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# Prior Informed Consent for Surgery in Children: Cross Sectional Study of Understanding and Recall of Risks by Parents and Guardians and Review of Relevant Medico Legal Literature

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## ABSTRACT

**Introduction:** In medical fraternity, all doctors, either physician or surgeon, do have ethical and legal duty, to take Informed Consent (IC) before any diagnostic or therapeutic procedure. Information to patient should be adequate enough to decide him voluntarily about taking or refusing treatment or procedure.

**Materials and methods:** This prospective longitudinal observational study was carried out at a tertiary care teaching hospital. Study period was 5 months from November 2020 to March 2021. Due to ongoing pandemic, the numbers of emergency as well as non-emergency cases were low. However, a total of 54 children (n=54) as surgical patients of minor age group were included in study.

**Results:** Out of total 54 patients, complete understanding score of 12 was achieved by 20.3% (n=11). Incomplete understanding was shown by 43 (79.6%) patient attendant. Overall, out of 54, 35 (64.8%) were emergency cases and 19 were non emergent cases. Of total 43 patients with incomplete understanding, 28 were emergency cases.

**Conclusion:** Our study highlighted that in prior informed consent procedure, risk recall or understanding of complications was far from satisfactory. Lower education status and emergency situations may have some adverse impact on understanding of parents. This may create grounds for parental dissatisfaction which are basis of possible medico legal situations if some adverse results or outcome arise.

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## Introduction

In medical fraternity, all doctors, either physician or surgeon, do have ethical and legal duty, to take Informed Consent (IC) before any diagnostic or therapeutic procedure. Information to patient should be adequate enough to decide him voluntarily about taking or refusing treatment or procedure. Basic pre-requisite is absence of coercion and presence of capacity to decide. An IC is usually a process of agreement between patient and treating doctor which may be labelled as "shared decision making". If the patient is incompetent or lacks the capacity to provide IC, surrogated decision makers are required to consent or refuse the treatment or procedure. If the patient is a minor, then parents or Person with Parental Responsibility (PPR) or guardian is required to decide on behalf of a child. The legal age for giving consent in India is 18 years [1]. A child above 12 years can give a valid consent for physical or medical examination.

However, for performing any procedure in patient below 18 years of age, consent of parents or PPR is needed to keep the consent valid.

## Principles of informed consent

Following a landmark case of *Salgo vs. Leland Stanford Jr University Board of trustees* in 1957 [2], decision of California court of appeals led doctrine of informed consent firmly embedded in medical ethics and law [3]. Thereafter informed consent had become essential ingredient of modern medicine.

## Basis of informed consent

This fundamental procedure is based on ethical and legal principle of autonomy, beneficence, and justice. Recognizing right of each individual to take decision about one's own life or his or her body is respecting autonomy. However this is valid in situation when the patient is competent major. For minor, the decision is to be taken by parents or PPR. Similarly an obligation on physician for proposing only those interven-

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tions which shall promote the well-being of patient is principle of beneficence. Patient or the parents need to be informed about alternative procedures available which help them to take decision about choice of procedure. Principle of justice requires that patient should be treated fair and without bias. He or she has right to expect that proposed intervention is no different from one given to any other patient under similar circumstances [4].

### **Essential principles of informed consent and related case study**

- a. Consent should be procedure specific [5].
- b. Fresh consent should be taken for repeat procedure as In *Dr. Shailesh Shah vs. Aphraim Jayanand Rathod* [6].
- c. A consent taken for surgery is not sufficient to cover anaesthesia care. Informed consent for anaesthesia should be taken by anaesthesia provider. It may be documented on surgical consent form in handwritten format or separate anaesthesia consent form [7].
- d. Consent should be properly documented and witnessed which make them legally more dependable [8,9].
- e. An adult patient or PPR or parent has right to withdraw consent anytime during performance of procedure. The Doctor should address the concern and may continue if patient or parents agree. However, if stopping procedure puts life at risk then doctor should continue the procedure till the time risk no longer exists [10].

### **Critical elements of informed consent**

There are four critical elements which include

- A. Physicians should provide adequate information which helps patient or parent to take decision.
- B. Information should include full understanding of indications, risks, and alternatives.
- C. A competent patient or a legal proxy (parent or PPR in case of minor) to understand point 'B' and should
- D. Voluntarily consent for the proposed intervention.

In this context, Lord Templeman in 'Sidway' in *Canterbury V Spence* [2], mentions "The duty of the doctor in these circumstances, subject to his overriding duty to have regard to the best interest of the patient, is to provide the patient with information which will enable the patient to make a balanced judgment if the patient choose to make a balanced judgment".

### **Valid informed consent and Indian law**

Law in India does not prescribe written consent on mandatory basis. What law needs is mere consent. However when a patient is subjected to anaesthesia, any procedure with possibility of severe pain, written

consent is helpful. There is no mandate that doctor should always obtain a written consent and failure of it would hold him or her liable. The benefit of written consent is that a medical practitioner shall have greater ease in proving consent in court of law.

Professional regulatory body for doctors, National Medical Commission (NMC) had led down guidelines issued as regulation. Chapter 7 Clause 7.16 of Indian Medical council, professional conduct, etiquette and Ethics regulation, 2002 writes "Before performing an operation the physician should obtain in writing the consent from the husband or wife, parent or guardian in the case of minor, or the patient himself as the case may be. In an operation which may result in sterility, the consent of both husband and wife is needed" [11]. In present scenario, an amendment or update of this draft is needed to include terms like prior informed consent in language of understanding, diagnostic or therapeutic procedures, and rare cases of abandoned minor, competency of patient to enhance the scope of consent understanding among physician.

### **Indian constitution on consent**

Indian constitution in article 21, deals with the right to life and personal liberty [12]. Relationship between doctor and patient is contractual obligation between two parties who are competent. In accordance to Indian majority act, parties are competent if

1. Age of 18 years or above,
2. Sound mind
3. Are not disqualified by law to which they are subject to.

So, principles of Indian contract act and Indian Penal code applies to this relationship. According to contract law, consent of any party (patient/parent of patient in this case) that is obtained by coercion, undue influence, mistake, misrepresentation or fraud, will render the agreement invalid [13].

### **Competent minor doctrine in India**

Presently in India there is no judgment dealing with competency of minor, and this doctrine is not fully accepted or developed. But it is likely that from medical management point of view, judgment from foreign courts like the 'mature minor test' or Gillick's competency can be used [14]. The verdict was that a girl below 16 years had the legal capacity to consent medical treatment and examination, including contraceptive treatment if she had sufficient maturity and intelligence to understand the nature and implication of proposed treatment. The Medical Termination of Pregnancy (MTP) act 1971- in sec 4(a) states that "No pregnancy of a woman, who has not attained the age of 18 years, or who having attained the age of eighteen years

is a mentally ill person, shall be terminated except with the consent in writing of her guardian”.

According to Indian penal code s89A, child above 12 years can give a valid consent for physical or medical examination. However, for performing any procedure in patient below 18 years of age, consent of parents or PPR is needed to keep the consent valid. Still, even in India, physician should take following precautions in case of 'mature minor' to avoid potential legal issues;

1. If a minor patient visits a doctor for treatment, the doctor may choose to ask for parents or legal guardian or representative provided by state to accompany them. This shall be doctor's discretion.
2. If the minor is adamant about not bringing parents or PPR as he or she do not want to disclose health issues with them, then the doctor needs to assess the maturity of minor, on case-to-case basis utilizing factors like ability, experience, education, conduct, intelligence. Only when doctor is sure about maturity of minor, after taking consent, doctor can go ahead and treat to prevent the interest of minor.
3. Only in case of emergency when there is life threatening situation where they require treatment to survive, can a doctor overrule everything using their clinical judgment and assessment even if minor is not mature.
4. If both or either of parent does not agree to give consent and the minor is not mature but definitely requires treatment, then doctor cannot perform procedure as it shall violate clause 7.16 of ethical regulation of professional regulatory body.
5. If treatment is absolutely necessary but parents are not convincing in case of mature minor in India, better to follow clause 7.16 and try convincing parents. Doctor also have a option to contact child welfare department to make them convince.

In nut shell the minor's health interests should be safeguarded, use discretion in emergency and in non-emergency convince parents or contact child welfare department. Also, India being a party to United Nations Convention on Right of the Child (UNCROC) which recognizes and ensure that states shall take note of increasing autonomy of children as they mature, so shall adopt the mature minor doctrine and frame rules and tests for assessing the maturity of minor to take decision about their health and life.

### **Indian case laws related to consent**

Since ages paternalism as a virtue is prevalent among medical professional in India. Unfortunately, law does not accept this idea of paternalism. The first priority of law is right of autonomy of patient provided he or she is competent to consent. It is well understood that

if consent is obtained for a procedure from a patient or a parent, the procedure should be limited to those parameters and not beyond. There are certain case laws where doctor while doing procedure crossed the parameters for which no consent was obtained and was therefore held liable. In *Rambiharilal vs. Dr.,JN Shrivastava* case, where gangrenous gall bladder was removed under consent of appendectomy [14]. The patient died of hepatorenal failure and the court mentioned among decision “No consent of the husband, who was present outside, was taken for removal of the gall bladder. He should not have undertaken such a major operation in a hospital which was lacking in basic facilities.” So, if doctor goes beyond the parameters he may be held liable in court of law.

Similarly a consent obtained for diagnostic procedure is not valid for therapeutic procedure. As seen in *Samera Kohli vs. Dr.,Prabha Manchanda* and another case, a 44 year old unmarried female consulted a doctor and was advised “laparoscopy”. Consent forms for admission and surgery were taken. Consent form gave allowance for diagnostic and operative laparoscopy and in addition to that “laparotomy may be needed”. While patient was under effect of anaesthesia, proxy consent was taken from mother for hysterectomy and her uterus, ovaries and fallopian tubes were removed. Subsequently, it was ruled that “In view of our finding that there was no consent by the appellant for performing hysterectomy and salpingo-oophorectomy, performance of such surgery was an unauthorized invasion and interference with appellant's body which amounted to a tortious act of assault and battery and therefore a deficiency in service”. Doctor was held liable [5].

So, unless there is definite threat to life or an emergency situation, a procedure specific prior informed consent is mandatory. As seen in the decision in *Samera Kohli's* case, the validity of proxy consent by parental authority or any attendant is curtailed.

Contrary to above case, in *Arun Balakrishnan Iyer and Anr. vs. Soni Hospital and Ors.* on 17 June, 2003, court observed that “Emergency situation that had arisen necessitated to remove the uterus and she could not get the consent of the patient who was anaesthetized and hence got the consent of the husband who was there in the hospital. This is the maximum possible effort that could have been taken by the doctor at that point of time”. And also that “Therefore, this Court can come to the only possible conclusion from the evidence on record that D.2 has acted in good faith in the emergency and has taken all the steps possible for her at that time. This evidence has not been challenged at all; there is not even a suggestion that there was no such emergent situation which necessitated the removal of uterus and that the removal was not bonafide. In the

absence of any such challenge to the evidence of D.W. 1 (Diffusion-Weight), it proves that there was an emergency which necessitated the removal of uterus of P.W. 1 (Placental Weight)"[15].

In Indian scenario, wide gaps exist between levels of understanding for consent counselling. Many possible reasons exist and need to be evaluated. There are cultural, educational, linguistic and other demographic barriers. This evaluation is imperative to understand the fallacies of consenting procedure. The issues of failure to understand or recall may be due to patient's reason or may be due to physician reasons.

An educated parent if not properly explained may not recall or remember the risks and similarly an uneducated or illiterate person if properly explained may understand fully and recall to satisfaction. Similarly psychological status of parents or patient at the time of consent procedure may vary in emergency and non-emergency situation. They may be more receptive during later to understand and register risks better than former situation. Experience of physician explaining the consent procedure also may affect the impact on parents. In government teaching hospitals usually during emergency, registered surgical officers or post-graduates explain and its impact on understanding may be different from senior surgeon explaining the procedure.

Not many studies have evaluated the understanding or recall of consent from parents or PPR in children requiring surgery. Literature in India regarding this context is scarce. This assessment is important to analyze fallacies and gaps in consenting procedure, so that, the existing loop holes may be filled up. Although consent is no defense in situation of medical negligence, but the results of this assessment may help physician in court of law to overcome point of proper consenting. These may help avoid situation of litigation altogether arising due to consent related misadventure.

This is a cross sectional study in a tertiary level teaching hospital carried over with objective to assess the level of understanding of risks and other details explained to parents of children undergoing surgical procedures. Results were analysed and discussed along with relevant literature review.

### Objectives

1. To analyze prospectively, the level of understanding and recall of prior informed consent regarding risks, in parents of children subjected to surgery, using predetermined parameters.
2. To evaluate the effect of results of above study and compare with other available similar studies and discuss medico legal issues related to consent.

### Methods

This cross sectional study was carried out at a tertiary care teaching hospital in paediatric surgery ward of tier I city of central India. Study period was five months from November 2020 to March 2021. Due to on-going pandemic, the numbers of emergency as well as non-emergency cases were low. However, a total of 54 children (n=54) as surgical patients of minor age group were included in study by consecutive sampling. A standard format of informed consent before surgery was already utilized in department. This form was specially designed for the child surgical department in Hindi language for understanding of people catered by the department.

A standard format (Excel/pdf as attached) was designed for this study, which included parameters to assess the understanding of prior informed consent details as explained to parents or guardian before surgery. The parameters studied were emergency or non-emergency, education status, Seniority of doctor taking consent, verbal or written consent, and relationship with child undergoing surgery. Apart from that, six parameters forming part of prior informed consent were included *viz*; date and time of surgery, diagnosis of disease, type of surgery and alternative procedure, procedure specific and general complications during surgery, procedure specific and general complications after surgery, high risk surgery or risk to life following surgery. These parameters were assessed for level of understanding or recall of parents or PPR.

Initial consent was explained verbally by senior consultant and signature was taken by junior doctor of postgraduate level after writing necessary specific details. The assessment of understanding was done by a senior consultant including principal author who had not operated upon, or one who had not taken prior consent. This was done to avoid any bias. The assessment was done by the author within 24 hours of surgery in case of emergency and 24-48 hours after consent counselling in non-emergent cases but before the procedure. Mode of assessment was oral and accordingly answers were filled in excel format (sheet attached) score sheet of questionnaire.

A scoring of two for each of six parameters was given if complete recall of details was obtained and scores one for incomplete detail and score zero for no recall of any details was given. So out of total twelve as complete score of prior understanding of informed consent, scores of all 54 patients were noted in an excel format. Their scoring were analysed by percentage and tabulated in relation to different parameters like experience of counsellor, educational status of parent and emergent or non-emergent procedure. Out of six

parameters, those with minimum recall or less than two score were identified and analysed. Results of this analysis were as noted.

## Results

Out of total 54 patients (n=54), complete understanding score of 12 was achieved by 20.3% (n=11). Incomplete understanding was shown by 43 (79.6%) patient attendant (Table 1). Out of these, 20 patients (46.5%) had score 11, 16 patients (37.2%) had 10 and 6 patients (13.9%) had score 9. One patient had lowest score of 8. Overall, out of 54, 35 patients (64.8%) were emergency cases and 19 patients (35.1%) were non-emergent cases (Table 2). Of total 43 patients with incomplete

understanding, 28 patients (65.11%) were emergency cases. For all patients (n=54) senior consultant participated in prior informed verbal counselling. In 16 out of 54 patients (29.6%), senior consultant also took written signature of parents or guardians. In another 38 patients (70.37%), junior doctor also explained verbally and took written consent.

Among consenting parents, n=42 were father (77.77%), n=5 Mother (9.25%) and n=7 were PPR including (12.96%) maternal uncle, grandfather or grandmother. 34 fathers out of 42 had incomplete understanding score below 12. Five out of seven PPR and four out of five mothers also could not score complete 12 (Table 3).

**Table 1.** Showing percentage of parents/guardian with complete/incomplete understanding of informed consent.

Each point with score 2 (Informed consent)	Number of patient with score 2 (N=54, having complete knowledge)	Percentage with score 2 (in %)	Number of patient with score less than 2 (N=54, having incomplete knowledge)	Percentage with score below 2 (0 or 1)
Understanding diagnosis	48	88.88	6	11.11
Understanding nature of surgery and alternatives	48	88.88	6	11.11
Date of surgery	54	100	0	0
Understanding all complications during surgery	31	57.4	23	42.59
Understanding complication occurring after surgery	20	37.03	34	62.96
High risk or threat to life understanding	51	94	3	5.55

**Table 2.** Showing relationship on understanding informed consent in emergency and non-emergency surgeries.

	Emergency n=35 (%)	Non-emergency n=19 (%)
Incomplete understanding of complications during surgery	14 (40)	09 (47.36)
Incomplete understanding of complications after surgery	24 (68.57)	10 (52.63)
Incomplete understanding of high risk or threat to life	02 (5.7)	02 (10.52)



**Table 3.** Showing relationship of consenting adult with children and their understanding score.

Relationship with children n=54 (%)	Understanding/recall score	
	Complete (12)	In complete (<12)
Father, n=42 (77.77%)	08	34
Mother, n=5 (9.25%)	01	04
PPR*, n=7 (12.96%)	02	05

Incomplete understanding was noted mostly in two areas of prior informed consent. Out of 54 patient attendants, 23 attendees (42.59%) had incomplete understanding of complications during surgical procedure while 31 attendees (57.40%) had complete understanding. Similarly, 34 attendees (62.96%) had incomplete understanding of complications occurring after surgical procedure while only 20 patients attendant (37.03%) had complete understanding of this parameter (Table 1).

However, 51 (94%) out of 54 patients, could recall and understand that there was risk to life during or after surgery due to various reasons. Six patients (11.11%)

could not understand diagnosis and nature of surgery along with alternative procedure details. All 54 parents or PPR, (100%) could understand and recall the date for procedure (Table 1).

Of those who had incomplete understanding and score below 12, 34 parents (79%) out of 43 had educational level below intermediate (primary and middle level only). However, two parents with graduation also had score below 12 (9 and 11). One parent with minimum score of eight was educated up to intermediate (Table 2).

In incomplete understanding of complications during surgery, 10 (52.6%) parents out of 23 were educated at primary level only. Similarly, 18 parents (81.81%) who incompletely understood complications after surgery were educated at middle level. But, two graduate parents also failed to understand and recall complication following surgery (Table 4).

Incomplete understanding of complications during surgery and following surgery was noted in 14 (40%) and 24 (68.57%) cases during emergency (Table 2). Interestingly, 17 attendees (44.73%) and 22 attendees (57.89%) out of 39 consents where both senior consultant and junior doctor participated, showed incomplete understanding of complications during and after surgery, respectively (Table 5 and Supplementary table 1).

**Table 4.** Showing relationship of understanding consent with education level of parent or guardian.

	Number of patients	Uneducated N=3 (%)	Primary N=19 (%)	Middle N=22 (%)	Intermediate N=05 (%)	Graduate N=05 (%)
Incomplete understanding of complications during surgery	23	01 (33.3)	10 (52.6)	09 (40.9)	02 (40.0)	01 (20.0)
Incomplete understanding of complications after surgery	34	03 (100)	08 (42.10)	18 (81.81)	03 (60.0)	02 (40.0)
Incomplete understanding of high risk or threat to life	3	00 (00)	01 (5.2)	01 (4.5)	00 (00)	01 (20)

**Table 5.** Showing relationship of understanding prior informed consent with experience of counsellor.

	Senior consultant (%) n=16/54	Senior consultant and junior doctor (%) N=38/54
Incomplete understanding of complications during surgery	06 (37.50)	17 (44.73)
Incomplete understanding of complications after surgery	12 (75)	22 (57.89)
Incomplete understanding of high risk or threat to life	02 (12.50)	02 (5.26)

## Discussion

Operations in children, apart from being technically unique, also have issues of limitation of capacity for informed consent. While a prior informed consent is an ethical and legal requirement in any surgical procedure, these groups of patients are too young to understand the intricacies and take decision for them. Hence legally authorized persons, parents or person with parental responsibility are appointed to take decision for them. Normally, consent is obtained after thorough verbal discussion of diagnosis (nature of disease), type of procedure planned, any alternatives, risks involved and other relevant information. Here, the consenting parent or PPR needs to demonstrate capacity of understanding and recall of explanation imparted to them.

Few studies that were carried out in adult patients regarding assessment of understanding and recall of risks concluded poor overall risk recall results [16,17]. However, very few articles on this subject in children are published in English literature [18]. Our study was carried out with objective to assess the level of understanding and recall of prior informed consent regarding risks, in parents of children subjected to surgery, using predetermined parameters.

### Effect of relation and education of parents on understanding

In our study, majority of parents failed to recall the risks in procedure. Out of 42 father giving consent, 34 had incomplete understanding with scores below 12. Similarly four out of five mothers could not understand the risks. The reason for less participating mothers as consent provider in our study was due to the fact that although mothers accompanied children but during explanation they used to insist on fathers for counselling. This factor has a cultural importance in society as a respect or importance to father or male figures. In one prospective study of children undergoing ear, nose throat surgery, carried over on 34 patients, the author observed that maternal parent recalled the surgical risk better than paternal parents [18]. But in that study the survey participation was more by maternal parents (76%) as compared to paternal parents (18%). Statistically there was no significant correlation. In our study however, 77% of consenting parent were fathers, to whom the details were explained. Failure to recall risk and perform below score of 12 is 80.9%. This probably shows that either father were distracted by apprehension or anxiety of child's condition or counsellor spent less than required time on parent to help them understand the situation. The amount of time spent could have been different for different parents and was not calculated in this study.

Upon looking at the educational status of parents it was

noted that majority of those who had scores below 12 were below intermediate (either primary or middle) class educated. At the same time, however two graduate parents also had scores below 12. In this study the number of higher educated parents were insignificant to form a study group for comparison, still, the fact as seen, majority (79%) of those who had incomplete recall were all below intermediate grade. So, on analysing these results it may be argued that those with less education are probably less aware of surrounding conversation, demonstrate less skill of understanding or attentiveness than those with higher education. Contrary to this, one study showed lower education parents with military background demonstrated improved surgical risks recall as compared to higher education [18]. However other studies have shown higher education with better understanding of recall of risks [16,17]. These studies were from western literature. In Indian scenario, particularly in semi urban or rural setting, education is often a limiting factor. Parents instead of understanding details argue upon or negotiate on single factor that convinces them that the child shall recover. Every parent whether educated or less educated or uneducated expects answers in affirmative. Their mindset is unidirectional. This unidirectional mindset probably prevents them to understand what the physician is explaining. So, the author believes that a person with a stable mindset during counselling, irrespective of educational level can understand the risks better than the person with unstable mindset.

### Parameters of informed consent least understood

Out of six points of prior informed consent, two most important points were the one least recalled or understood by parents. 23 parents or PPR were not able to recall complications during surgery and 34 parents or PPR were not able to recall postoperative complications. This is interesting observation in our study which points towards either less stress is given on explaining these two parameters or less than adequate efforts are made to make them understand. Some studies have shown improved results of understanding with counselling along with detailed written printed hand-outs [16,17]. However in Indian contexts we believe pictorial presentation or animated video shall be more grasping rather than any written words. Parents in their apprehension or anxiety catch mostly the thing which they are expecting or the worst-case scenarios. Hence, as seen in our observation that almost all, which is 94% of them, were able to recall that there was a high risk to life during or following procedure due to variety of pre-existing morbidities. Six parents in this study could not understand diagnosis or type of disease clearly. Therefore, we believe this parameter re-

quires explanation in more lucid and layman language rather than confusing them with medical jargons. If a physician fail to consider the cultural and linguistic issues, such difficulties may arise [19]. Time has come when physician imparts a culturally compatible care to patient. Hospital can provide social co-coordinator or translator for making them understand as physician alone cannot cross all linguistic and cultural barriers.

### **Emergency and non-emergency surgery**

In our study, out of total 54 patients examined, 64.8% cases required emergency surgery within 24 hours of admission. Among them out of 43 parents with incomplete understanding, 65.11% were children requiring emergency surgery. Hence in our study although elective cases were less as compared to emergency, but most of the inabilities to recall risks completely were seen in emergency case scenario. This again indicates that apart from factors like education, understanding level or maturity level, the existing mind-set of parent affects the retention or receptive capability. However even in non-emergent surgery, 15 out of 19 could not score complete 12 as they were not able to understand and recall the explanation. This may be due to two reasons. Either they understood at the time of explanation and later they failed to recall during counselling or the message of these parameters of risks associated were not adequately conveyed to them. Either case scenario may create difficulties in court of law as it may be argued that the particular complication was not prior informed and signature or thumb impression on printed generalized consent form was taken in haste. Here, more efforts and larger studies are needed to understand the exact reason for failure of parents to understand and recall the risks after certain duration.

Law does not make any specific methodology for consenting mandatory, neither the professional regulatory body for medical professional mentions any specific methodology of consenting. Physician may, however, improve the outcome and understandability of patients or parents using certain innovative methods although with limited utility in emergency scenarios. These include pictorial presentation, Computer based interactive videos, pamphlets, or other audio-visual methods in different languages may make them understand better.

### **Experience of counsellor**

Although communicative skills vary from person to person and is a subjective quality, yet it may be argued with no definite evidence that a senior physician with all his experience and knowledge may counsel better than a postgraduate resident or junior doctor. In our study it was observed that senior consultant participated in verbal explanation in all 54 cases and in around

29% cases they also took written signature in prior informed consent. In another 70.37% cases junior doctors of the team took the prior informed consent. So, in many cases it was duplication of counselling. Still the results were far less than satisfactory. The process of taking consent or explaining was not observed and hence it may be believed that junior doctors or resident might have used different ways of executing discussion and consent process. This also gives us a hint that possibly experience of counsellors too does not have significant impact on understanding and recalling of risk.

Good communication skills are imperative for establishment of doctor patient relationship and successful understanding of consent process. These skills although inherent need to be sharpened in training modules. A competency based undergraduate curriculum for the Indian medical graduate 2018 by the then board of governors of medical council of India, proposed a revised curriculum for Indian medical graduate. Section 1 on competencies of Indian medical graduate, sub section 3 (3.3) describes need of training for doctor as a communicator with patients, families, colleagues and community. 3.3.1 "Demonstrate ability to communicate adequately, sensitively, effectively and respectfully with patients in a language that the patient understands and in a manner that will improve patient satisfaction and health care outcomes".

### **Summary and Conclusion**

Taking consent is a communication between two parties. The information delivered by physician should be received by patient or parents and should understand it and retain. The recipient of information should ask any question and clarify the doubts. Beliefs and understanding of parents may change sometimes and hence need to be reviewed at a different time again. Hence consent may not be a one-time process.

To conclude, our study highlighted that in prior informed consent procedure, risk recall or understanding of complications was far from satisfactory. Lower education status may have some adverse impact on understanding of parents. Emergency situations have higher rates of failure of understanding the severity or risk recall possibly due to disturbed mind-set of recipient. This may create grounds for parental dissatisfaction which may further progress to disgruntled parent. These are basis of possible medico legal situations if some adverse results or outcome arise.

Surgeon either experienced or a beginner should have good communicative skill with parent or patient and families to have a successful consenting outcome. Professional regulatory body for medical practitioner need to update consent related clauses keeping in view of deficiencies mentioned as above.



## Limitations

Our study had few limitations. One is small number of patient cohort. This was due to on-going pandemic during study period. A larger cohort and application of a different statistical method would have evidently established the relation of various factors. A larger randomized trial, prospective study is needed to establish these facts in Indian settings.

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