. Respondents could exit the
130 survey at any point. Demographic data was collected from each respondent including sex,
131 annual case volume, lifetime case volume, years of experience, type of practice,
132 subspecialty, group size, and continent of practice.

133

134 Eleven hypothetical cases were written highlighting past and contemporary advances in
135 neurosurgical instrumentation, methodology, or both. For each case, respondents were
136 asked to select their opinion via Likert scale assessment (strongly disagree, disagree,
137 neither disagree nor agree, agree, strongly agree) on the following statements: 1) This
138 case is an example of innovation in neurosurgery; 2) By not having obtained some sort of

139 approval from the IRB or an innovation committee for this case, the neurosurgeon
140 violated ethical standard in this case; 3) Advancing the field of neurosurgery was valued
141 more than individual patient care. Lastly, respondents were asked what type of innovation
142 they considered each case: none, minor modification of a standard procedure, major
143 modification of a standard procedure, or a radical innovation. Likert scales, rather than
144 open-ended answers, were chosen to help foster a sense of consensus among a
145 heterogeneous population. The eleven cases were chosen based on themes identified in
146 recent neurosurgical literature, including technical and technological advances that were
147 considered by the authors to include relatively minor to more radical advancements.
148 These cases are listed in **Table 1**.

149

150 *Survey Distribution*

151 The survey was sent to members of the Committee on Ethics and Legal Affairs of the
152 World Federation of Neurosurgical Societies (WFNS) and the Ethico-Legal Committee
153 of the European Association of Neurosurgical Societies (EANS). Members were
154 encouraged to distribute the survey within the departments of their respective home
155 institutions. The survey was subsequently distributed to all individual members of the
156 EANS. The overwhelming majority of responses was collected in the first week of
157 distribution. A reminder was sent at two weeks after initial distribution. Following
158 several days without incoming responses, the survey was then closed. Responses were
159 collected from November 21, 2016 to December 30, 2016.

160

161 *Data Analysis*

162 Survey data was collected and analyzed in IBM SPSS Version 22 (IBM, Armonk, New
163 York, USA, 2013). Nominal variables, including basic respondent demographics and
164 Likert scale responses, were summarized using counts and percentages. Subsequent
165 dichotomization of Likert scale responses was performed, such that one category ranged
166 from strongly disagree to neither disagree nor agree, and another category included agree
167 to strongly agree. In determining whether there was consensus of opinion, an a priori set
168 value of 75% or more of respondents falling in either category was used as a cutoff for all
169 questions in this study.

170

171 **Results**

172 *Respondent Demographics*

173 A total of 355 of approximately 1500 neurosurgeons (~23.7%) completed the survey, an
174 expected response rate for this kind of questionnaire;¹⁷ 85% were male, with respondents
175 from all continents excluding Antarctica. Demographics and practice characteristics are
176 summarized in **Table 2**. No significant demographic variables (including sex, annual or
177 lifetime volume, experience, practice type, subspecialty, practice size, or continent of
178 origin) were determined to influence how participants responded to the following
179 questions (data not shown).

180

181 *Question 1: This case is an example of innovation in neurosurgery.*

182 Initial Likert scale responses to Question 1 and subsequent dichotomization are shown in
183 Supplementary **Table 1** and **Figure 1**, respectively. Notably, cases 5, 6, 7, 8, and 10 were
184 considered more innovative by neurosurgeons ($\geq 75\%$ indicated agree or strongly agree).

185 These cases corresponded to laser-resection of a meningioma, focused ultrasound for
186 meningioma, viral injection into a tumor cavity, DBS treatment for addiction, and PTD
187 for an irresectable glioma, respectively. Conversely, case 1 was rarely considered
188 innovative ($\leq 25\%$ indicated agree or strongly agree). This case corresponded to the dura
189 substitute.

190
191 *Question 2: By not having obtained prior approval, ethical standards were violated.*
192 Likert scale responses to Question 2 are shown in Supplementary **Table 2**.
193 Neurosurgeons generally responded that the virus for GBM in case 7 violated ethical
194 standards without prior approval from an IRB or innovation committee. Although the
195 dura substitute in case 1 was not considered innovative (**Table 3, Figure 1**), most
196 neurosurgeons believed that ethical standards were violated by not seeking prior approval
197 from IRB or an innovation committee (Supplementary **Table 2, Figure 2**). Finally,
198 neurosurgeons predominantly ($\geq 75\%$) did not believe that any ethical standards were
199 breached in the endoscopic third ventriculostomy in case 4 nor using the new high-speed
200 drill in case 11.

201
202 *Question 3: Advancing the field of neurosurgery was valued more than individual patient*
203 *care.*

204 The survey responses for Question 3 are presented in Supplementary **Table 3** and **Figure**
205 **3**. Neurosurgeons displayed a consensus ($\geq 75\%$) that advancing the field of neurosurgery
206 was not valued more than individual patient care in cases 4, 9, and 11, but these were just
207 over the set threshold of 75%. These cases were the endoscopic third ventriculostomy,
208 laser resection of meningioma, and the new high-speed drill, respectively. Before
209 dichotomization, neither disagree nor agree was a common (20-30%) answer for almost
210 every case.

211
212 *Question 4: What type of innovation is this?*
213 The results for Question 4 are presented in Supplementary **Table 4** and **Figure 4**.
214 Considering consensus at 75%, cases 1, 2, 4, 9, and 11 fell were generally considered less
215 innovative, while case 7 was generally considered more innovative. Cases 3, 5, 6, 8, and
216 10 showed less consensus.

217
218
219 **Discussion**
220 These findings indicate that, similar to other fields of surgery¹⁸⁻²⁰, neurosurgery lacks a
221 clear consensus about what constitutes innovation. The varied responses shown here are
222 likely a reflection of the complexity and lack of consensus in defining innovation and
223 determining appropriate oversight for innovative procedures. For example, it is
224 interesting to note that only 10% of respondents did not consider an oncolytic virus to be
225 innovative, yet more than double this number at 22% of respondents did not believe an
226 IRB or equivalent was necessary. Because this scenario is still considered experimental
227 therapy, our findings may indicate a lack of consistency in educating neurosurgeons on
228 ethical standards in investigative research across the globe.

229

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

233

234 *The Need for Standardizing a Definition*

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

241

242 Often, the person introducing the innovation is the surgeon using the novel technique or
243 device. In scenarios where the surgeon is the one who strongly believes in the promise of
244 the innovation, innovator bias may prevent the surgeon from thoroughly evaluating the
245 potential harms associated with the new intervention.²² Such lack of perceived clinical
246 equipoise, as well as other personal conflicts of interests are therefore just as important to
247 be aware of as financial conflicts of interests.²³ Non-biased evaluation may help to limit
248 the effect of such conflicts of interest in cases where a new idea is clearly defined as an
249 innovation.

250

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

261

262 The principle of justice can also be explored, both in regard to over-enrolling vulnerable
263 patient populations as well as under-enrolling patients from disadvantaged backgrounds.
264 Because severely ill neurosurgical patients may not have the cognitive ability to
265 adjudicate risks and benefits, as well as having a strong emotional drive to attempt any
266 option feasible, these patients are susceptible to being easily persuaded into a novel
267 treatment.²⁸ Regarding under-access, minority and low-income neuro-oncology patients
268 have worse access to surgical care than Caucasian patients or those who have higher
269 incomes, respectively.²⁹ Since many new innovations tend to be costly, low-income
270 patients may not be able to access the latest and potentially most effective treatments.³⁰
271 Conversely, dangerous innovations may be forced onto minority populations as has
272 occurred in Tuskegee.³¹ Without a proper framework of innovation or appropriate
273 oversight, these injustices are prone to exacerbation. Potentially compromising these core
274 ethical principles thus necessitates a standard definition of innovation in order to promote
275 ethical and practical patient safety.

276

277 *The Difficulty in Defining Innovation in Neurosurgery*

278 Innovations are not unique to neurosurgery. They occur in numerous medical specialties
279 as well as every industry outside of medicine. In the business literature, innovations can
280 broadly be categorized into sustaining and disruptive innovations.³² Sustaining
281 innovations improve an existing product and maintain the incumbent firm. One example
282 can be the latest version of an existing smartphone. Disruptive innovations introduce a
283 new firm that radically disturbs an existing industry, such as the effect of Uber on the taxi
284 industry.³³ Businesses can predict the type of innovation something will be, because they
285 use consumer reports and market predictions to guide the development and marketing of
286 their products. Surgery, however, is not driven primarily by consumer requests and other
287 market forces. It is guided by surgeon preference, patient outcomes, and peer review.³⁴
288 In addition to differences between business and medicine, innovation in surgery
289 specifically varies from other fields of medicine.²⁷ Medical innovations, such as devices
290 or new drugs, undergo a rigorous and thorough evaluation before they are approved for
291 the clinical market. Once they are introduced, these innovations are believed to be safe
292 and effective in achieving the desired effect. Thus, there is a clear border between
293 research and clinical care in medicine. Surgery is more complicated. Since the Food and
294 Drug Administration or an equivalent organization does not typically review the safety
295 and efficacy of new surgical procedures,³⁵ it is noteworthy that research and clinical care
296 are not mutually exclusive in surgical hypothesis testing. Surgical innovation in both the
297 research and the clinical paradigm may contain untested novel ideas,⁷ but innovation in
298 research is aimed at generating generalizable knowledge,^{36,37} while innovation in clinical
299 care is aimed at improving the outcome of the individual patient.³⁶ When new surgical
300 procedures are implemented in patients, generating universal knowledge thus coincides
301 with the aim of ameliorating the suffering of the individual patient. Such overlap, along
302 with the lack of oversight, has obfuscated a clear definition of innovation in the surgical
303 field.

304

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

321

322 *Lack of definition: implications for oversight*

323 As indicated, these results show that neurosurgeons do not agree on what constitutes
324 innovation, and achieving a definition would allow appropriate regulation. Some fear that
325 oversight may stifle innovation and the continual advancement of surgery;⁴¹ however,
326 appropriate oversight that balances patient safety and the surgeon's autonomy is the goal.
327 Many proposals have been suggested for achieving appropriate oversight in cases where
328 deviations from the norm take place, whether they be technical or technological
329 deviations. We have previously reviewed⁶ the proposals for various types of innovations,
330 including those which suggest national regulation for major modifications or radical
331 innovations⁴² as well as those that suggest an institutional surgical innovation committee
332 (SIC).^{22,43,44}

333
334 The first step in determining appropriate oversight for an innovative surgery is to
335 determine which operations require an evaluation. On one extreme, every operation may
336 be considered a deviation from the norm as surgeons tailor their operations to the
337 uniqueness of each presentation.³⁴ However, it would be impractical and inefficient to
338 evaluate every deviation from the norm. The Macquarie Surgical Innovation
339 Identification Checklist (MSIIT) has been introduced as a simple checklist that is
340 currently being tested in its ability to identify when a procedure qualifies as
341 "innovative".⁴⁵ It suggests that scenarios where the techniques, instruments, and/or
342 devices used are new to the hospital or new to the surgeon should acquire further
343 information regarding necessary training, patient communication, and an evaluation of
344 past use of the novelty elsewhere. If a technique, instrument, and/or device is being used
345 for a new indication, in a sex or age where such differences or comorbidities are relevant,
346 the MSIIT suggests that further information should be acquired regarding potential
347 consequences of the innovation, whether such outcomes are publishable, and whether
348 special preparations should be put in place to accommodate the innovation. The value of
349 the MSIIT is not that it seeks to create stringent criteria for what constitutes innovation,
350 but rather aims to identify which surgical procedures warrant further information and
351 oversight when necessary. Another noteworthy endeavor is the IDEAL (Idea,
352 Development, Exploration, Assessment, Long-term follow up) collaboration,⁴⁶ which
353 seeks to discuss appropriate oversight at all stages of innovation. It includes suggestions
354 such as a negative database of failed ideas, mandating detailed technical descriptions of
355 novel approaches, exploring the learning curve of new innovations, expanding and
356 assessing the innovation in multi-center trials, and finally monitoring long term
357 outcomes. Recent review of two neurosurgical procedures, namely the endoscopic
358 endonasal approach for skull base meningiomas and the WovenEndobridge for
359 endovascular treatment of intracranial aneurysm, suggest that the process of innovation
360 does not currently follow the path outlined in the IDEAL framework,⁴⁷ emphasizing the
361 need for more appropriate oversight.

362
363 After identifying which procedures warrant further oversight, the regulation that is
364 deemed appropriate could be determined by an SIC. An SIC may be comprised of
365 experienced surgeons, ethicists, engineers, and other relevant stakeholders. When a new
366 technique or device is being introduced, the SIC can critically evaluate the scientific
367 validity of the proposal, ensure that the patient is truly informed about all known risks

368 and the novelty of the procedure, and confirm that the necessary adaptations to the novel
369 procedure are made available to the surgeon. When an innovation has been proven
370 effective, there will be a learning curve that must be overcome before other colleagues
371 are able to effectively incorporate it into common practice.^{48,49} SIC's can serve as
372 facilitators that connect experiences surgeons with similar ideas and experiences to foster
373 educational dialogue between colleagues.

374
375 Overall, surgical innovation is a ubiquitous phenomenon that remains poorly defined.
376 Without a proper definition, patient safety and ethical care are at risk. Despite the
377 difficulties in producing an exact definition of surgical innovation, programs that
378 facilitate critical feedback and opportunities for experienced surgeons to share their
379 knowledge⁵⁰ would promote an environment conducive to collaborative learning and
380 appropriate patient safety.

381
382 *Strengths and Limitations*

383 This is the first survey of its kind to acquire the opinions of hundreds of neurosurgeons
384 from numerous continents. It shows that neurosurgery, like many other fields of surgery,
385 does not have a universal definition of innovation. This paper discusses the ethical and
386 practical concerns associated with not having a unified definition and offers suggestions
387 to overcome barriers in place.

388
389 Although these results were created based on response from 355 respondents, 75% of the
390 respondents are based in Europe. Further surveys should involve larger numbers of
391 respondents from other continents in order to determine if opinions vary based on
392 respective continental and national regulations. Additionally, 68% of respondents are
393 from academic institutions and thus may have underlying user bias in assessing what
394 constitutes innovation. Another limitation is that first-hand experience with innovation
395 was not directly inquired about in the respondent demographics, which may have also
396 revealed bias in the responses. Furthermore, the cases present a limited spectrum of
397 innovation as these cases can be considered possible extensions of current surgical
398 practices, rather than genuinely novel approaches or treatments. Finally, although this
399 study discusses the necessity for a unified definition of innovation in neurosurgery, it
400 does not present a clear-cut algorithm that can be applied to determine if a new idea
401 qualifies a surgical innovation. Further studies could elicit possible definitions from
402 neurosurgeons first-hand, how common innovation is seen in their respective practices,
403 and the factors involved in surgeons deciding to adopt innovative practices.

404
405 **Conclusion**

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

413

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536 **Figure Legends**

537
538 Figure 1. Survey Responses to Question 1: This case is an example of innovation in
539 neurosurgery.

540
541 Figure 2. Survey Responses to Question 2: By not having obtained prior approval, ethical
542 standards were violated.

543
544 Figure 3. Survey Responses to Question 3: Advancing the field of neurosurgery was
545 valued more than individual patient care.

546
547 Figure 4. Survey Responses for Question 4: What type of innovation is this case?

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 supra-maximal 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 Ultrasound	A patient presents with a skull-base meningioma. Rather than attempting traditional resection, the surgeon employs focused ultrasound 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.

Table 2. Respondent demographics and practice characteristics.

Sex		Percentage (%)
	Male	85
	Female	15
Annual Volume		
	<50	6
	501-100	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
	5001-10000	14
	>10000	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
	CV	12
	Tumor	22

	Spine	17
	Trauma	3
	General (None)	38
Practice Size		
	1-2 neurosurgeons	11
	3-5 neurosurgeons	21
	6-10 neurosurgeons	35
	11-15 neurosurgeons	19
	>15 neurosurgeons	14
Continent		
	NA	4
	SA	2
	Europe	75
	Africa	7
	Asia	12
	Australia	0.3

Note that cells contain % of total responses

Supplementary Table 1. “This case is an example of innovation in neurosurgery.”

	SD	D	N	A	SA
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 Ultrasound	7	10	8	54	21
Virus for GBM	1	4	5	45	45
DBS 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

Note that cells contain % of total responses

SD: Strongly Disagree, D: Disagree, N: Neither disagree nor agree, A: Agree, SA: Strongly Agree

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.”

	SD	D	N	A	SA
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 Ultrasound	3	16	13	41	27
Virus for GBM	3	8	11	29	49
DBS 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

Note that cells contain % of total responses

SD: Strongly Disagree, D: Disagree, N: Neither disagree nor agree, A: Agree, SA: Strongly Agree

Supplementary Table 3. “Advancing the field of neurosurgery was valued more than individual patient care.”

	SD	D	N	A	SA
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 Ultrasound	5	22	22	38	13
Virus for GBM	5	22	19	33	21
DBS 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

Note that cells contain % of total responses

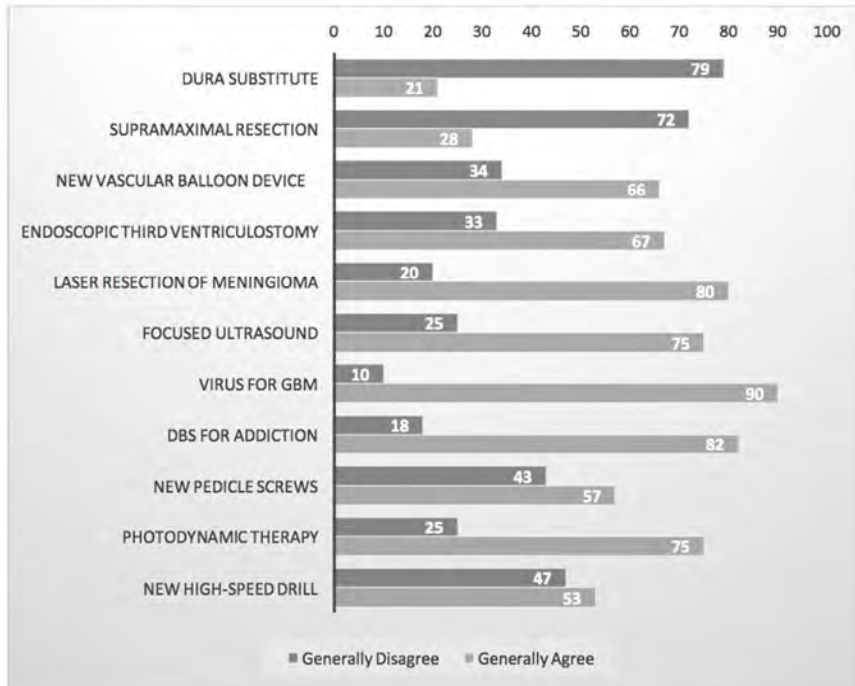
SD: Strongly Disagree, D: Disagree, N: Neither disagree nor agree, A: Agree, SA: Strongly Agree

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 Ultrasound	15	14	26	45
Virus for GBM	5	9	29	57
DBS 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

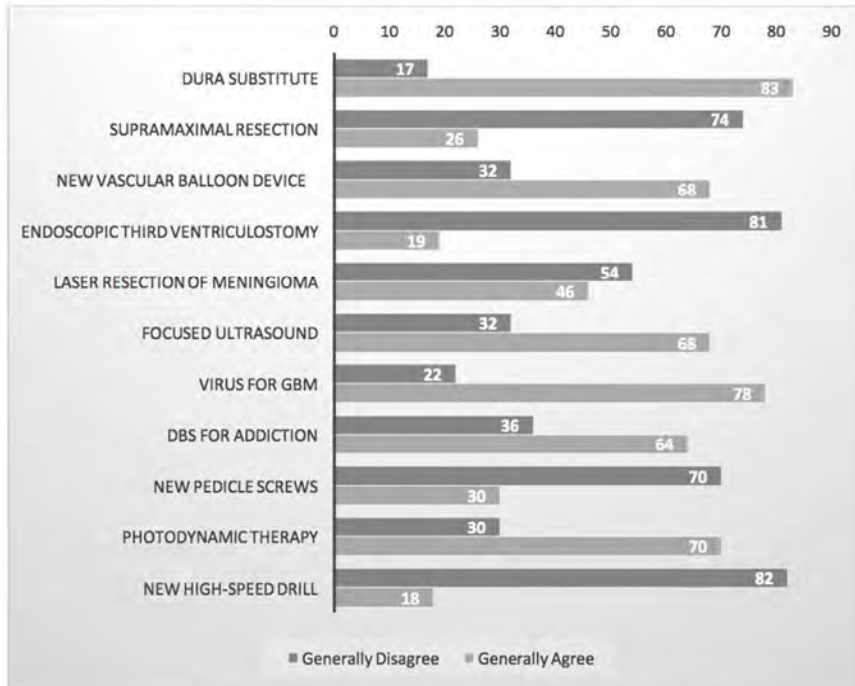
Note that cells contain % of total responses

Figure 1. Survey Responses to Question 1: This case is an example of innovation in neurosurgery.



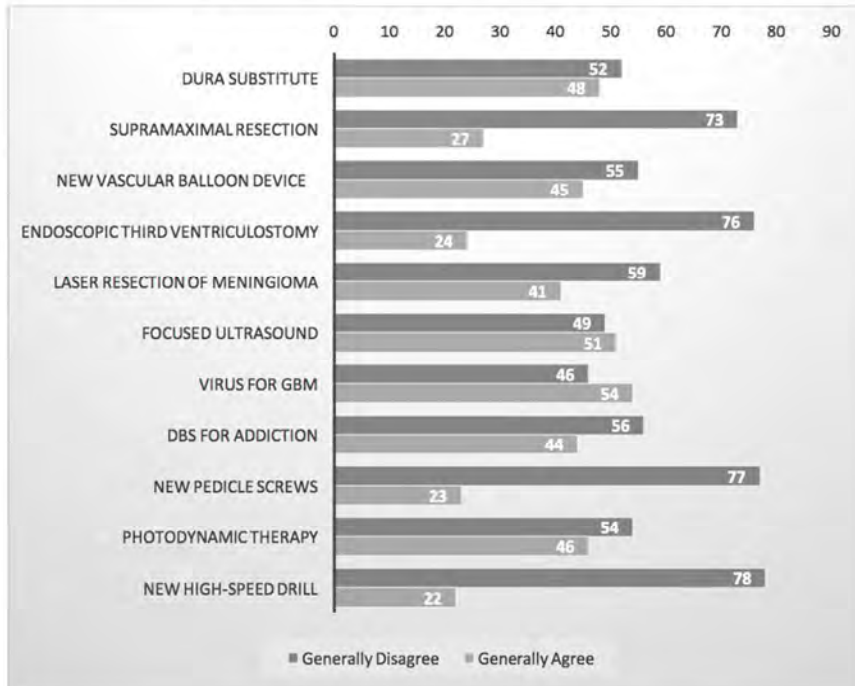
Note that Generally Disagree includes "neither disagree nor agree"

Figure 2. Survey Responses to Question 2: By not having obtained prior approval, ethical standards were violated.

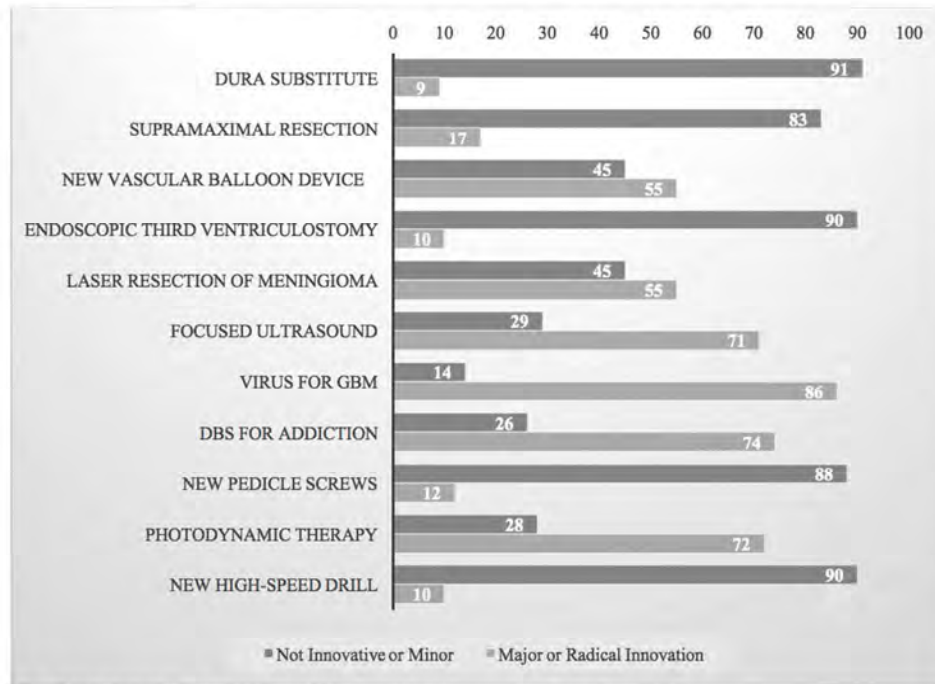


Note that Generally Disagree includes "neither disagree nor agree"

Figure 3. Survey Responses to Question 3: Advancing the field of neurosurgery was valued more than individual patient care.



Note that Generally Disagree includes "neither disagree nor agree"

Figure 4. Survey Responses for Question 4: What type of innovation is this case?

Note that Generally Disagree includes "neither disagree nor agree"

Highlights

- A definition of innovation in neurosurgery is currently lacking
- There is wide heterogeneity of opinion among neurosurgeons on what constitutes innovative procedures
- There are significant ethical implications in the absence of a clear definition
- Steps should be taken to help identify which innovations warrant further oversight without stifling scientific progress

Abbreviations

DBS, Deep Brain Stimulation; EANS, European Association of Neurosurgical Societies; GBM, Glioblastoma Multiforme; MSIT, Macquarie Surgical Innovation Identification Checklist; PTD, Photodynamic therapy; SIC, Surgical Innovation Committee; WFNS, World Federation of Neurosurgical Societies

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