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Original Article

Informed consent in neurosurgery – Evaluation of current practice and implementation of future strategies

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ABSTRACT

Background: In recent times, clinical negligence claims against National Health Service hospitals have doubled, with 8% of claims being made due to "failure to warn/informed consent." This study aimed to assess the current compliance of the neurosurgical division within a large tertiary neuroscience center with the national legal framework and professional guidelines around the issue of surgical consent and to develop strategies to improve the consent process.

Methods: Electronic patient records (EPR) were accessed to collect demographic data and information regarding the surgical procedures. Telephone questionnaires were carried out. Neurosurgical registrars were interviewed. The author met with the trust's Legal team, the neuropsychology lead, and the trust's consent lead.

Results: Fifty-eight patients were included in the analysis. Of the respondents to the questionnaire, 98% felt that they were adequately informed during the consent process. When consenting patients, all registrars felt that they explained the reason for the procedure, detailed benefits, and major risks, including uncommon and rare risks. However, 50% admitted to not specifically discussing the postoperative recovery time or alternatives. Only 15% admitted to documenting on the EPR or through a letter to the patient's General Practitioner.

Conclusion: Informed consent is a delicate moment of communication between a clinician and the patient. Regular training and good communication skills help staff to focus on the most relevant aspects of consent, which should be delivered in an appropriate environment and with family support. Audio-visual aids can support the process but do not replace good communication.

Keywords: Informed consent, Litigation, Neurosurgery, Test of materiality, Three-legged stool

INTRODUCTION

Neurosurgery is one of the highest risk specialties for malpractice within the National Health Service (NHS), second only to Obstetrics and Gynecology.[19] This occurs not only as a consequence of the morbidity and mortality that may be incurred from surgical procedures but also as a result of the natural progression of the disease process, for example, worsening myelopathy with a cervical disc prolapse.

Consent is central to everything that occurs in healthcare, be that the consent needed to examine a patient or consent for a procedure. The principle of consent reflects the patient's right to determine

what happens to their body both when having physical examinations and when undergoing investigations and procedures.[4,7] In UK law, there is no threshold above which formal written consent must be taken, but as a general rule, the more invasive the examination, investigation, or procedure, the greater the need for informed consent.[23] Written consent is not, however, synonymous with valid informed consent. The consent form provides some evidence that a discussion between a patient and a doctor has taken place but does not testify to the patient's understanding. Informed consent is a multi-media interaction where both parties can adapt their dialog to tailor information to patients' specific concerns[3] and, thus, facilitate their understanding of the risks to them as individuals.

In recent times, there has been a doubling of clinical negligence claims against NHS hospitals,[19] with approximately 8% of claims between 2012 and 2017 being made as a result of "failure to warn/informed consent."[11] NHS Resolution (the operating name of the NHS Litigation Authority) was set up in 1995 to indemnify all NHS hospitals within England, with the aim of providing compensation to patients who have suffered as a result of clinical negligence and defending claims that are felt to be without merit.[11]

Informed consent claims are usually brought in the tort of negligence; not negligence in carrying out the treatment but negligence in advising the patient about the risks. Two fundamental elements are needed in order for the claim to be successful: [14] breach of duty and causation (if the claimant had known the risk, they would either not have had the treatment or they would have delayed it).

Before obtaining consent, the surgeon must provide the patient with information about alternative treatments and the risks of not undergoing surgery. The surgeon must then explain the nature of the proposed surgery, the intended benefits, material risks (to that particular patient), and potential complications. Surgeons must use their clinical judgment in discussion with the patient[9] but must include risks common to all surgeries and risks specific to the proposed surgery, even if they are rare. Risks that may cause the patient to refuse surgery are especially important, as are the specific circumstances for individual patients. For example, if an opera singer were to undergo cervical spine surgery for degenerative changes, it would be imperative they know that an anterior approach to the neck may alter their voice quality, whereas this specific risk would not apply if the cervical spine were approached posteriorly. In most patients, this may not change their decision to undergo surgery, but in this specific patient, the consequences may be life changing. Suppose a patient does not understand the material risks to them as an individual from having surgery and a complication happens. In that case, the quality of consent may be called into question.

While the responsibility for ensuring a valid consent process has taken place remains with the doctor, the process of consent now requires the more active involvement of the patient, taking into account not just their profession but also their hobbies, interests, and general wishes when recommending a course of treatment.[4,5] This shift from what a reasonable doctor would do to what a reasonable patient would want to know, in addition to the increase in medicolegal claims, has resulted in uncertainty within the medical community.[23]

Other studies around the matter of consent have been conducted internationally, such as the ones by Anderson and Wearne,[2] Wheeler,[23] and Weckbach *et al*.[22] Attempts have been made to improve and facilitate the consent process. Sources of information include clinical consultations, multimedia learning modules, nurse and staff training, printed documents, and Internet-based resources. The most common aids to consent include the provision of additional written information, audio-visual/multimedia interventions such as online videos, extended informed consent discussions such as those undertaken in a consent clinic, and test/feedback techniques. Audio-visual recording of the consent process is common in the US for medicolegal purposes[2,13,20-22], but at present is less common in the UK.

NHS organizations must provide a framework to ensure that Trusts comply with regulatory requirements, that a standard of care is established, and that employees are supported in their work. The lack of standardized guidelines represents a risk to individual health-care professionals and NHS Trusts. Failing to obtain informed consent may result in disciplinary action from the employing Trust and/or professional bodies[5] and can result in legal action. Common law states that touching a patient without their prior consent/lawful authority may constitute battery or assault.[18] If valid consent is not obtained, either through omission or the lack of patient understanding, and the patient was to come to harm due to treatment, the clinician or the Trust may be found to be negligent. An organization that does not provide support to its employees risks not only its reputation and financial stability but also has increased risks that patient care may be compromised. For these reasons, each trust should have an up-to-date consent policy, and issues related to the consent process should be recorded in the risk register.[4]

This study aimed to assess the current compliance of the neurosurgical division within a large tertiary neuroscience center with the national legal framework and professional guidelines around the issue of surgical consent and to develop divisional wide clinician and patient-centered strategies to improve the consent process. The results of this study are generalizable to other centers and other surgical specialties.

MATERIALS AND METHODS

During the preliminary phases of the study, a stakeholder analysis was carried out to ascertain the key components of the consent process and inform the rest of the project [Figure 1]. Patients who had suffered a complication were identified from the departmental morbidity and mortality data over 2 years (January 2019–December 2021).

The project was registered with the trust's audit and legal departments. Telephone consent was obtained from all patients taking part in the telephone questionnaire. Electronic patient records (EPR) were accessed to collect demographic data and information regarding the surgical procedure. Telephone questionnaires were carried out to ascertain the patient's understanding of the procedure and whether the patient fully understood the risks and benefits of surgery, including alternative treatments and the emotional and physical impact of the complication. Patients were also asked about their thoughts on how to improve the consent process. Patients who underwent emergency surgery were excluded as both the timing and context of the consent process differ significantly between elective surgery and emergency/life threatening surgery.[1] Patients who lacked capacity at the time of consent, who had died, or were pursuing active litigation against the Trust at the time of the project were also excluded from the study.

The questionnaire was designed *de novo* by the researcher, with question choice being informed by a literature review around the matter of consent, in particular from studies that reference optimal consent practices.[2,13,22,23]

Questions 1–6 refer to the overall satisfaction with the consent process and the context of where the consent process took place. Question 7 refers to the test of materiality. Questions 8–14 refer to the "three-legged stool." Questions 15–19 are related to the patient's perception of the consent process and their opinion on how we could improve this.

Neurosurgical registrars were interviewed [Appendix 1] after obtaining verbal consent. This allowed the researcher to ascertain the level of experience among the registrar body in our department and the level of understanding of the underlying principles and ethical/professional standards of consent. The registrars were also asked for their opinions on how the consent process could be improved. Clinical letters were reviewed to ascertain if the consultant had discussed consent in the clinic and documented it in the letter.

The author met with the trust's Legal team to discuss issues pertaining to consent and obtained data from NHS resolution on previous (within the past 5 years) and ongoing litigation in the trust. The author also met with the neuropsychology lead to ascertain the impact of consent on the patient and to discuss factors that can increase a patient's understanding of the consent process and how this can be enhanced. Discussions were held with the trust's consent to gain an understanding of current trust policies and the results of previous consent audits.

RESULTS

The patients

Sixty-eight patients were identified to have suffered a complication during the study period and were eligible

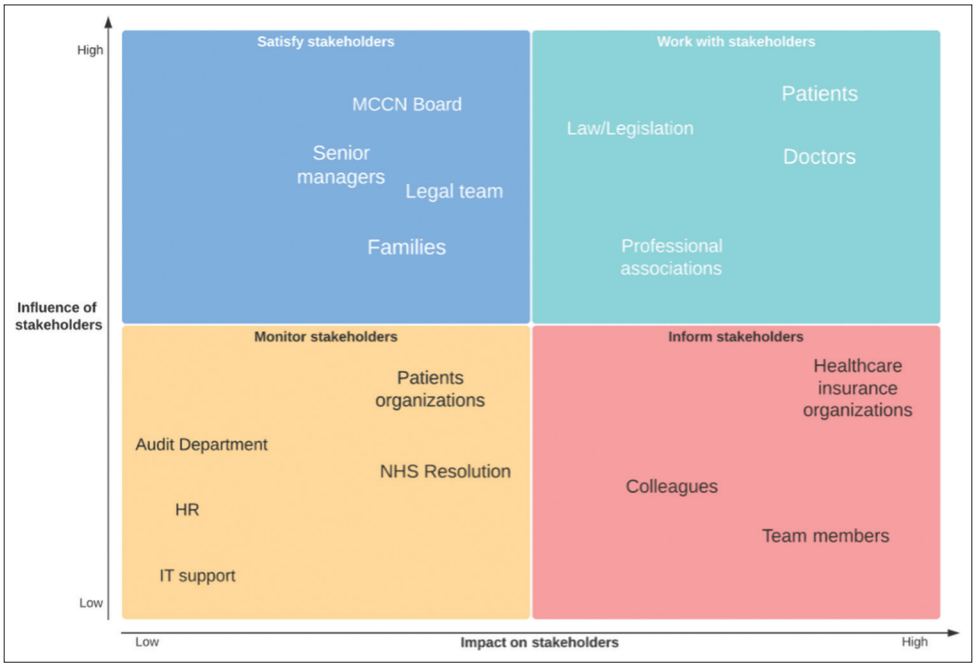

Figure 1: Stakeholder map. MCCN: Manchester center for clinical neurosciences.

to participate in this study. Three declined to participate, two were cognitively impaired at the time of consent, and therefore, surgery was carried out with a consent form 4, three had undergone emergency surgery, and two had subsequently died, leaving 58 patients in the analysis group. About 71% of this group filled in the telephone questionnaire. This study is focused on qualitative descriptors with the aim of understanding the patient's experience of the consent process; therefore, we do not believe that the analysis of the patient's response would be invalidated by the lack of response of the 17 patients who did not fill in the questionnaire. The results that have been presented are based on the answers of the patients who did respond to the questionnaire.

The mean age of the patient was 51 years (range 18–84). About 57% of participants were female, while 55% were from a White British ethnic background. About 26% were employed, while 33% were retired at the time of surgery [Table 1]. About 45% of patients had previous experience of the consent process of which only 7% had had previous neurosurgery. Figure 2 demonstrates the type of complication suffered, while Figure 3 demonstrates the main treatment required to remedy the complication.

Of the respondents to the questionnaire [Table 2], 98% felt that they were adequately informed during the consent process, while 88% felt that they were given enough time and an appropriate environment to consent to surgery. About 80% of patients were able to have a family member present for the discussion (of note, the study period also includes a period of COVID restrictions) either in person or over the phone/video consultation.

About 17% of patients felt that not enough emphasis was put on postoperative care and recovery time. All patients felt that they understood the indications and benefits of surgery, and only one patient felt that they did not understand the major risks. About 68% of patients felt that they understood what a complication would mean to them and what this may mean in terms of ongoing care.

About 83% of our patients received either an information leaflet or a QR code from the clinic, although only 59% received a copy of their consent form in the clinic.

All patients had consent confirmed on the morning of surgery, with only one patient feeling that they were not given sufficient opportunity to ask questions. Despite having had a complication, 90% of patients, when questioned, would choose to have the operation again. Figure 4 demonstrates the impact of the complication on the patients, while Figure 5 demonstrates patient recommendations for improvement in the consent process.

The healthcare professionals

Eighteen of the 19 neurosurgery registrars responded. Their average surgical experience was 6 years (range 3–14 years).

Table 1: Descriptive results of patients included in the study.

Descriptive statistics	Number
Total number of patients	68
Agreed to participate	58
Declined	3
Cognitively impaired	2
Dead	2
Emergency surgery	3
Mean age (range)	51 (18–84)
Gender	
Male	25
Female	33
Ethnic background	
White British	32
Other White	2
Asian	6
Black	1
Unknown	17
Employment status	
Employed	15
Unemployed	6
Retired	19
Student	1
Unknown	17
Previous surgery	
Yes	26
No	15
Unknown	17
Specialty	
Skull base	20
Oncology	11
Spine	23
Hydrocephalus	1
Vascular	2
Functional	1

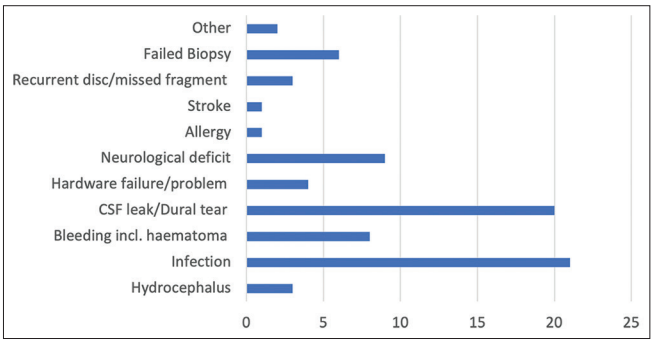

Figure 2: Type of complication (a total of 78 individual complications occurred in 58 patients).

Only 22% had had formal consent training. About 50% were aware of the Bolam test, 56% of the materiality test, 72% of the ethical principles, and 78% of the General Medical Council (GMC) guidance. Nobody had read or knew about the trust consent policy. When consenting patients, all registrars felt

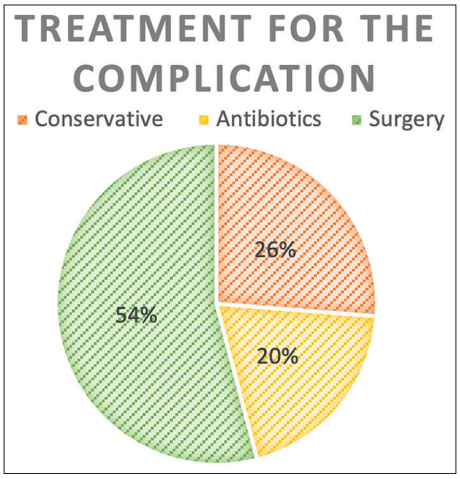

Figure 3: Treatment for the complication (conservative management includes those patients with a dural tear who had the tear repaired during the primary surgery but did not require further intervention).

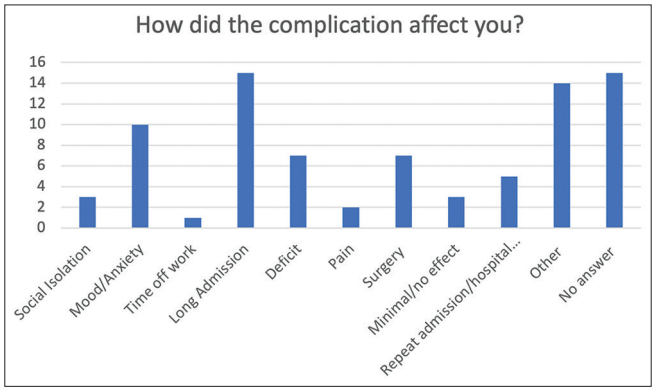

Figure 4: Impact of the complication on the patient.

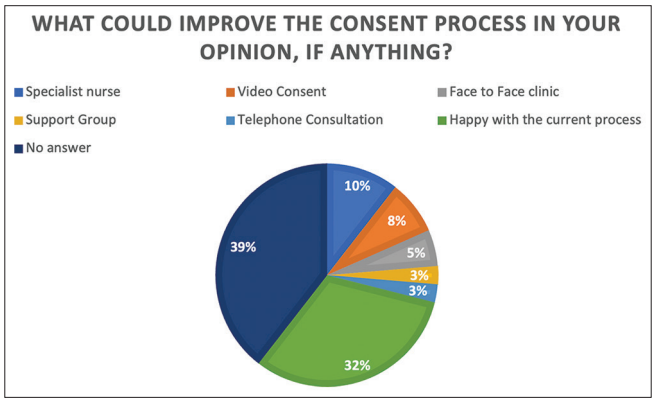

Figure 5: How patients felt the consent process could be improved.

that they explained the reason for the procedure, detailed benefits, and major risks, including uncommon and rare risks. However, 50% admitted to not specifically discussing the postoperative recovery time or alternatives.

About 39% stated that they always gave a copy of the consent form to take home; only 17% always gave information leaflets, with many being unaware that these resources existed. Only 15% admitted to documenting on the EPR or through a letter to the patient's General Practitioner. However, the registrars were generally only reconfirming consent rather than starting the process of consent. The consultants were the ones starting the consent process in the clinic and they had documentation about what was discussed and sent to the patient. All clinicians felt that they offered patients opportunities to ask questions about the procedure or its complications and felt that they discussed consent in lay terms with a good rapport with the patient. Common themes to improve the consent process include information leaflets or online resources, the training of doctors, consent clinics either through phone or in person, access to specialist nurses at all stages, and more time to carry out the consent consultation.

All patients, apart from four, were verbally consented to the clinic by the responsible consultant. The risks and benefits of the procedure were discussed and documented in the clinical letters. The four patients who did not have a clinical letter documenting the consent process were oncology patients who were admitted to the ward directly following a multidisciplinary meeting discussion.

NHS resolution

Three claims were made against the trust between January 2016 and December 2021. In all the cases, failure to consent was not the reason for the claim or the pay-out but just collateral to the main complaint.

The audit department

A trust-wide consent audit is undertaken annually by all specialties, which is then reported at a divisional level. The overall performance of the department has been satisfactory. Areas for improvement include documentation of demographics, evidence either on EPR or on the consent form that information leaflets have been provided, and evidence that the clinician has checked the patient's understanding. Most times the patient did not receive a copy of the consent.

A strengths, weaknesses, opportunities, and threats analysis was carried out utilizing the results of the patient/registrar questionnaires, trust audit department, and NHS litigation [Figure 6].

Neuropsychology input

The consultant lead for neuropsychology was interviewed through video-consultation. Her suggestions included:

- Where possible, a relative of the patient should be present during the consultation, to absorb some of

Table 2: Responses to patient telephone questionnaire.

Question number	Question	Yes	No	Unknown
1	Did you feel that the consent process was adequate for you to make an informed decision?	40	1	17
2	Was this your first surgical procedure?	19	22	17
3	Did you discuss the consent in the clinic?	34	7	17
4	Did you think the environment for discussion was appropriate?	36	5	17
5	Did you have enough time to make a decision?	36	5	17
6	Was a member of your family present/involved?	33	8	17
7	Did the surgeon explain			
	a. The reason for the procedure	41	0	17
	b. The details of the procedure	41	0	17
	c. The benefits of the procedure	41	0	17
	d. The major risks	40	1	17
	e. The uncommon risks	38	3	17
	f. The rare but severe risks	39	2	17
	g. The postoperative care and recovery time	34	7	17
	h. The consequences of not having the procedure/alternative treatment	34	7	17
	i. Was the language used simple enough	40	0	18
	j. Was the surgeon empathic/did you establish a rapport with them	39	1	18
8	Did you receive any material to take home (leaflet/QR code)?	34	7	17
9	Did you receive a copy of the consent?	24	17	17
10	Do you remember the most relevant complications of the procedure? (check what they remember and if relevant/appropriate)	31	10	17
11	Did you understand what the complications meant and what they would imply in terms of ongoing care?	28	13	17
12	Did the surgeon check that you understood the procedure/complications?	37	4	17
13	Was the consent confirmed with you on the morning of the surgery?	41	0	17
14	Did you have opportunities to ask questions before surgery?	40	1	17
15	Having now had a complication – would you make the same decision regarding surgery? (if no, why?*)	37	4	17
16	How did the complication affect you?			
	Social isolation	3		
	Mood/anxiety	10		
	Time off work	1		
	Long admission	15		
	Deficit	7		
	Pain	2		
	Surgery	7		
	Minimal/no effect	3		
	Repeat admission/hospital attendance	5		
	Other	14		
	No answer	15		
17	Do you feel that the complication is still affecting your quality of life, and based on this, would you have made the same decision	21	20	17
18	Would you have liked any more			
	a. Information on the day	7	34	17
	b. Material to take home (if yes, what: video/QR code/leaflet)	4	37	17
	c. Telephone consultation before surgery to check understanding/questions	7	34	17
19	What could improve the consent process, in your opinion, if anything?			
	Specialist nurse	4		
	Video consent	3		
	Face to face clinic	2		
	Support Group	1		
	Telephone consultation	1		
	Happy with the current process	12		
	No answer	15		
	Other	4		

*is the expansion of why the patient would not want to have surgery. Reason 1: life changed, experienced leg weakness and low mood. Reason 2: despite tumour regrowth the patient would not have surgery again due to previous complications

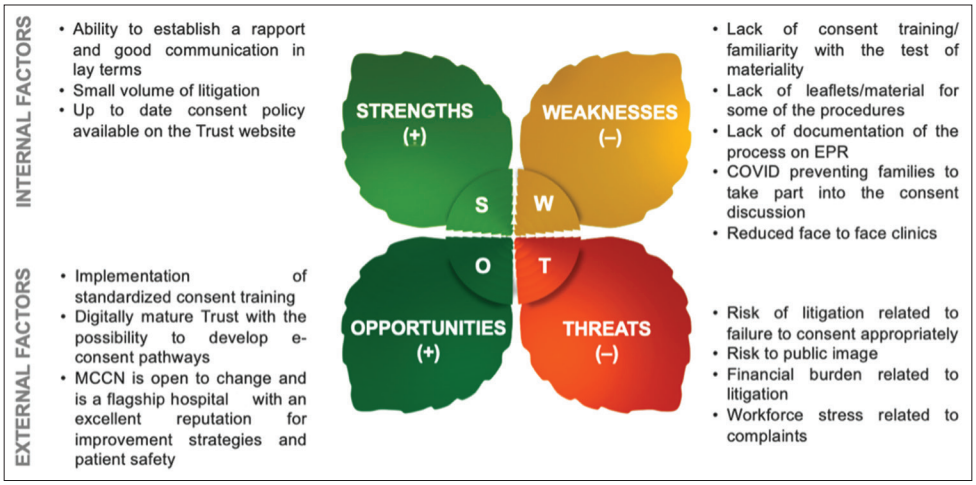

Figure 6: SWOT analysis. MCCN: Manchester Center for Clinical Neurosciences, EPR: Electronic patient record, SWOT: Strengths, weaknesses, opportunities and threats

the emotional distress and provide reassurance to the patient. The relative can also help to retain information and relay it to the patient at a later stage.

- Ensure leaflets/take home materials are available and include risks, alternative treatments, and an explanation of the most relevant complications.
- Clinicians responsible for the consent process should undertake legal/ethical mandatory training and communication skills training.
- Specialist nurses play a fundamental role in supporting patients in the pre-and post-operative period.

DISCUSSION

The need for informed consent arises from the legal concept of battery and the ethical principle of autonomy. In 1985, the Bolam test was questioned publicly for the 1st time after the ruling of *Sidaway versus Bethlem Royal Hospital Governors*.[12] In this case, a patient underwent a cervical cord decompression for neck and arm pain. The consenting doctor did not mention the <1% risk of causing paraplegia with surgery, and the patient woke up from surgery paralyzed. At the time, the case was dismissed as it was felt she had been adequately consented. Templeman *et al*. felt that volunteering unnecessary information may lead to a deterioration in the patient's physical or mental health as the patient may not undergo the treatment that they need. However, Lord Scarman dissented and stated that the Bolam test should not be applied to the issue of informed consent and that a doctor has to tell the patient the inherent and material risks of the treatment offered.[10]

This paternalistic culture was further called into question in 2004 when *Chester versus Afshar* was found in favor of the patient[12,16], but it was not until 2015 that the Bolam test was finally felt to be not applicable to issues pertaining to consent. This change materialized when *Montgomery versus Lanarkshire Health Board* found in favor of a diabetic pregnant woman who was not informed that she had a 10% risk of shoulder dystocia with vaginal delivery.[12] Ms Montgomery's son was born with cerebral palsy secondary to shoulder dystocia during delivery. The court agreed that if the patient had been told about the risk of dystocia, she would have chosen a cesarean section, and the baby would not have had cerebral palsy.

This case recognized the shift in health care from a paternalistic culture to a partnership between the patient and the doctor, with the patient having the right to know all risks that would be relevant to them as an individual. This test of materiality has replaced what the reasonable doctor would do with what the reasonable patient would want to know.[4,12] Whether consent was adequate or not in a clinical negligence claim would no longer be assessed with the Bolam test but by the test of materiality. Doctors must inform patients about all material risks, which are risks to which a reasonable patient would attach significance. This change has made it more challenging for hospitals to defend claims for failure of informed consent, which highlights the need for improved professional guidance and organizational strategies to help mitigate potential problems with informed consent.

The main ethical consideration related to informed consent is the concept of autonomy. Patients have the right to determine what treatment they consent to, and doctors must respect their wishes.[18] Patient's understanding and knowledge make the difference between consent and informed consent.[8] The concept of informed consent means that the patient understands their diagnosis and the different treatment options available (including the option of not intervening), together with advantages, disadvantages, and possible outcomes for each option.[5] Informed consent

must be given voluntarily, with no coercion or deceit, by an individual who has the capacity and has been fully informed.[15]

This study demonstrated that the consent process within the neurosurgery department of our trust is overall satisfactory, though there were areas for improvement. This is evidenced by the overall satisfaction of patients with the consent process, as demonstrated by the patient questionnaires and very small numbers of litigation cases related to failure to consent.

Our trust has already implemented several strategies to support the consent process, such as an up-to-date consent policy available online, leaflets, and QR codes for some of the most common procedures. Yearly consent audits are carried out and consent is also reconfirmed on the morning of surgery to offer a further opportunity for patients to clarify anything that they are unsure of. The literature reveals a multitude of issues that can cause the consent process to fail, including too much or not enough information, too much medical jargon, information leaflets pitched at a level the patient cannot understand, and time pressures, to name but a few.[17] While there is little evidence that multimedia improves comprehension of the consent process,[6] this may help if used synergistically with a consultation with the surgeon or in people with low literacy levels.

COVID-19 had a significant impact on standard practice throughout the UK, as a limited number of face-to-face clinics were available, and family members were not allowed to come into the hospital. The patients' questionnaire and neuropsychology input have highlighted the importance of family support and face to face consultations for an optimal consent process.

The report from the NHS resolution and the findings of the clinicians' questionnaire have been discussed with the Legal team that supports the trust. Consent training has been identified as an area of weakness. More importance needs to be given to the patient's understanding of the complications of a procedure and how these may affect them as an individual/their quality of life. Registrars need to be made aware that, further to signing the consent form, they need to record the encounter with either a clinic letter or a note on EPR.

The findings of this study have once again confirmed the invaluable contribution of specialist nurses. Patients value the possibility of reaching out to them pre-and post-operatively, as they play an irreplaceable role in reassuring patients and their families and answering questions/conveying information. The lack of patient support groups has been highlighted and attempts are being made to try and re-establish these in some specialties in the post-COVID era.

As a result of the project, areas of improvement were identified that could be applied to most hospital trusts to improve the consent process. These include:

1. Regular consent teaching sessions for clinicians, supported by the trust legal team. Topics should be based around the "three-legged stool" and should include the legal and ethical principles of consent and the importance of accurate documentation
2. These sessions could be recorded and included as part of mandatory training on Induction of new registrars
3. Clinicians should be encouraged to attend communication skills courses
4. Face to face consultations should be the preferred modality when patients need to be consented. Family members should be encouraged to attend
5. "Consent clinics" have been considered as a possible strategy, but they pose issues in terms of staffing and the availability of clinical space. Allied healthcare professionals such as physiotherapists or neuropsychologists may be able to offer support to either deliver information or confirm consent.
6. Leaflets and QR codes can be developed to cover more procedures
7. Patients who had experienced prolonged hospital stays and complications could lead patient support groups
8. More specialist nurses in different subspecialties can offer further support to patients and families
9. Electronic consent pathways will be helpful in reducing paperwork, facilitating recording of the process, and helping shared decision making.

CONCLUSION

Informed consent is a delicate moment of communication between a clinician and the patient. Regular training and good communication skills help staff to focus on the most relevant aspects of consent, which should be delivered in an appropriate environment and with family support. Audio-visual aids can support the process but do not replace good communication.

Ethical approval

The research project has been registered with the Hospital's Audit department and has been conducted according to the ethical principles of the Declaration of Helsinki for medical research (The World Medical Association 2008).

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

Use of artificial intelligence (AI)-assisted technology for manuscript preparation

The authors confirm that there was no use of artificial intelligence (AI)-assisted technology for assisting in the writing or editing of the manuscript and no images were manipulated using AI.

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APPENDIX

Appendix 1: Survey questionnaire for healthcare professionals.

1. How many years of experience in neurosurgery do you have?
2. Have you been formally trained to obtain consent for surgical procedures?
    - If yes, when/in what context
    - If not, how have you learnt how to consent to a patient
3. Are you aware of the "Bolam test"? What does it mean?
4. Are you aware of the Montgomery ruling/test of materiality? What does it mean?
5. Are you aware of the ethical principles behind the consent process/shared decision making?
6. Are you aware/have you read the GMC guidance and the Royal College of Surgeons guidance on consent?
7. Are you aware that the Trust has a consent policy?
    - Have you read it?
8. When you consent to a patient, do you explain
    - The reason for the procedure
    - The details of the procedure
    - The benefits of the procedure
    - The major risks
    - The uncommon risks
    - The rare but severe risks
    - The postoperative care and recovery time
    - The consequences of not having the procedure/alternative treatment
9. Do you record the above process in EPR/dictate a letter to the GP?
10. Where do you normally obtain consent from patients?
11. How much time do you give them to make a decision?
12. Do you give the patient opportunities to ask questions before surgery/clarify doubts?
13. Do you check that the patient understood the procedure/complications?
14. Do you involve family members?
15. Do you use simple/lay terms?
16. Are you empathic/do you establish a rapport with the patient?
17. Do you normally provide any material to take home (leaflet/QR code)?
18. Do you provide a copy of the signed consent form to the patient?
19. Do you confirm consent on the morning of surgery?
20. What could improve the consent process, in your opinion, if anything?