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ORIGINAL ARTICLE

Consent in paediatric neurosurgery: adequacy of documentation and parental perspectives

Adikarige H. D. Silva[1] · Haren Wijesinghe[1] · Nilesh Mundil[1] · William Lo[1] · A. Richard Walsh[1] · Guirish A. Solanki[1] · Desiderio Rodrigues[1]

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Abstract

Introduction Consenting paediatric patients for surgical procedures remains inherently unique in that it is underpinned by principles such as parental responsibility, assessment of the child's capacity to consent, and adherence to national/legal guidelines. Quality record keeping is an important objective evidence to demonstrate the highest standards of medical care provided to our patients. The consent form is a crucial medical record encapsulating the attainment of informed consent from a parent/guardian for performing a procedure on their child. We aimed to prospectively evaluate the consenting process in our department to assess adequacy of documentation and parental perspectives.

Methods A prospective study using qualitative descriptive design was conducted with parents of 50 children requiring neurosurgical procedures over a 3-month period.

Results All patients understood the primary diagnosis and type of surgery. Procedure-specific risks were understood by 98% and 84% could remember the mentioning of general risks of surgery. Only a minority of parents (24%) could recollect that alternative options of management including no treatment were discussed. In cases where relevant, laterality was only documented in 56% of consent forms. All patients felt that an informed decision regarding consent to surgery was made. However, 12% suggested areas where further improvement could be made in the timing of consent and the way information could be better provided.

Discussion Consent is more than a signature on a form. It provides objective evidence of a shared decision-making process between the surgeon, patient, and their parent/guardian. Our initial study highlights multiple areas for improvement.

Keywords Consent · Paediatric · Capacity

Introduction

Consent is the provision of approval granted by a competent patient or his/her legal representative, to receive medical intervention, after full consideration of facts and implications [1]. Consent may be implied (not expressly granted but inferred from actions) or expressed (verbal, non-verbal, written, clearly, and unmistakably stated). Informed consent encompasses four criteria with the ability to:

1. Understand the information provided
2. Retain the information provided
3. Use the information provided to make a logical/reasonable decision (whether or not it is perceived to be in keeping with the patient's best interests)
4. Convey that decision

Consenting children for surgical procedures is inherently unique. It is underpinned by strict medico-legal principles including paediatric assent, identification of parental responsibility, and assessment of the patient's capacity to consent whilst adhering to legal and national guidelines [2]. Importantly, the consenting process requires immaculate documentation as evidence of this negotiation [3, 4] with high-quality record keeping, universally recognised as an important objective evidence of shared and informed decision-making that demonstrates the quality and standard of care afforded to our patients. Consent forms are an important medical record

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✉ Desiderio Rodrigues
Desiderio.Rodrigues@nhs.net

[1] Department of Neurosurgery, Birmingham Children's Hospital, Steelhouse Lane, Birmingham B4 6NH, UK

encapsulating attainment of informed consent from a patient, or in paediatrics, a parent or guardian, for performing a procedure on their child. It is also used during the pre-operative World Health Organization (WHO) surgical safety checklist for confirmation of patient, procedure, site, and laterality [5].

The process of consent therefore requires an extremely sensitive approach and loss of effective communication at any point in this continuous patient-physician interaction will result in failure to obtain informed consent. Thus, by law, any medical intervention that follows breaches the partnership of care with subsequent legal implications.

Patients most often seek legal advice in relation to invasive procedures with unexpected outcomes or in situations where patients feel the clinician has overstepped their authority and has neglected the patient's right to self-determination (autonomy). The National Health Service Litigation Authority's (NHSLA) annual report strongly reflects this: surgical specialities receive the highest number of clinical negligence claims [6], costing the Clinical Negligence Scheme for Trusts (CNST) over three million pounds in compensation (thirty-three thousand claims) since April 1995 [7]. The complexity of paediatric consent is more than an agreement for intervention [8].

The literature is sparse on documentation adequacy and parental perspectives on consent and the process by which parents make informed decisions in paediatric neurosurgery. A systematic review (Embase, Medline, and Web of Science) demonstrated few articles addressing the search terminology (keywords: paediatrics, consent, parent perspectives, documentation). Expert reviews regarding ethical considerations of consent [9, 10] and medico-legal aspects predominate. One study evaluated the consent process in current neurosurgical practice based on an adult population [11].

We aim to prospectively evaluate in our unit: (1) parental perspectives of the consent process and (2) adequacy of documentation of parental consent, to ascertain effectiveness and identify areas for improvement.

Methods

Permission and ethical approval

The hospital internal audit review department sanctioned our study.

Study design and setting

A qualitative descriptive study was undertaken prospectively over 3 months (September—December 2013) in the Neurosurgical department at Birmingham Children's Hospital.

Participants and data collection

All patients (elective and emergency admissions) during the study period, who consented for neurosurgical intervention, were invited to participate. Initially, the primary aim evaluated parental perspectives on the process of consent, via provision of a questionnaire (Supplement Fig. 1). The patient's parent/legal guardian and main signatory on the consent form completed this questionnaire. Questionnaires were completed following the procedure and submitted anonymously at any time, up to the point of discharge.

Following the first eight patients enrolled, the study was expanded to also assess adequacy of consent documentation. From this point on, consent forms and medical records of participating patients were also analysed for documentation adequacy against available best practice recommendations. Neither patients nor consenting doctors had knowledge of the study prior to completion of the consent form.

Data analysis was performed using a content analysis method to allow comparisons with published literature [11].

Results

Parents of 50 patients who underwent neurosurgical procedures participated. Questionnaire completion rate was 100% with all parents responding. Data for the initial eight patients only contained parental perspectives surrounding the consent process. In the remaining 42 patients, data included both parental perspectives and documentation adequacy. To maintain the study's prospective nature, we elected not to perform retrospective analysis of documentation adequacy of the consent forms/notes of the first eight patients. Rather only procedure name was recorded (Fig. 1).

Adequacy of documentation surrounding consent process

Of the 42 patients, 30 patients underwent neurosurgical procedures (seven emergency; 23 elective) and 12 craniofacial surgeries (all elective). Patient identifiable details were correctly documented in 100%. In 10% (4/42), identifying hospital number was not documented, and in 14% (6/42) neither was the responsible consultant surgeon.

The procedure was documented in all cases. In operations where laterality was relevant (16/42), it was documented in 56% (9/16). Procedure benefits were documented in 100% of cases. Specific surgical risks pertaining to the procedure were deemed adequate in 40/42 cases (95%)—Table 1.

General risks of undergoing surgery (e.g. deep venous thrombosis, pulmonary thromboembolism, chest/urinary

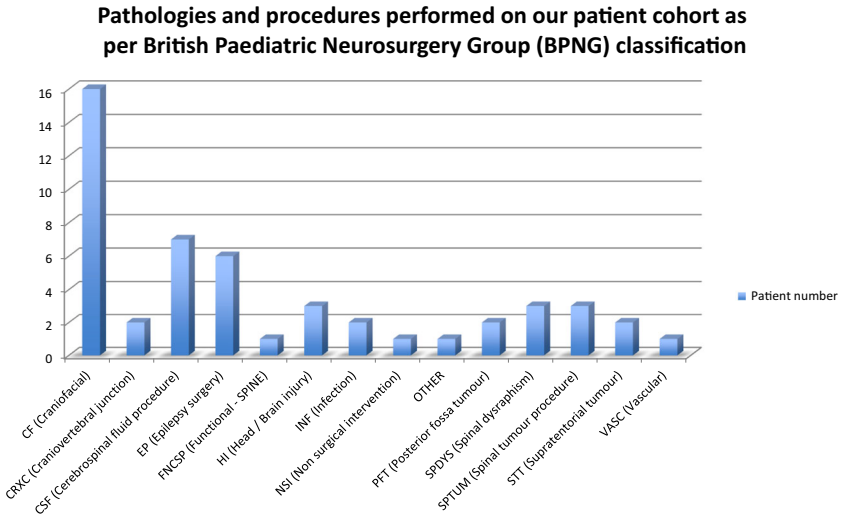

Fig. 1 Pathologies and procedures performed on our patient cohort as per British Paediatric Neurosurgery Group (BPNG) classification

infection, metabolic/nutritional abnormalities) were documented in 6/42 (14%).

In 3/42 cases (7%), apart from a signature, parent/guardian identification details whose consent was obtained had not been documented. Of the remaining 39 cases, the patient's mother provided consent in 24/42 and the father in 15/42. Of interest, in all 15 cases where the father provided consent, there was no documentation in the consent form/notes of confirmation of the father's legal parental responsibility to provide consent for the child.

The child had also signed the consent form in 5/42 cases (a parent had also provided consent in all these cases). In 1 case, the patient was over 18 years, therefore legally able to give consent. In the remaining 4 patients (one was 13 years; the other three were 15 years), there was no mention in the patient's consent form/notes of confirmation of their competence to provide consent (Table 2).

Parental perspectives surrounding the process of consent

In evaluating parental perspectives, 50 patients were evaluated: 34 neurosurgical procedures (7 emergency; 27 elective) and 16 craniofacial surgeries (all elective). All parents understood both diagnosis and type of surgery their child required. In one case (1/50; 2%), procedure-specific risks had not been understood.

On risks of surgery in general, 8/50 patients felt that they had not appropriately understood these risks (neurosurgery: elective—3, emergency—2; craniofacial—3).

Thirty-eight out of fifty parents (76%) did not recall alternatives to surgery, including 'no treatment', being discussed whilst 12/50 (24%) parents did. In the former subgroup, the reasons provided by parents as to why alternatives to surgery were not discussed were (1) they were told surgery was the only option in 22/38 cases and (2) could not recall other alternatives being mentioned in 16/38 cases (Table 3).

Table 1 Cases where procedure laterality had not been documented and procedure-specific surgical risks documented on the consent form were deemed to be inadequate

Procedures in which laterality was deemed relevant but not documented (7/16)	
Neurosurgery—elective ($n = 5$)	•Endoscopic fenestration of cyst + external ventricular drain insertion
	•Endoscopic third ventriculostomy (2 cases)
	•Insertion of vagal nerve stimulator
	•Biopsy of tumour
Neurosurgery—emergency ($n = 2$)	•External ventricular drain insertion
	•Ventriculo-peritoneal shunt insertion
Procedures in which documented specific surgical risks pertaining to procedure were deemed inadequate (2/42)	
Neurosurgery—elective ($n = 2$)	•Insertion of vagal nerve stimulator
	•MRI under general anaesthetic and removal of Intrathecal device

Table 2 Summary of positive findings in adequacy of documentation surrounding the consent process

Consent form section documentation	Present in	%
Identifying hospital number	38/42	90
Responsible consultant	36/42	86
Side of procedure (if relevant)	9/16	56
Specific surgical risks explained	40/42	95
General surgical risks explained	6/42	14
If father took consent, was legal parental responsibility assessed and documented	0/15	0
If child consented, was formal assessment of competence to do so documented	0/4	0

All parents felt they had come to a fully informed decision regarding their child's treatment. The majority (88%) stated they were fully satisfied in terms of the consent process with no improvements required. Only 6/50 parents (neurosurgery: elective 4/27, emergency 2/7) felt some improvements could be made including provision of more information and change in timing and location of consent process (Table 4). Whilst formal statistical analysis wasn't performed due to paucity of total figures, there were not any qualitative differences between perception of consent between emergency and elective cases nor between who took consent (consultant/attending surgeon or resident/board-certified fellow).

Discussion

Doctors have a duty of care and candour to ensure capacity to consent, providing patients with sufficient information to make informed decisions on surgical intervention [10–14]. Information required includes nature of the patient's condition, nature and purpose of the procedure, procedure-specific risks, general risks of surgery, and alternatives including no treatment. These should be discussed and documented within patient notes and the consent form appropriately [11, 14]. Knowledge of and adherence to relevant national legal guidance surrounding consenting paediatric patients for surgical intervention are important.

Table 3 Procedural categories in cases where parents felt alternatives to surgery had not been discussed

Surgery felt to be the only option (22/38)
•Neurosurgery—elective (11 out of 22)
•Craniofacial (9 out of 22)
•Neurosurgery—emergency (2 out of 22)
No alternatives discussed (16/38)
•Neurosurgery—elective (8 out of 16)
•Craniofacial (4 out of 16)
•Neurosurgery—emergency (4 out of 16)

Quality standards for comparison

There are no studies evaluating consent process in paediatric neurosurgery. One study examined this process in an adult neurosurgical population [11] and few studies reviewed documentation in adult general surgery [10, 14]. The WHO Surgical Safety Checklist states the minimum record of consent should include patient details, intervention details, site of access, and laterality [5].

Identifying hospital number

Four patients did not have hospital identification numbers documented on their consent forms. In theatre, patients are identified using name, date of birth, and identifying hospital number and corroborated on their hospital wrist-tag, their preoperative imaging and consent form.

Laterality of operation

There was a low documentation rate of operation laterality (44%, 7/16). In some cases, laterality was assumed (e.g. vagal nerve stimulator insertion). However, some procedures involved cerebrospinal fluid diversion, endoscopic cyst fenestration, and most importantly tumour biopsy. In all of these, the operating surgeon would have decided on procedure laterality. Guidance from governing bodies

Table 4 Procedures in which parents felt improvements could have been made regarding the consent process (6/50)

Neurosurgery—elective
•Right temporal subdural grid electrodes
•Occipito-cervical fixation
•Image-guided burr-hole biopsy of tumour
•Removal of residual tumour
Neurosurgery—emergency
•Insertion of ventriculo-peritoneal shunt
•Craniotomy and evacuation of subdural haematoma and insertion of intracranial pressure monitor

such as the Royal College of Surgeons [3] emphasises that documentation of operation laterality is essential to good practice where relevant.

Documentation of specific surgical risks

Documentation of specific surgical risks was deemed inadequate in 2/42 cases (5%): in both, consent was obtained and documented by the responsible consultant. Whilst the operating surgeon discussed risks they deemed significant, an independent consultant felt that more documentation on specific surgical risks was required. However only in one case did the parents feel they had not understood procedure-specific risks. This highlights a discrepancy in what is explained to patient/parents and what is actually documented, mirrored in the comparative adult study: specific procedure risks were inadequately documented in 33% but only in 17% of patients felt they were inadequately informed about these [11].

Documentation of risks of surgery in general

General surgical risks were documented in 14% of consent forms. However, the vast majority of patients (84%) stated that they understood the aforementioned risks, again similar to the adult study where only in 17% of cases was there adequate documentation of this fact but a higher proportion (33%) expressed sufficient understanding [11].

Together with our adult neurosurgical colleagues [11], we feel that general risks of surgery include important complications that can cause significant postoperative morbidity and mortality, sometimes even exceeding specific operative risks. It is therefore important to mention and document these. Certainly, there is disparity within our department with evidence that some surgeons mention and document these risks whilst others perhaps did not. This is also reflected in general surgery where emphasis of risks of 'surgery in general', are separate to procedure-specific general surgery risk [14].

Discussion of alternatives to surgery

The majority of parents (38/50; 76%) commented that they did not feel that alternatives to surgery and implications of non-treatment were discussed. This was similar to the results in the adult study [11]. A key facet in attaining consent for a procedure is thorough discussion of risks and benefits of that approach, but also for alternative options including a conservative/surveillance/no treatment option [10, 14]. Whilst the latter is often non-applicable in life-threatening emergencies, alternatives should be discussed for elective procedures.

What information should be provided?

Patients are entitled to information about their condition and available treatment options, whilst healthcare providers have the duty to relay relevant details in a sensitive and simple manner. The General Medical Council (GMC) [1] and Royal College of Surgeons [3] guidelines highlight that information provided to each patient varies depending on (1) the condition and its severity, (2) treatment/procedure complexity, (3) risks of treatment, and (4) patient's wishes on how much they want to know.

The overall goal maximises patient information and empowers informed decision-making, whilst respecting their final verdict. All relevant management options must be discussed, including the outcome of receiving no treatment, an aspect emphasised in ethical discussions on consent [9, 10].

Documentation of legal parental responsibility

Legal parental responsibility to provide consent is important in the context of consenting paediatric patients for surgical procedures. In the UK, parents are those with parental responsibility for the child or young person. Such a person, by law, has parental rights including right to consent to medical treatment up to the age of 18 years in England, Wales, and Northern Ireland, and 16 years in Scotland. Mothers automatically acquire parental responsibility, but fathers do not.

In 15/42 cases where the father provided consent for the procedure, legal parental responsibility to provide consent was assumed and not formally assessed or documented. Although the authors accept this is controversial and may be uncomfortable for the father and parents, consent guidance in the UK defines criteria for parental responsibility. Thus, one should consider confirmation of legal parental/responsibility during the consent process.

Documentation of child's capacity

In 4/42 cases (all 4 were below age of 16 years), the child consented for the procedure on the consent form. There was no issue regarding consent validity: parents had also provided consent. However, capacity to consent in a child below 16 years should not be assumed. There had been no formal documentation on the child's competence to provide consent—a critical principle. In circumstances whereby a child has provided consent, the surgeon should document that child's capacity to consent has been appropriately assessed and confirmed.

Table 5 Level of quality of adequacy of documentation of consent using our devised rating scale

Adequacy of documentation of consent	Our results ($n = 42$)
Adequate completion of consent form	3/42 (7%)
Little omission	24/42 (57%)
(Complete for the most part with majority of common and/or significant risks mentioned but some data missing)	
Major omissions	15/42 (36%)
(Inadequate identifying information, procedure laterality)	

Overall assessment of the adequacy of documentation of consent

The authors evaluated each consent form and categorised it to one of three levels (Table 5).

Our study identified multiple areas for improving consent process and documentation. Other quality assurance reviews of consent documentation also indicated major deficiencies [10, 14] with only 26% of consent forms including the essential elements pertaining to a procedure (risks, benefits, alternatives) [10]. We implemented an 'informed consent training day and education program' within our department as well as a pro-forma checklist that confirmed adequacy of documentation. Such programs (simulation exercises, role-play on consent) improve confidence in the ability to obtain informed consent and leads to improved documentation [15]. A significant positive was that overall, in 100% of cases, parents felt they had been able to make an informed decision in providing consent for their child to undergo surgery. Most parents were fully satisfied with the consent process.

Limitations

Our prospective study has a few limitations. Our sample size is small; however, the only available adult study [11] had comparable numbers (60 cases). None of the consenting doctors had prior knowledge of the study, and consent forms were scrutinised for documentation adequacy in the immediate postoperative period. Comparison can only be made against best practice guidelines and data from the adult study on consent. There is always a degree of subjectivity amongst study authors in scrutinising consent forms and determining adequacy of documentation with regard to risks. The authors remained as general as possible in evaluating documentation adequacy.

Regarding parental perspectives on the consent process, parents were given the questionnaire in the immediate postoperative period after their children had had their procedure and when it was deemed they were clinically stable. It would have been ethically and morally difficult to put parents through this questionnaire, prior to their child having had their procedure. It would also have been difficult to ask patients to complete the questionnaire in circumstances whereby the procedure had resulted in immediate postoperative complications for obvious emotional reasons. This does bias our results.

In the adult study, patients were given the perspective questionnaire before and after surgery. The study authors felt, in the context of a paediatric population undergoing neurosurgical procedures, this would not be appropriate. The emotional status in the context of their child undergoing a procedure and presence or absence of postoperative complications would have had an effect on responses. There would also be an element of recall bias including psychological factors affecting degree of recall, if indeed specific factors such as alternatives of surgery had been discussed earlier in a clinic setting.

Our study represents the opinion of British parents and as such, validity and applicability to extrapolate results and recommendations to other regions of the world is difficult, as the way of consenting patients/parents will differ in every country. This is somewhat compounded by differences in the legal frameworks across the world.

It is difficult to address the question of 'how we should consent' with evidence, as this is much less dependent on scientific evidence but rather the ethical process of how we as surgeons perceive it should be done [9, 10]. Non-medical societal influences ranging from ethnic and cultural, religious, and social media—all inherently non-evidence based—all play major roles. Communication is vital and especially important in surgery where communication issues were noted to be the most frequent root cause of adverse events reported [10] and in Canada, 65% of medico-legal actions on consent involved surgeons with only 1/5 of these decided in favour of the surgeon [14]. Informed consent, a key staple of medical ethics and law since 1970, should be based on patient autonomy and beneficence highlighting the value of continuous patient-physician interaction to foster trust so that the physician understands not only the patient's condition but their moral beliefs and social circumstances allowing the physician to support the patient/parent in weighting possible benefits and harms, making shared decisions with substantial patient autonomy and satisfaction [9].

Conclusions

Whilst it is difficult to draw overall conclusions and make specific recommendations owing to inherent cultural and legal variability across differing regions in the world, it is clear that we as treating surgeons must take great care to consult and consent parents in an adequate way, and also audit and evaluate from time to time, the quality with which we perform. Our study attempts to provide a framework to assess this practice.

The importance of informed consent was eloquently summed up by eminent neurosurgeon Professor Albert L. Rhoton Jr.: essential [to success] is having a patient and family members who are well informed about the contemplated operation and who understand associated side effects and risks. The surgeon's most important ally in achieving a satisfactory postoperative result is a well-informed patient [16]. Further studies to improve consenting practice are highly recommended and we hope this study serves as a starting point onto a neurosurgeon-led effort and discussion on how the process of consent should be, with elucidation of some basic principles that remain valid across national, legal, cultural, and religious distinctions.

Compliance with ethical standards

The hospital internal audit review department sanctioned our study.

Conflict of interest On behalf of all authors, the corresponding author states that there is no conflict of interest.

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