Ain Shams Journal of Forensic Medicine and Clinical Toxicology
January 2025, 44: 1-11

Assessment of the Consenting Process Obtained for Neurosurgical Interventions

Esraa Gamal Gaber[1], Gamal Nasser Eid El Sayed[1], Mohamed Abdel Rahman Mohamed[2], Emad Ahmed El Sayed Mostafa[1]

[1] Department of Forensic Medicine and Clinical Toxicology, Faculty of Medicine, Ain Shams University, Cairo, Egypt.
[2] Neurosurgery Department, Ain Shams University Hospital, Cairo, Egypt.

Abstract

Background: Informed consent for surgical procedures is a vital part of surgical practice, surgeons cannot practice their trade without valid informed consent.
Aim & Objective: The present study aimed to assess the current status of the medical consenting process for neurosurgical interventions.
Methods: A total number of 200 files of patients who underwent neurosurgical intervention in the neurosurgery department at our institution were included in the study and divided equally into two groups; 100 files of patients operated upon on an elective basis and 100 files of patients operated upon on an emergency basis. Assessment of the consenting process in each case was evaluated according to a designated checklist. The acquired data was statistically analyzed.
Results: In the present study, there were no considerable differences between the consent forms for the patients undergoing elective and emergency surgeries. Overall, the consent process in both groups of surgeries was of adequate quality.
Conclusions: The existing consent process performed reasonably well in adherence to general standards. While overall adherence to standards was satisfactory, there is an opportunity to enhance patient-centered care by expanding discussions regarding alternative options and their risks. Providing patients with detailed information about the potential outcomes of various treatment options, including the option of no treatment, can empower them to make more informed and personalized decisions about their health.

Received in original form: 8 September 2024
Accepted in a final form: 14 November 2024

Key words Ethics, Informed consent, Neurosurgery, elective, emergency

Introduction

Valid consent is a central requirement in all forms of health care. For surgery, informed consent (IC) has become a critical component of surgical practice; surgeons cannot practice their trade without valid consent (Hanson and Pitt, 2017).

Informed consent blends law, medicine, and bioethics in a multifaceted process to enhance patient understanding and obtain permission before healthcare interventions (Madeira et al., 2017).

Informed consent achieves two fundamental moral values: patient well-being and autonomy. It emphasizes the meaning of human dignity as clarified in the Universal Declaration of Human Rights (Cordasco, 2013).

In surgery, the informed consent process should ensure that the patient fully understands the risks, benefits, and alternatives to a proposed surgical procedure before agreeing to undergo it. It is a shared decision-making process between the patient and the healthcare provider (Conti, 2017).

Getting or giving consent is frequently a process, not a one-off occurrence. Patients can change their minds and withdraw consent at any moment. If they desire, they can withdraw consent after signing a form; the signature is proof of the consent-giving procedure, not a binding contract (Bernat and Peterson, 2006).

Different studies in Western (Netherlands, UK) and Middle East (Pakistan) countries revealed that the practice of proper surgical informed consent (SIC) among health-care providers was suboptimal and did not meet the minimum standards when they conducted informed consent with patients. These studies found that the informed consent process contained incomplete information and often did not ensure their patients' direct involvement in the process (Hall et al., 2012; Leclercq et al., 2013; Akyuz et al., 2019).

Neurosurgical procedures, in particular, often assume high risks to the physical as well as mental health of the patients, dictating more respect for the consent of the patient to be operated upon (Schmitz and Reinacher, 2006).

The 1986 American Association of Neurological Surgeons Code of Ethics implied medicolegal liability for the failure to obtain informed consent (Shlobin et al., 2020).

For consent to be valid, the patient must have the capacity and competence to take the particular decision, and surgeons must provide sufficient information to the patient, who should not be acting under duress. Added to this, the surgeon must keep up with patient and legal expectations (Hanson and Pitt, 2017).

In recent decades, the medical community has become increasingly concerned about inadequate documentation and inappropriate consent practices prior to surgical intervention (Hanson and Pitt, 2017).

Egypt established clear legal compliance with the informed consent process. Following Egyptian Penalty Law (Subjects 240 and 241), the practitioners may be blamed if they fail to get sufficient informed consent and the patient is harmed as a result of their conduct (National Legislative Authorities, Egypt, 1937) and (Mohamed et al., 2024).

This study aimed to assess the current status of the medical consenting process for neurosurgical interventions.

Materials and Methods

Study Type:

This study was a retrospective cross-sectional study.

Study Setting:

Data about the informed consent were obtained from the archive of the Ain Shams University Hospital.

Study Population:

Inclusion criteria:

- Files of patients who underwent neurosurgical interventions on an elective or urgent basis in 2022.

Files were randomly selected using systematic random sampling.

Exclusion criteria: none

Patient selection and sample size:

During the period of the study, 2534 patients visited the neurosurgery department for surgical interventions; out of them, there were 1058 elective cases and 1476 emergency cases.

Assuming the rate for adequate consenting process of 15% ranging between 3% and 22%, a sample of 62 patients files for each group were enough to detect such rate at 90% confidence level, this sample was expanded to include 200 patients files: 100 patients who were operated on an elective basis and 100 patients who operated on an emergency basis.

Files used for the study were randomly selected using systematic random sampling (number of total files/sample size), choosing a random start, and then selecting every (i^{th}) unit at regular intervals (each 11^{th} file for the elective group and the 15^{th} file for the emergency one).

The elective and emergency groups were compared with each other to fulfill the standard criteria of the consenting process.

Study tools

The consenting process in each case was evaluated according to a designated checklist. The items on the checklist and the criteria for each item have been selected from the accessed scientific literature (Leclercq et al., 2013; Bajada et al., 2017 and Kamer et al., 2018) to assess the validity and quality of the consenting process.

Checklist Items (Parameters of Valid Consenting):

i. The presence of hospital policy about the process of valid consenting.
ii. Checking for the consent components.
iii. Fulfilling the items of the preconditions.
iv. Fulfilling the items of information (disclosure).
v. Voluntariness.

Every item on the checklist characterizing a good consenting process was scrutinized in the selected patient files for its presence and characteristics. Every item was evaluated as follows:

a. Absent.
b. Present but improperly fulfill the required standard criteria.
c. Present and properly fulfill the required standard criteria.

According to the above classification, each item was scored 0, 1, or 2, respectively.

Ethical Considerations

The study protocol was approved by the Research Ethics Committee of the Faculty of Medicine at Ain Shams University (FWA 000017585) on January 15, 2023.

Official permission was obtained from the manager of the surgery hospital and the head of the Neurosurgery Department. All patients' data were kept anonymous to ensure the confidentiality of records.

Data Analysis and Statistical Study

The data collected in each group according to the valid consenting checklist were revised, coded, tabulated, introduced to a PC, and analyzed using a statistical package for social sciences (IBM SPSS 20.0). Data was presented and suitable analysis was done according to the type of data obtained for each parameter.

Results

Demographic data:

This present study included 200 patients: 100 patients who were operated upon on an elective basis and 100 patients operated upon on an emergency basis.

Out of the 200 patients, 66 were below the age of 18 (30 in the elective group and 36 in the emergency one) while there were 134 patients over the age of 18 (70 in the elective group and 64 in the emergency) with 106 patients were males and 94 were females as shown in table (1).

Assessment of checklist items:

I. The validity of the standardized policy.

As shown in table (2) the hospital follows a policy supporting the consenting process and specific guidelines for obtaining consent for elective surgery.

II. Checking for items of the consent components

As shown in table (3) there was a statistically significant difference between elective and emergency groups of neurosurgical interventions regarding fulfilling the consent components items.

The consent document was completely present in both groups. In the elective group, only 67% of the consents were written in a clear, concise, complete, without abbreviations, legible, in ink, and understandable manner. In comparison, this percentage was higher (84%) in the emergency group.

Regarding the time of the consent, it was signed before the operation in about 20% of elective cases, but about 76% was signed on the same day of the operation. In the emergency group, the consents were signed on the same day of the emergency operation.

III. Checking for the fulfillment of the elements of the preconditions

Table (4) shows a statistically significant difference between the elective and emergency groups as regards fulfilling the preconditions where the patient signature was not properly filled in about 9% of the elective files and 22% of the emergency being either the patients name was not completely written or a relative signed instead of the patient.

The personal information of the patients and the patient's competency to make decisions were properly fulfilled in both groups.

The information about the operating surgeon was not applicable in both groups as a team of surgeons did the operations so; it was difficult to determine a specific surgeon. The signing doctor was almost a neurosurgical resident.

IV. Items of disclosure of information

Table (5) shows a statistically significant difference between the emergency and elective groups regarding fulfilling the items of disclosure where the presence of the diagnosis, indication/s of operation, the type/nature of the neurosurgical procedure, the potential risks and complications of the surgery were properly mentioned in both groups.

The consequences of not undergoing surgery were not mentioned in any file. There is a statistically significant difference between the emergency and elective groups regarding the presence of alternative medical options like conservative treatment in favor of the elective group.

The type of anesthesia and its risks were more explained and fulfilled in 26% of the elective group files and was written without mentioning its risks in 74% of elective files compared to the emergency cases files it was 2% and 98% respectively.

V. Checking for evidence of voluntariness

Table 6 shows that there was no statistically significant difference between the elective and emergency groups as regards fulfilling the items of voluntariness.

In 96% of elective cases, the patients signed the consent, but in 4%, it was unclear who the relative was and why.

As shown in Table (7), there was no statistically significant difference between the elective and emergency groups when comparing the total score of checklist items out of the highest score of 32 (16 items*2).

Table 1: Age and sex distribution of the studied patients.

Variables		Elective group No. = 100	Emergency group No. = 100	Test value	P-value
Age (years)	Median (IQR)	33 (9 - 47)	28 (10 - 49.5)	-0.402‡	0.688 (NS)
	Range	0.02 – 70	0.003 – 87		
	Age < 18	30 (30.0%)	36 (36.0%)	0.814*	0.367 (NS)
	Age ≥ 18	70 (70.0%)	64 (64.0%)		
Sex	Female	60 (60.0%)	34 (34.0%)	13.569*	0.000 (HS)
	Male	40 (40.0%)	66 (66.0%)		

P-value >0.05: Non-significant (NS); <0.05: Significant (S); < 0.01: highly significant (HS). *: Chi-square test; ‡: Mann Whitney test.

Table 2: Checklist items related to hospital policy for valid consenting process.

Checklist Items	Score
1. Presence of policy supporting proper medical consenting	2
2. Presence of guidelines for obtaining consent for elective surgery	2

Table 3: Comparative statistical analysis regarding consent component items among the files of patients who underwent neurosurgical interventions (elective or emergency) in the neurosurgery department ASUH from January 2022 to December 2022.

The consent component items	Score	Elective group	Emergency group	Test value	P-value
		No. = 100	No. = 100		
1) Presence of consent	0	0 (0.0%)	0 (0.0%)	NA	NA
	1	0 (0.0%)	0 (0.0%)		
	2	100 (100.0%)	100 (100.0%)		
2) Quality of consent documentation	0	2 (2.0%)	0 (0.0%)	8.701*	0.013 (S)
	1	31 (31.0%)	16 (16.0%)		
	2	67 (67.0%)	84 (84.0%)		
3) Date of the Consent	0	4 (4.0%)	0 (0.0%)	133.333*	0.000 (HS)
	1	76 (76.0%)	0 (0.0%)		
	2	20 (20.0%)	100 (100.0%)		
The total highest score of the consent component items (6)	Median (IQR)	5 (4 – 5)	6 (6 – 6)	-10.357‡	0.000 (HS)
	Range	3 – 6	5 – 6		

P-value <0.05: Significant (S); < 0.01: highly significant (HS). *: Chi-square test; ‡: Mann Whitney test / NA: Not Applicable.

Table 4: Chi-square and Mann-Whitney tests comparing the fulfilment of the items of preconditions among the files of patients who underwent neurosurgical interventions (elective or emergency) in the neurosurgery department ASUH from January 2022 to December 2022.

The preconditions items	score	Elective group	Emergency group	Test value	P-value
		No. = 100	No. = 100		
1) Personal information about the patient (name, age, sex)	0	0 (0.0%)	0 (0.0%)	NA	NA
	1	0 (0.0%)	0 (0.0%)		
	2	100 (100.0%)	100 (100.0%)		
2) Patient's competency to make the decision	0	0 (0.0%)	0 (0.0%)	NA	NA
	1	0 (0.0%)	0 (0.0%)		
	2	100 (100.0%)	100 (100.0%)		
3) Patient signature or fingerprint with an identity card number	0	1 (1.0%)	8 (8.0%)	13.396*	0.001 (HS)
	1	9 (9.0%)	22 (22.0%)		
	2	90 (90.0%)	70 (70.0%)		
4) Operating surgeon information	0	NA		NA	NA
	1				
	2				
5) The signature of the staff member *(Full name /Signature (At a minimum, signatures must include the first initial of the first name and the full last name)/Licensure and/or designation (e.g., MD, M.S) /Date of signature	0	15 (15.0%)	28 (28.0%)	32.438*	0.000 (HS)
	1	58 (58.0%)	72 (72.0%)		
	2	27 (27.0%)	0 (0.0%)		
The preconditions total highest score (10)	Median (IQR)	7 (7 – 7)	7 (6 – 7)	-5.862‡	0.000 (HS)
	Range	4 – 8	4 – 7		

P value < 0.01: highly significant (HS), *: Chi-square test; ‡: Mann Whitney test / NA: Not Applicable.

Table 5: Chi-square and Mann-Whitney tests comparing the fulfilment of the items of disclosure among the files of patients who underwent neurosurgical interventions (elective or emergency) in the neurosurgery department ASUH from January 2022 to December 2022.

The information (Disclosure) items	Score	Elective group	Emergency group	Test value	P-value
		No. = 100	No. = 100		
1) Diagnosis and indication of the operation	0	0 (0.0%)	0 (0.0%)	NA	NA
	1	0 (0.0%)	0 (0.0%)		
	2	100 (100.0%)	100 (100.0%)		
2) The type/nature of the neurosurgical procedure	0	0 (0.0%)	0 (0.0%)	NA	NA
	1	0 (0.0%)	0 (0.0%)		
	2	100 (100.0%)	100 (100.0%)		
3) The potential benefits of the operation	0	0 (0.0%)	0 (0.0%)	NA	NA
	1	0 (0.0%)	0 (0.0%)		
	2	100 (100.0%)	100 (100.0%)		
4) The consequences of not undergoing surgery (The risks and benefits of doing nothing)	0	100 (100.0%)	100 (100.0%)	NA	NA
	1	0 (0.0%)	0 (0.0%)		
	2	0 (0.0%)	0 (0.0%)		
5) The potential risks and complications of the surgery	0	0 (0.0%)	0 (0.0%)	NA	NA
	1	0 (0.0%)	0 (0.0%)		
	2	100 (100.0%)	100 (100.0%)		
6) Alternative options; their risks and benefits	0	94 (94.0%)	100 (100.0%)	6.186*	0.04* (S)
	1	4 (4.0%)	0 (0.0%)		
	2	2 (2.0%)	0 (0.0%)		
7) The type of anesthesia and the risks of it	0	0 (0.0%)	0 (0.0%)	23.920*	0.000 (HS)
	1	74 (74.0%)	98 (98.0%)		
	2	26 (26.0%)	2 (2.0%)		
The total highest score of (Disclosure) (14)	Median (IQR)	9 (9 – 10)	9 (9 – 9)	5.392‡	0.000 (HS)
	Range	9 – 12	9 – 10		

P-value <0.05: Significant (S); < 0.01: highly significant (HS), *: Chi-square test; ‡: Mann Whitney test; NA: Not Applicable.

Table 6: Mann-Whitney test comparing the fulfilment of the items of voluntariness among the files of patients who underwent neurosurgical interventions (elective or emergency) in the neurosurgery department at ASUH from January 2022 to December 2022.

The item	Score	Elective group	Emergency group	Test value	P-value
		No. = 100	No. = 100		
1) Who signed the consent and why?	0	4 (4.0%)	1 (1.0%)	1.846*	0.174 (NS)
	1	0 (0.0%)	0 (0.0%)		
	2	96 (96.0%)	99 (99.0%)		

P-value >0.05: Non-significant (NS). *: Chi-square test

Table 7: Mann-Whitney test comparing the elective group and the emergency group scores regarding the fulfillment of all checklist items of the consenting process mentioned in the previous tables.

The total score of all checklist items (32)	Elective group	Emergency group	Test value	P-value
	No. = 100	No. = 100		
Median (IQR)	23 (22 – 24)	23 (23 – 24)	-0.646‡	0.518 (NS)
Range	18 – 27	20 – 25		

P-value >0.05: Non-significant (NS). ‡: Mann Whitney test.

Discussion

The present study was a retrospective cross-sectional study that evaluated the consenting process in neurosurgery. The study included 200 cases of patients' files that were divided into two equal groups; elective and emergency groups.

Upon comparing checklist items of the consenting process between both the emergency and elective groups, the following data were obtained:

I. Checking for the validity of the standardized policy

In the present study, the presence of a hospital policy regulating the consenting process is considered a good practice as without a defined standard policy, the consenting process might vary between individual healthcare professionals, potentially leading to unequal or incomplete information for patients.

In addition, without clear guidelines, patients might not be fully aware of their rights and options (Olejarczyk and Young, 2022).

A well-defined consent policy in surgical specialties is crucial for standardization, patient empowerment, legal compliance, ethical adherence, and educational training. It ensures consistency across departments minimizes variations and promotes patient autonomy (https://guides.unmc.edu/books/hrpp-policies-and-procedures/chapter/section-5-informed-consent).

II. Checking for the consent component items

In the current study, the presence of the consent forms in all files of the study sample indicates that the significance of this document was appreciated.

Additionally, a cross-sectional observational study by Patil et al. (2023), conducted over one year at an urban hospital, found that 219 (99%) of the cases had informed consent forms for surgery.

In contrast, Vieira et al. (2023) reported that only 47% of the informed consent documents were found in the clinical files. This difference could be because of cultural variations, where patients in some situations completely rely on their doctors to make health-related decisions (Nsahlai et al., 2022).

Good consent forms a medico-legal defense for the treating surgeon in case of an adverse outcome or complaint, even in an emergency (France and Hayhurst, 2018).

In the present study, the quality of the written consent was acceptable. In the emergency cases, it was even better which may be explained as the urgency of these procedures often demands immediate action. This can create a sense of urgency and focus, leading to more concise, yet informative documentation.

This is inconsistent with Sönmez et al. (2020), who use special formulas for calculating the readability level of consent forms and found that elective informed consent forms (ICFs) are more readable compared to those of emergency procedures and concluded that the level of illegibility can cause problems for doctors at the legal stage.

Also, consent forms that are easy to read and understand should be provided to account for morbidity and mortality and improve prognosis.

In addition, Shemesh et al. (2019), who conducted personal interviews with patients to assess the quality of the informed consent process in trauma compared with elective orthopedic patients, observed that patients in the elective group had an overall higher quality of consent, as reflected by a mean score of 17.03 ± 4.2 versus a mean score of only 13.73 ± 4.7 in the trauma group ($p = 0.005$, 95% CI: 1.02–5.57).

Moreover, Wood et al. (2016), who conducted interviews with doctors in two teaching hospitals in the UK, noted that working in time-pressured environments affects the quality and amount of information given to patients.

Legibility is one of the key components of consent that can be lacking in handwritten consent forms, so literature has revealed that consent forms that have already been printed make the consenting process more effective (Baker et al., 2021) because there is less writing to do so, less time pressure, and patient experience and comprehension are improved by preprinted consent forms (Dyke et al., 2023).

In this study, the difference in time of signing the consent between the elective and emergency interventions was justified as in the emergency there is no luxury of timing in contrast to the elective cases.

The elective cases are admitted to the university hospital two or three days before the day of their operation for adequate anesthetic preparation. During this time, the patients and their relatives could ask questions and completely understand their options and prognosis. Thus, we found that most of the consents for elective procedures were signed on the same day of the procedure.

Consistent with a study done by Munawar et al. (2023), who conducted a Google Form questionnaire with patients who had undergone elective surgical procedures at the Department of General Surgery, Lahore, Pakistan, found that in 96.7% of cases, consent was obtained just before surgery.

The time spent communicating with the patient is an integral part of the health treatment path (Pallocci et al., 2023).

III. Checking for the fulfillment of the preconditions

Assessing a patient's capacity is crucial for ensuring ethical and legal decision-making in healthcare. It protects patients from undergoing procedures they cannot understand or consent to (Poppe et al., 2020).

In the present study, the patient's decision-making capacity was carefully assessed. This indicates that the patients fully understood the nature of the procedure, its potential risks, and benefits.

Capacity or lack of capacity should not be assumed based on a patient's diagnosis or condition. For example, a patient with an intellectual disability may be able to make decisions about their health treatment if information is provided to them appropriately (NSW, 2020).

It is crucial to have a designated surrogate decision-maker when dealing with individuals who

might lack the capacity to consent due to age, illness, disability, or other factors (Lane et al., 2021).

In the current study, the signature of the staff member who obtained the consent was present in only 157 (87.5%), and the staff member who took the consent was always the resident which can be justified as the residents are in contact with patients more than other surgeons in the team.

In contrast, a prospective cross-sectional study conducted in the Department of Gynecology and Obstetrics of University Clinical Hospital Mostar for 6 months by Perić et al. (2018) revealed that most patients (83%) signed informed consent at the demand of a nurse.

This is heterogeneous with Arshad et al. (2022), who conducted a cross-sectional study from February to August 2018 at a tertiary care hospital in Lahore, Pakistan, and reported that the operating consultants informed 41 (40.6%) patients about the surgery.

The law does not state who on the surgical team is responsible for obtaining informed consent. Younger members of the surgical team are frequently in charge of gaining consent. However, the main surgeon should be responsible for obtaining adequate informed consent (Kumar et al., 2021).

In the present study, none of the patients knew the name of the surgeon responsible for the surgery. It can be justified that most neurosurgical interventions in university hospitals are performed by a team of surgeons like the spine team, pediatric neurosurgery team, trauma team, etc.

Similarly, Vikas et al. (2021), who conducted a prospective study over 12 weeks in various surgical departments of a 1000+ bedded tertiary care hospital, found that none of the forms (0%) contained the names of all practitioners performing the procedure.

IV. Checking for the fulfillment of the information (disclosure) items

The appropriateness of disclosure in informed consent should be a clinical judgment, with medical standards set by the medical profession. The ideal informed consent process should be a layered structure, with each item logically arranged. The doctor should explain the diagnosis, ramifications, prognosis, recommended procedure, alternatives, and patient questions, including potential benefits, risks, burdens, and side effects (Shemesh et al., 2019).

Furthermore, many experts agree that there is a challenge with the amount and complexity of information that surgeons have to present to their patients (Nsahlai et al., 2022).

In this study, information about the diagnosis was provided in all consent forms. This finding demonstrates that the consenting process was conducted ethically and transparently.

In contrast to Kurt et al. (2016), who performed a study at Gulhane Medical Faculty between July 2012 and July 2013 on patients who were on the third postoperative day after various surgical procedures and reported that only 73.5% (n = 294) of the patients were informed about the diagnosis and treatment of the disease.

Also, a study done by Patil et al. (2023) stated that information about the nature and indication of the surgery was given to 200 (90.5%) and 215 (97.28%) patients, respectively.

Patients must be respected and supported to make decisions about their health and well-being, recognizing their legal and moral right to set personal goals and make treatment choices. For this to happen in practice, patients should understand the effects of suggested surgeries and treatments and consider lifestyle preferences in their decisions (Pirotte et al., 2023).

In the current study, information about the surgical details, and the potential benefits and complications of the operation were received by all patients. This is consistent with a study by Patil et al. (2023) that revealed 90% of patients were informed about the nature and indication of the surgery.

Similarly, Vikas et al. (2021), stated that all the patients were informed about their clinical condition or problem, while only 34% were informed about the risk and 26% about the alternative options. All the forms (100%) had a statement regarding the nature of the neurosurgical procedure.

Unlike a study by Li et al. (2014), which revealed that patients were inadequately informed on the complications of the proposed procedure, alternative forms of treatment, risks, and benefits of the surgical procedure. They emphasized that healthcare providers should provide adequate information regarding the proposed surgical operation and they should make sure patients understand the risks and benefits before signing the consent.

Since all invasive operations have some degree of danger, it is the surgeon's legal duty to fully disclose to patients the risks and advantages of the surgery (Sarker, 2020).

Patients must be informed of the benefits, drawbacks, and available treatment options essential for making wise decisions (Jalal et al., 2023).

Mussa et al. (2014), who studied the consent of elective total hip and knee replacement surgeries, mentioned that information about the benefits and risks of surgery was documented in 89% of the consent forms.

Tamire and Tesfaw et al. (2022), reported that nearly half (68, 48.9%) of the patients were informed of the benefits of the surgical procedure.

Mentioning the risks of not undergoing the surgical procedure in consent forms is crucial for patients who need a complete understanding of both options to make informed choices. Also, knowing potential consequences empowers them to weigh risks and benefits aligned with their values (Hanson and Pitt 2017).

This transparency builds trust between patients and surgeons prevents unrealistic expectations about what could happen without the surgery and improves compliance with pre- and post-op instructions as patients understand the potential risks of not following them.

Telling the patients about alternative options and their risks and benefits is a valid concern and patients need to be aware of all their treatment options. Even if surgery might be the best course of action, the patients still should be informed of this.

Tamire and Tesfaw, (2022) found that 66 (47.5%) of patients were informed of alternatives to surgery. Patil et al. (2023) proved that the alternative treatment options to the consented operative procedure were informed to 91 (40.72%) patients.

Also, Kurt et al. (2016), mentioned that 76.8% of patients (n = 307) were informed about the treatment options alternative to surgery and their benefits and risks.

Patients should be educated about different treatment options, including surgical and conservative options, along with the risks and advantages of each. This is part of the informed consent process. Following unrestricted access to all treatment choices, the patients will collaborate with the operating surgeon to determine the best course of action (Patil et al., 2023).

In this study, most patients were informed about the type of anesthesia to be used without mentioning its risks. This is because of a separate anesthesia consent form in each patient's file informed by the anesthesia team.

This finding was congruent with the study conducted in South Eastern Ethiopia, where the majority of respondents were not informed about the type of anesthesia to be used (Negash et al., 2021), and another study by Patil et al. (2023), where 58.37 % of the patients knew the type of anesthesia used for their elective surgery.

Munawar et al. (2023) conducted a Google Form questionnaire with patients who underwent surgical procedures at the Department of General Surgery, Pakistan, and found that 13.7% of patients were informed about the type of anesthesia. However, Mussa et al. (2014) stated that types of anesthesia were documented in 92% of the consent forms.

V. Checking for evidence of voluntariness

In the current study, almost all the patients or their relatives (when indicated) signed the consent voluntarily.

A comparative analysis of the informed consent process for elective and emergency interventions revealed no statistically significant differences. Both groups demonstrated substantial adherence to established standards, suggesting that the consenting process is consistently applied across intervention types.

This is inconsistent with Akkad et al. (2004), who found significant differences in the consent process between elective and emergency procedures.

Vieira et al., (2023) found that the compliance in filling out the informed consent was lower in emergency surgeries, with only 38% of signed consents in such procedures.

Our study is consistent with Shemesh et al. (2019), who conducted a prospective observational study at an Orthopedic Department, over 2 years through personal interviews using a proposed informed consent score and concluded that patients undergoing trauma surgery were significantly more likely to have an inadequate understanding of the proposed treatment.

The distinction between elective and emergency surgery lies in the patient's capacity to consent. In emergencies, doctors may use a surrogate decision-maker.

If the patient is incapable and no replacement decision-maker is available, the doctor's treatment is considered appropriate. In clinical emergencies, treatment may be given if the patient's wishes cannot be ascertained (Lin et al., 2019).

Strategies to Improve the Informed Consent Process

While the process of informed consent is designed to transfer knowledge of the risks and benefits of treatment and to engage patients in shared medical decision-making, this is poorly done in routine clinical care (Spertus et al., 2015).

A situation which necessitated innovative strategies to accomplish the Institute of Medicine's goals for safer, more efficient, evidence-based care that respects patients' individual preferences (Institute of Medicine, 2001).

Surgeons should be informed about modern standards in surgical informed consent. They must keep up to date with patient and legal expectations. Improving the efficiency of obtaining patient consent enhances patient comprehension and quality of care. Patient safety and quality of care are at risk if the informed consent process does not emphasize patient comprehension (Abujarad et al., 2017).

A strong policy reinforces ethical principles like informed consent and shared decision-making, fostering trust and relationships. In neurosurgical departments, core principles like informed consent, voluntariness, and competence are common. The policy should cover introduction, roles, disclosure, documentation, exceptions, and education (https://www.powerdms.com/policy-learning-center/what-is-the-purpose-of-policies-in-the-workplace).

Understanding the baseline health literacy level, knowledge, and information needs of each patient regarding the treatment will help neurosurgeons tailor their communication to an appropriate level (Renovanz et al., 2019).

Engaging the patient's support system, including spouses or family members when possible, will improve patient recall through shared family recall (Saigal et al., 2015; Shlobin et al., 2020).

Incorporating a specialized consent form with points to check off upon discussion found that 100% of patients correctly recalled their diagnosis and planned procedure, and 98.1% of alternative treatments and 97.4% of risks were recalled correctly (Berg et al., 2001).

The introduction of an interactive educational website improved the patients' knowledge than before its introduction (Shlobin et al., 2020).

Lastly, recall examinations can be used to optimize the consent process by guiding teaching methods, prompting the use of additional educational

resources, and directing the surgeons to focus on certain content (Saigal et al., 2015).

When used together interactively, these strategies will interact synergistically to improve patient understanding (Marcus, 2018).

Ensuring patients have realistic expectations for their possible outcomes is critical to facilitating a smooth consenting process and providing good communication skills (Maher et al., 2021).

Conclusion and Recommendations

The study examined how well-informed consent was given for neurosurgery procedures. It found that the process generally followed established guidelines but could be improved by discussing more treatment options with patients. This would help patients make better choices about their care. To improve informed consent in neurosurgery, it's important to include more diverse patients in studies, educate everyone about correct consent practices, and teach patients about the consent process. Regular reviews of the process can help find areas for improvement. Monitoring changes and studying legal cases related to informed consent can also provide valuable insights for planning future improvements.

References

Abujarad F., Alfano S., Bright T. J., Kannoth S., Grant N., Gueble M. et al. (2017): Building an informed consent tool starting with the patient: the patient-centered virtual multimedia interactive informed consent (VIC). In AMIA Annual Symposium Proceedings. American Medical Informatics Association,374:2-17.

Akkad, A., Jackson, C., Kenyon, S., Dixon-Woods, M., Taub, N., and Habiba, M. (2004): Informed consent for elective and emergency surgery: questionnaire study. BJOG: an international journal of obstetrics and gynaecology, 111(10): 1133–1138.

Akyuz E., Bulut H. and Karadag M. (2019): Surgical nurses' knowledge and practices about informed consent. Nurs Ethics, 12:1–13.

Arshad, M. A., Omar, N., Amjad, Z., Bashir, K., Irfan, M., and Ullah, I. (2022): Perceptions and practices regarding the process of obtaining informed consent from surgical patients at a tertiary care hospital. Annals of Medicine and Surgery, 73 (103195).

Bajada, S., Dwamena, S., Abdul, Z., Williams, R., and Ennis, O. (2017): Improving consent form documentation and introduction of procedure-specific labels in a district general hospital. BMJ Open Quality, 6(1): u211571-w4730.

Baker D., Amin M. H., Ch'ng S., and Chaudhary R. (2021): Evaluation of preprinted consent forms for retinal detachment repair surgery: a short report. BMJ open quality, 10(1), e001264.

Berg J. W., Appelbaum P. S., Lidz C. W., and Parker L. S. (2001): Informed consent: legal theory and clinical practice. Oxford University Press. Available at: https://books.google.com.eg/books/about/Informed_Consent.html?id=b6w7V7gCkSIC&redir_esc=y.

Bernat J. L., and Peterson L. M. (2006): Patient-centered informed consent in surgical practice. Archives of Surgery, 141(1): 86-92.

Conti A. A. (2017): From informed consent to informed dissent in health care: historical evolution in the twentieth century. Acta bio-medica: Atenei Parmensis, 88(2): 201–203.

Cordasco, K. M. (2013). Obtaining informed consent from patients: brief update review. Making health care safer II: An updated critical analysis of the evidence for patient safety practices, 2013, 461-470.

Dyke R., St-John E., Shah H., Walker J., Loughran D., Anakwe R., and Nathwani D. (2023): Comparing shared decision making using a paper and digital consent process. A multi-site, single centre study in a trauma and orthopaedic department. The Surgeon, 21(4): 235-241.

France J. and Hayhurst C. (2018): Consent in Adults, Adolescents and Children in Emergency Departments. The Royal College of Emergency Medicine Best Practice Guideline.

Hall, D. E., Prochazka, A. V., and Fink, A. S. (2012): Informed consent for clinical treatment. CMAJ: Canadian Medical Association journal = journal de l'Association medicale canadienne, 184(5):533–540.

Hanson, M., and Pitt, D. (2017): Informed consent for surgery: risk discussion and documentation. Canadian journal of surgery. Journal canadien de chirurgie, 60 (1): 69–70.

Institute of Medicine (2001): Crossing the Quality Chasm: A New Health System for the Twenty-first Century. National Academy Press; Washington: 2001. https://pubmed.ncbi.nlm.nih.gov/25057539/.

Jalal, A. H., Chatzopoulou, D., Marcus, H. J., and Pandit, A. S. (2023): Aids to Improve Statistical Risk Communication in Patients Consenting for Surgery and Interventional Procedures: a Systematic Review. medRxiv, 2023-01.

Kamer, E., Tümer, A. R., Acar, T., Uyar, B., Ballı, G., Cengiz, F., Özoğul, M., and Hacıyanlı, M. (2018): Importance of informed consent defined by General Surgery Associations in Turkey. Turkish journal of surgery, 34(2): 97–100.

Kumar B., Ali M., Kumar M., Sinha A. K., Kumar A., and Anand U. (2021). Consent in surgical practice. Indian Journal of Surgery, 83(6): 1345-1352.

Kurt, E., Ucar, M., and Atac, A. (2016): Quality of an Informed Consent Prior to a Surgical Intervention? Experience of a Teaching Hospital. Pakistan journal of medical sciences, 32(1): 206–210.

Lane, T., Brereton, E., Nowels, C., McKeehan, J., Moss, M., and Matlock, D. D. (2021). Surrogate informed consent: a qualitative analysis of surrogate decision makers' perspectives. Annals

of the American Thoracic Society, 18(7), 1185-1190.

Leclercq, W. K., Keulers, B. J., Houterman, S., Veerman, M., Legemaate, J., and Scheltinga, M. R. (2013): A survey of the current practice of the informed consent process in general surgery in the Netherlands. Patient safety in surgery, 7 (4):1-7.

Li, F. X., Nah, S. A., and Low, Y. (2014): Informed consent for emergency surgery—how much do parents truly remember?. Journal of Pediatric Surgery, 49(5), 795-797.

Lin Y. K., Liu K. T., Chen C. W., Lee W. C., Lin C. J., Shi L., and Tien Y. C. (2019): How to effectively obtain informed consent in trauma patients: a systematic review. BMC medical ethics, 20: 1-15.

Madeira J.L., Coyne K., Jaeger S.S. et al. (2017): Inform and Consent: More Than Just "Sign Here". Maurer School of Law: Indiana University. Indiana University Maurer School of Law. 2721. Available at https://www.repository.law.indiana.edu/facpub/2721

Maher D.I., Serpell J.W., Ayton D. and Lee J.C. (2021): Patient reported experience on consenting for surgery — elective versus emergency patients. Journal of Surgical Research. ISSN: 0022-4804, (265): 114-121.

Marcus H. J., Jain A., Grieve J., and Dorward N. L. (2018): Informed consent for patients undergoing transsphenoidal excision of pituitary adenoma: development and evaluation of a procedure-specific online educational resource. World Neurosurgery, 118: e933-e937.

Mohamed O. I., Khedr R. I., Ali H. M., and Abdelaziz S. A. M. (2024): A Survey on Applying Ethics of Informed Consent Among Egyptian Surgeons. Mansoura Journal of Forensic Medicine and Clinical Toxicology, 32(1): 121-133.

Munawar, T., Ismail, F., Mehmood Qadri, H., Haq, A. U., Munawar, A., Zahid, A. S., Sheraz, M., and Babar, M. S. (2023): Practices of Informed Consent for Emergency Procedures at a Tertiary Care Hospital in Lahore, Pakistan. Cureus, 15(12): e50322.

Mussa MA., Sweed TA. and Khan A. (2014): Informed Consent Documentation for Total Hip and Knee Replacement Using Generic Forms with Blank Spaces. Journal of Orthopaedic Surgery. 22(2):214-217.

Negash W., Assefa N., Baraki N. and Wilfong T. (2021): Practice and Factors Associated with Informed Consenting Process for Major Surgical Procedures Among Health-Care Workers, South Eastern Ethiopia. Int J Gen Med, 14:7807-7817.

Nsahlai, C., Samuel, O., Engelbert, L., Eric, N., Elvis, T., Mathias, G., Kingsley, O. and Pascal, F. (2022): Informed Consent Prior to Elective Gynaecological Surgery in Two Reference Hospitals in Yaoundé, Cameroon: A Mixed Methods Study. Open Journal of Obstetrics and Gynecology, 12: 958-978.

Olejarczyk J.P, Young M.(2022): Patient Rights and Ethics. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available at: https://www.ncbi.nlm.nih.gov/books/NBK538279/.

Pallocci M., Treglia M., Passalacqua P., Tittarelli R., Zanovello C., De Luca L. et al. (2023): Informed Consent: Legal Obligation or Cornerstone of the Care Relationship?. International journal of environmental research and public health, 20 (3), 2118.

Patil A., Chawathey S. and Malim A. (2023): Adequacy of Informed Consent in Elective Surgical Procedures: A Study in a Navi Mumbai Tertiary Care Centre. Cureus, 15(7): e41777.

Perić, O., Tirić, D., and Penava, N. (2018): Patients' experience regarding informed consent in elective and emergency surgeries. Medicinski Glasnik, 15(2).

Poppe, C., Elger, B.S., Wangmo, T. et al. (2020): Evaluation of decision-making capacity in patients with dementia: challenges and recommendations from a secondary analysis of qualitative interviews. BMC Med Ethics, 21 (55).

Pirotte B.D., Benson S. (2023): Refusal of Care. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available at: https://www.ncbi.nlm.nih.gov/books/NBK560886/.

Renovanz M., Haaf J., Nesbigall R., Gutenberg A., Laubach W., Ringel F., and Fischbeck S. (2019): Information needs of patients in spine surgery: development of a question prompt list to guide informed consent consultations. The Spine Journal, 19(3): 523-531.

Saigal R., Clark A.J., Scheer J.K., et al. (2015): Adult spinal deformity patients recall fewer than 50% of the risks discussed in the informed consent process preoperatively and the recall rate worsens significantly in the postoperative period. Spine 40 (14): 1079–1085.

Schmitz, D. and Reinacher, P. C. (2006): Informed consent in neurosurgery--translating ethical theory into action. Journal of medical ethics, 32(9): 497–498.

Shemesh, S., Sidon, E., Heller, S., Cohen, N., Kosashvili, Y., Dovrat, R. et al. (2019): The quality of informed consent obtained for orthopedic surgeries—elective versus trauma: A prospective interview-based study. Journal of Orthopaedic Surgery, 27 (2).

Shlobin N. A., Sheldon M., and Lam S. (2020): Informed consent in neurosurgery: a systematic review. Neurosurgical focus, 49(5): E6.

Sönmez, M. G., Sönmez, L. Ö., Kozanhan, B., and Dündar, Z. D. (2020): Is There a Difference Between the Readabilities of Informed Consent Forms Used for Elective and Emergency

Procedures in Turkey?. Therapeutic Innovation & Regulatory Science, 54: 626-630.

Spertus J. A., Bach R., Bethea C., Chhatriwalla, A., Curtis J. P., Gialde E. et al. (2015): Improving the process of informed consent for percutaneous coronary intervention: patient outcomes from the Patient Risk Information Services Manager (ePRISM) study. American heart journal, 169(2): 234-241.

Sarker. Sudip K. (2020): Legal & ethical dilemmas in incidental findings during surgery: Review article, International Journal of Surgery,75:107-113.

Tamire T. and Tesfaw A. (2022): The practice of obtaining informed consent for elective surgery and anaesthesia from patients' perspective: An institutional based cross-sectional study. Clinical Ethics, 17(1):57-62.

Vieira, A.L., Infante, C., Santos, S., Asseiro, M. and Ferreira, C. (2023): A survey on current practice of informed consent process in surgical specialties of a Portuguese tertiary teaching hospital center: What is the state of play?, Ethics, Medicine and Public Health, 28: 100910.

Vikas, H., Kini, A., Sharma, N., Gowda, N. R., and Gupta, A. (2021): How informed is the informed consent?. Journal of family medicine and primary care, 10(6): 2299–2303.

Wood, F., Martin, S. M., Carson-Stevens, A., Elwyn, G., Precious, E., and Kinnersley, P. (2016): Doctors' perspectives of informed consent for non-emergency surgical procedures: a qualitative interview study. Health expectations: an international journal of public participation in health care and health policy, 19(3): 751–761.

Electronic References:

https://www.powerdms.com/policy-learning-center/what-is-the-purpose-of-policies-in-the-workplace. [Last accessed: 2 April 2024].

https://guides.unmc.edu/books/hrpp-policies-and-procedures/chapter/section-5-informed-consent. [Last accessed: 25 May 2024].

NSW (2020): Health Consent to Medical and Healthcare Treatment Manual. consent-section-4 (www.health.nsw.gov.au) [Last accessed: 22 April 2024].

National Legislative Authorities, Egypt. (1937): 'Penal Code [Egypt], No. 58 of 1937 (Amendments up to Law No. 95 of 2003)', available at: https://www.refworld.org/docid/3f827 [Last accessed 17 February 2024].

تقييم إجراءات عملية الموافقة التي تم الحصول عليها لتدخلات جراحة المخ والأعصاب

اسراء جمال جابر [1] و جمال ناصر عيد[1] و محمد عبد الرحمن محمد[2] و عماد أحمد السيد مصطفى[1]

الملخص العربي

الخلفية العلمية: موافقة المريض المستنيرة للجراحة هي عملية التأكد من أن المريض يفهم تمامًا تشخيص حالته، والتدخل الجراحي المقترح، وفوائده ومخاطره، والتدخل البديل بما في ذلك عدم إجراء أي تدخل جراحي على الإطلاق مع شرح الفوائد والمخاطر المحتملة في كل منها. **الهدف من الدراسة:** هدفت الدراسة الحالية إلى تقييم الوضع الحالي لعملية الموافقة الطبية للتدخلات جراحة المخ والأعصاب وتم أيضًا مقارنة مدى استيفاء معايير الحصول على الموافقة في كل من الجراحات الطارئة والمخطط لها. **طريقة البحث:** أجريت هذه الدراسة المقطعية المرجعية على ملفات مرضى جراحة المخ والأعصاب المؤرشفة والتي ضمت مائتي ملف (مئة ملف لمرضى حالات تدخل جراحي مخطط له ومئة أخرى للحالات الطارئة). كانت القوائم المرجعية المستخرجة من الأدبيات المتاحة هي المقياس لتحديد جودة عملية الموافقة المستنيرة وقد تحقق من وجود سياسات صحيحة في المستشفى، وتوفير جميع المعلومات اللازمة، وقدرة الشخص الذي يمنح الموافقة، وفهم هذا الشخص للمعلومات وحقه في اتخاذ قرار بشأن الجراحة. تم تلخيص النتائج وتحليلها إحصائياً. **النتائج:** أظهرت مقارنة نتائج التدخلات الجراحية المخطط لها والطارئة عدم وجود فرق إحصائيًا كبير بين المجموعتين فيما يتعلق باستيفاء بنود عملية الموافقة، وكانت كلاهما وفقًا للمعيار وفي النهاية، يمكن أن تُعزى استيفاء المعايير المطلوبة للموافقة المستنيرة الأخيرة في الملفات المدروسة إلى وجود سياسة للمستشفى موثقة ومعلنة حول أهمية عملية الموافقة. **الاستنتاج:** أوضحت الدراسة مدى الحصول على موافقة مستنيرة لإجراءات جراحة الأعصاب ووجدت أن العملية تتبع عمومًا الإرشادات المعمول بها، ولكن يمكن تحسينها من خلال مناقشة المزيد من خيارات العلاج مع المرضى. من شأن ذلك مساعدة المرضى على اتخاذ خيارات أفضل بشأن رعايتهم.

التوصيات:لتطوير عملية الموافقة المستنيرة في جراحة الأعصاب، من المهم تضمين المزيد من العناصر المستخدمة للتقييم في الدراسات القادمة، وتثقيف الجميع بشأن ممارسات الموافقة الصحيحة، وتثقيف المرضى حول عملية الموافقة. يمكن أن تساعد المراجعات الدورية للعملية في العثور على مجالات للتحسين. يمكن أيضًا أن يوفر مراقبة التغييرات ودراسة القضايا القانونية المتعلقة بالموافقة المستنيرة رؤى قيمة للتخطيط للتحسينات المستقبلية.

1. قسم الطب الشرعي والسموم الاكلينيكية – كلية الطب جامعة عين شمس، القاهرة، مصر.

2. قسم جراحة المخ والأعصاب – كلية الطب جامعة عين شمس، القاهرة، مصر.