

Introduction of Module on Informed Consent Training for Interns during Compulsory Surgery Rotation

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Abstract

Background: The use of consent in patient care is a critical skill it is as essential as any other basic standard on which surgical exercise relies. In the present study, an effort was made to formulate a module for training interns on this skill. **Materials and Methods:** After taking permission from IEC, 140 interns were enrolled for the study. After needs assessment, a module for training the interns for taking informed consent in all scenarios was prepared and validated. Interns were assessed using directly observed procedural skill (DOPS). Feedback was taken from interns and faculty on training through this module at the end of their posting. **Results:** A total of 140 interns undertook 3 DOPS each and all the interns performed: nonsatisfactory in DOPS 1 (below 4 in each subcompetency), satisfactorily in DOPS 2 (4–6 in each subcompetency), and satisfactorily in DOPS 3 (6–8). Comparison of DOPS 1, 2, and 3 done was done using repeated measure ANOVA and *P* value was highly statistically significant (*P* = 0.000). Comparison of progression of scores showed statistically significant *P* value (*P* = 0.000). **Conclusion:** DOPSs is an effective and feasible assessment tool for assessing interns for taking informed consent.

Keywords: Assessment, curriculum, informed consent, internship, rotation, workplace

INTRODUCTION

Between a patient and doctor the informed consent is the communication method that eventually outcomes in patient's agreement to undergo a treatment or practice.^[1]

Informed consent initiates from legal and ethical right a patient has to direct what happens to their own body, it is the procedure by which fully informed patients can create the best choices for their health care.^[1] Any doctor's failure to obtain informed consent from patient can amount to medical malpractice.

“Without ‘consent’ in any human interactions, there is an ethical violation” - Henry Johnson Jr.

Medical education is a process of acquiring knowledge, psychological skills, positive values, and attitude^[2] and aim of medical education is to provide highly educated and qualified doctors to combat health issues^[3] Rotatory internship is part of this Indian medical education which is unstructured and most of times students are busy in copying the logbooks and

record procedures which they might have not observed and students acquires least information (reasoning feature), lowest required skills (psychological characteristic), and minimum of obligatory conduct beliefs (affective aspect)^[2] to attain results in exams and certification.

As there is a lot of hue and cry against doctors and hospitals in recent days. The Consumer Protection Act has done irreparable damage to doctor–patient relationship. Increasing medico-legal litigation related to failure to take informed consent has been labeled as a type of medical carelessness or may give rise to a cause of act for medical battery.^[4,5]

Types of consent

- Implied consent: It is consent which is not obviously given by the person, but is incidental from the individual's action or inactions. They specify their requirements short

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of essentially affirming them, for example, holding arm of patient out for a blood pressure cuff to be applied

- Verbal consent: Has a medico-legal significance. It is when an individual clearly states their agreement to an intervention or procedure. For example, the insertion of intravenous cannula, insertion of indwelling catheter, wound dressing, removal of drains, examination of genitals, rectum, and breast
- Written consent: Should be in detail in written form in medical records in patient's local language and should be signed by him and relatives. Essential be attained once treatment, examinations or technique is invasive or noteworthy probable difficulties or side effects, may unfavorably affect a patient's service, individual relationship or hobbies, affect the current or future fertility, scarring, risk to fetus or medical research or trials
- Informed consent: It is an agreement from a patient or their career to undertake specific treatment. Informed consent is an important chain for the maintenance of doctor-patient relationship. Knowledgeable approval is operationalized in operating exercise over the guideline of shared conclusion constructing.^[6] The surgeon and patient comprise an executive partnership, in communal pronouncement creation. Informed consent is greatest viewed as a procedure, not an occasion. It is an ongoing discussion among physician and patient through patient's carefulness. It initiates with a preoperative analysis and endures over surgery and postoperative action.

Confirming satisfactory conversation with patients patient-doctor relationship has been revealed to have a subordinate advantage, a decrease of operating negligence claims.^[7] Agreement must instigate with a transitory clarification of the deliberate process, counting anesthetic complex. It is wise to describe what the patient may expect to experience during surgery. Any another actions, hazards, and advantage of liability nothing adequate evidence to make a result should also contain an clarification of dangers and welfares complex.^[8,9] Medical care/operation cannot initiate except they provide knowledgeable agreement As long as, mature patients are intellectually able to make their own choice. If the patient is underage, has a severe mental incapacity, or cannot give permission, then the parents or relatives, legal guardians, or a person authorized by the court necessity give permission.

There are four basic principles of ethics^[10] while recording consent

Autonomy

The patient has self-determination of meaning, thought, and decision-making in surgery. Respect the autonomy of the patient regarding risks, benefits, and success of treatment. The patient has choice to refuse treatment even when the surgeon thinks that patient is wrong. Surgeon should have good communication skills.

Beneficence

Surgery is done for the benefit of patient. Any procedure should be done with sound judgment and responsibility. Ensure

functioning of equipment as surgeon relies on technology from diathermy to OT lights. Faculty equipment compromise patient care and increase surgical complication.

Nonmaleficence

Make sure that the procedure does not harm patient or others in society. Recognize limits of one's professional competence. Continually, update training, skills, and knowledge.

Justice

The distribution of scarce health resources and sure treatment with fairness and equality.

Open and honest communication is an integral part of the doctor-patient relationship, so ethically it is the duty of doctor to inform the patient of all the facts necessary to understand.

Constituents of an acceptable knowledgeable consent are:

- Comprehensive disclosure
- Understanding
- Approval
- Complete conversation between the patient and treating surgeon:
 - Why is the surgery optional and what is most suitable surgery?
 - What are another treatments existing?
 - Anticipated result and prognosis
 - What are the assistances, hazards, and problems of different treatment selections
 - Some surprising hazards of planned surgery.
- Whole certification of the conversation in medical record,^[11] signature on the consent form is evidence that the discussion took place and that the patient understood and decided.

Principles of consent

- Site ought to be peaceful and silent place
- Permission form must be in patient's language
- Principal person should be surgeon or qualified doctor
- Entry should be in case record sheet
- Technical language must be Avoid
- Establishment of translators
- Clarification of doubts
- Should not be taken in operation theater
- Nowadays record consent in front of webcams
- In surgical technique, approval for participation of trainees.

Examples of some influences that may mark a patient incompetent of given that capable consent either permanently or temporarily is:

- Mental retardation or mental illness
- Drug intoxication and alcohol
- brain injury, altered mental status
- Actuality too beginning to legally make judgments with reference to health care.

Adequate informed consent is rooted in respecting a person's dignity.^[11] Hence, teaching the process, need, and importance of informed consent at the level of undergraduates can

improve doctor–patient relationship and decrease medico-legal litigation.

Informed consent is traditionally taught during forensic medicine in the second semester. The training is in form didactic lectures and no hands-on training is given, in internship, the interns observe informed consent taking, but no formal training is given to interns on this most important aspect. So to address to this important need, we designed a training module to teach informed consent training. We adopted workplace-based methods, directly observed procedural skills (DOPSs) as a formative assessment tool for collecting information about interns' performance in their rotational internship duty.

Purpose of adopting workplace-based assessment^[12]

- Emphasis on scientific abilities with the necessary easy assistances (communiqué, performance, competence, ethics, and attitude)
- Statement (in real condition) and response
- Specificity of content and content
- Recompenses for some short comings in the traditional valuation approaches
- Alignment of learning with actual working.

DOPS - it is unique methods of ability valuation and was primarily established through the Royal College of Physicians in the United Kingdom,^[13] necessitates an evaluator to directly detect a learner responsibility a practice and then grade the presentation of precise predetermined mechanisms of the technique. In adding to the practice itself, these assistances also comprise statement and the informed consent procedure.

This way of the assessment can evaluate student's performance, providing feedback, and identifying areas for improving performance and filling identified gaps.

In the present study, our focus is that, after completing internship, doctors are licensed to practice, but it is very important to know how to take informed consent as due to lack of training of interaction and communication with patient one cannot develop good doctor–patient relationship.

As the extent of clinicians exercise diminishes, even though the growing attention in the content of surgical prospectus, the law leading the progression of attainment consent has been given slight responsiveness. The initiation of nonmedically experienced surgical experts advances questions approximately the extent of understanding that is necessary to confirm that valid consent is attained. The use of consent in patient care is a critical skill it is as essential as any other basic standard on which surgical exercise relies.^[14]

It is an attempt to protect patients from anxiety. Medical profession since ancient times is one of the noblest professions and doctors were regarded as next to god by society. Are we same? If not why? What wrong has happened?

Aims and objectives

- Aim is to introduce training of INFORMED CONSENT for interns

- Intern should be able to demonstrate taking informed consent in real-life scenario
- Should be able to communicate effectively with the patient
- Assessing the feasibility and acceptability of DOPS as formative assessment tool for informed consent training.

MATERIALS AND METHODS

The project was carried out with interns in the Department of Surgery during compulsory rotatory internship at Punjab Institute of Medical Sciences, Jalandhar. Faculty of the department of surgery was sensitized to the concept of DOPS assessment as a tool of formative assessment and their role as assessors. One hundred and forty interns were divided into 7 batches and each batch of 20 students. Batch of 20 interns was enrolled for the training of informed consent. The interns were also made aware of the project. During the first 7 days of posting of enrolled interns, they were given an interactive lecture on importance and principles of informed consent. After that, they were demonstrated the procedure of informed consent. Then interns were given hands on training in different scenarios through role play. DOPS assessment sheet was prepared by members of the project team. Fifteen subcompetencies were designed. Then, this assessment tool was validated by some members of MEU who are trained through ACME. Three assessors assessed each intern during three DOPS. On each of 15 subcompetencies on a scale of 1–9 (one being the lowest nine being the highest). These 15 subcompetencies were as follows:

1. Self-introduction: Greets patient well
2. Spoke with a patient in respectful manner: Demonstrates effective communication and respect to patient by vocal and nonvocal gestures
3. Attempted to establish rapport with patient: Demonstrates effective communication skills to establish rapport with patient
4. Used language that patient could easily understand: Demonstrates the need and understanding of vernacular language and translates if requires
5. Shows empathy: Demonstrates active listening and understand feelings of patient
6. Maintains appropriate boundaries with the patient: Demonstrates vocal and nonvocal gestures which are necessary for maintaining boundaries
7. Explained reasons for surgery: Determines awareness and communication abilities of explaining reasons of surgery
8. Explained procedure of surgery: Determines awareness and communication abilities of procedure of surgery
9. Explained risks of Surgery: Determines awareness and communication abilities of all risks associated with procedure
10. Explained benefits of surgery to patient: Determines understanding and communication skills regarding benefits of surgery
11. Explain what will happen if the patient does not opt for surgery: Demonstrates knowledge and communication

- skills to explain patient regarding what will happen if patient does not opt for surgery
12. Explained other treatment options/surgery: Demonstrates knowledge and communication skills regarding explaining other treatment option
 13. Ask patient to repeat what he has understood about surgery: Encourages the patient about clarity of procedure
 14. Doubts and concern about confidentiality: Provides reassurance and check discomforts concerns and complications
 15. Documentation: Documents the whole informed consent including problems and complication, arranges, and documents if any at risk consent.

After each assessment teacher gave feedback using PEDELTON'S rule. A revalidated feedback questionnaire was taken from the students and teachers at the end of their posting.

Planning

- Due clearance was taken from institutional ethical committee
- Planning of implementation of this method was done in consultation with all the faculty members and patients to be covered for informed consent were decided after discussion with the faculty. Informed consent to be taken for common surgeries (cholecystectomy, appendectomy, hernia surgery, and hemorrhoidectomy).

Data collection

- Grading in DOPS
- Mean scores of 20 interns in each subcompetencies were noted for DOPS 1, 2, and 3
- Progression of scores from DOPS 1–3 was recorded. Comparisons of scores between 1, 2, and 3 was done using ANOVA test
- If the intern scored above 4 in the DOPS test his score was satisfactory. If not, his score was unsatisfactory. The grading was done on DOPS sheet [Annexure I]
- Overall performance of procedure in DOPS 1, 2, and 3 was also noted
- Intern and faculty feedback [Annexures II and III]
- The qualitative and quantitative data were collected and thematic analysis of the qualitative data was done.

Data analysis

All the data compiled was entered into the Microsoft excel sheet. The data were analyzed using SPSS software (IBM Corp. Released 2017. IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp). Comparison of scores DOPS 1, 2, and 3 using repeated measure ANOVA test was done.

OBSERVATIONS AND RESULTS

The results of the study are as under:

1. Types of cases: Common surgeries for which consent was to be taken by interns are [Figure 1]:
 - Cholecystectomy

- Appendectomy
- Hernia
- Hemorrhoids.

2. Mean scores in each subcompetency for DOPS 1, 2, and 3: Shown in Table 1
3. Progression of scores along with *P* value “shown in Table 1
4. Overall performance of interns for performance of informed consent: Shown in Table 2
5. Feedback from faculty:

All the faculty members gave favorable response to the introduction of training of informed consent in interns during compulsory surgery rotation and expressed interest in continuing with it. Some of the comments given by faculty members were as follows:

“It’s a great concept and it is not mere recording of informed consent rather conduct of ethical surgery illustrates good citizenship and respecting human dignity.”

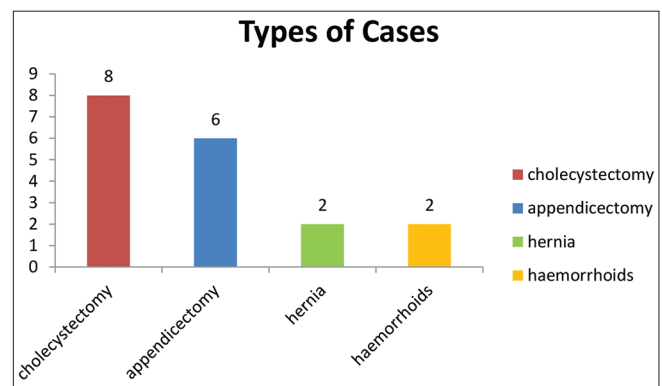


Figure 1: Different type of surgeries for which informed consent training was done

Table 1: Mean scores in each subcompetency for directly observed procedural skill 1, 2, and 3

DOPS 1 (n=20)	DOPS 2 (n=20)	DOPS 3 (n=20)	P (comparison of score DOPS 1, 2 and 3)
2.75	5.50	7.00	0.000
2.85	5.40	6.90	0.000
2.90	5.75	6.70	0.000
2.95	5.80	6.50	0.000
2.90	6.00	6.75	0.000
2.80	5.90	6.80	0.000
2.95	5.80	7.00	0.000
2.90	5.20	6.80	0.000
2.80	5.80	6.55	0.000
2.75	5.70	6.70	0.000
2.60	5.60	7.10	0.000
2.75	5.50	6.55	0.000
2.65	5.30	6.50	0.000
2.80	5.15	6.80	0.000
2.55	5.10	6.70	0.000

**P* value was significant as calculated by repeated measure ANOVA.

DOPS: Directly observed procedural skill

Table 2: Overall performance of procedure (informed consent)

DOPS 1 Trainee needs assessor with the patient	DOPS 2 Trainee needs assessor nearby	DOPS 3 Trainee could take informed consent independently and did not require any supervision	P
2.75	5.5	7.0	0.000

Level of supervision trainee needs for the procedure and Average score of 140 interns in DOPS 1, 2 and 3

“Though the MCI guidelines clearly state that medical students must be taught concept of informed consent and evaluated. None of public or private sector medical colleges in the country have made it a mandatory part of their curriculum during the final year posting in surgery or during internship. By doing this, though everybody is not going to become surgeon but by this intern will be able to communicate with the patient and develop good doctor patient relationship”

6. Feedback from interns:

“Interns gave positive response to feedback questionnaire. The feedback given by them was constructive, immediate, and helpful to them in future.

Some comments made by them are as follows:

“Do continue with it, I am more confident to interact with patient now and know the topics discussed in more details so as to explain the patients.”

“Never knew how any consultant spending so much time on patients to explain details of surgeries and its outcome and consultants taking so much pain to teach interns rightfully.”

Summary of results

A total of 140 interns undertook 3DOPS each and all the interns performed: Non satisfactory in DOPS 1 (below 4 in each subcompetency), satisfactorily in DOPS 2 (4–6 in each subcompetency), and satisfactorily in DOPS 3 (6–8) by the last DOPS. Comparison of DOPS 1, 2, and 3 done was done using repeated measure ANOVA and *P* value was highly statistically significant (*P* = 0.000). Overall performance in DOPS 1 was 2.75 (trainee needs assessor with the patient), 5.5 in DOPS 2 (trainee needs assessor nearby), and 7.0 in DOPS 3 (trainee could take informed consent independently and did not require any supervision). Comparison of progression of scores showed statistically significant *P* value (*P* = 0.000). All the faculty members and interns gave a favorable response to introduction of training of informed consent in interns during compulsory surgery rotation using DOPS as a formative assessment method.

Discussion

Informed consent is the primary paradigm for protecting the legal rights of patients and guiding the ethical practice of medicine.^[1] Clinicians should document the content of these discussions to provide evidence of their good-faith efforts. It has many implications and an Indian medical graduate must understand the process, importance, and how to document

informed consent. The medical students learn the process of taking informed consent by observing and are not formally assessed for same. Hence, their training in this important concept is not up to the mark. This project was carried out in the department of surgery to address to this need.

Interns enrolled in this study were assessed using DOPS. In first DOPS, the results showed that their skills in each subcompetency necessary for acquiring skill of taking informed consent were below 3 on an average. By this, it was established that there is a need for formal training for process of informed consent. This was in concordance with a study done by AlMahmoud *et al.* that reported heightened perception among the final year medical students of the need for greater attention to be paid to informed consent education and training.^[15]

During the second DOPS, there was improvement of overall performance as per DOPS sheet (above 4 in each subcompetency). During feedback, the interns came to know about the strengths and weaknesses. The assessor gave them feedback on areas of improvement. During third DOPS the intern's improvement (above 5 in each subcompetency) was significant as compared to first and second and *P* = 0.000. Some other studies have also reported that using DOPS gives positive impact on learning and improvement in performance of procedural skills.^[16,17]

In this study, we also recognized DOPS as an effective tool for feedback. Among the reasons cited it was reported that feedback was descriptive, in the context, private and immediate. In some other studies also importance of DOPS as a toll for effective feedback was established.^[18-20] It was reported that trainees appreciate the formative benefits which derive from the assessments, namely feedback, reassurance of satisfactory performance, and in the case of DOPS/additional one-to-one training from consultants.

On the context of feasibility and acceptability of DOPS as a formative assessment tool, both the interns and faculty gave favorable views regarding DOPS as a formative assessment tool for teaching informed consent. However, assessors were concerned about time constraints. Both interns and faculty recommend teaching informed consent for future batches and use DOPS as an assessment and teaching tool for same. However, in study done by Kundra and Sing^[21] it was reported that DOPS is a feasible and acceptable tool under Indian settings but it requires initial faculty training and some extra time.

Moreover, as MBBS students have already been tested for knowledge and somewhat for their skills domain till

internship so for knowing their clinical competence in internship, workplace-based assessments are best suited. Workplace-based valuation DOPS was considered to simplify observation and arrangement feedback on the presentation of learners in scenarios of real time.^[22] Work-place created valuation done by DOPS gives chance of improvement, as being observed, assessed, or given feedback.^[23] DOPS was a great tool for feedback because feedback was detailed, private, nonthreatening, and immediate. Interns were confident after undertaking DOPS in our study and they commented that feedback given to them was constructive and will help them in further cases.

CONCLUSION

Informed consent training can be done effectively using DOPS as a formative assessment tool. It eventually leads to better skill training in taking informed consent. DOPS is also an effective tool for feedback as the feedback given is contextual, descriptive and private. The study adds to develop good doctor–patient relationship, taking of informed consent is a great way to communicate and interact for interns. Moreover, clarity of surgical procedure before explaining everything regarding surgery to the patients and relatives. Hence, this study adds that Informed consent training can be done in a structured format which was left to chance and like any other procedure DOPS can be used as a formative assessment tool for teaching informed consent. Interns and faculty enthusiasm and participation were encouraging.

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Conflicts of interest

There are no conflicts of interest.

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Annexures: Introduction of module on INFORMED CONSENT training for Interns during compulsory surgery rotation
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ANNEXURE-I

PROCEDURE DETAILS

S.N	Observations	Below expected	Satisfactory	Above expected
1.	Self-Introduction: <i>Greets patient well.</i>			
	<input type="checkbox"/> Not observed or applicable	<input type="text" value="1"/> <input type="text" value="2"/> <input type="text" value="3"/>	<input type="text" value="4"/> <input type="text" value="5"/> <input type="text" value="6"/>	<input type="text" value="7"/> <input type="text" value="8"/> <input type="text" value="9"/>
2.	Spoke with a Patient in respectful manner: <i>Demonstrates effective communication and respect to patient by vocal and non vocal gestures.</i>			
	<input type="checkbox"/> Not observed or applicable	<input type="text" value="1"/> <input type="text" value="2"/> <input type="text" value="3"/>	<input type="text" value="4"/> <input type="text" value="5"/> <input type="text" value="6"/>	<input type="text" value="7"/> <input type="text" value="8"/> <input type="text" value="9"/>
3.	Attempted to establish rapport with patient: <i>Demonstrates effective communication skills to establish rapport with patient.</i>			
	<input type="checkbox"/> Not observed or applicable	<input type="text" value="1"/> <input type="text" value="2"/> <input type="text" value="3"/>	<input type="text" value="4"/> <input type="text" value="5"/> <input type="text" value="6"/>	<input type="text" value="7"/> <input type="text" value="8"/> <input type="text" value="9"/>
4.	Used language that Patient could easily Understand: <i>Demonstrates the need and understanding of vernacular language & translates if requires.</i>			
	<input type="checkbox"/> Not observed or applicable	<input type="text" value="1"/> <input type="text" value="2"/> <input type="text" value="3"/>	<input type="text" value="4"/> <input type="text" value="5"/> <input type="text" value="6"/>	<input type="text" value="7"/> <input type="text" value="8"/> <input type="text" value="9"/>
5.	Shows Empathy: <i>Demonstrates active listening and understand feelings of patient.</i>			
	<input type="checkbox"/> Not observed or applicable	<input type="text" value="1"/> <input type="text" value="2"/> <input type="text" value="3"/>	<input type="text" value="4"/> <input type="text" value="5"/> <input type="text" value="6"/>	<input type="text" value="7"/> <input type="text" value="8"/> <input type="text" value="9"/>
6.	Maintain appropriate boundaries with the patient: <i>Demonstrates vocal and non vocal gestures which are necessary for maintaining boundaries</i>			
	<input type="checkbox"/> Not observed or applicable	<input type="text" value="1"/> <input type="text" value="2"/> <input type="text" value="3"/>	<input type="text" value="4"/> <input type="text" value="5"/> <input type="text" value="6"/>	<input type="text" value="7"/> <input type="text" value="8"/> <input type="text" value="9"/>
7.	Explained reasons for surgery: <i>Demonstrates knowledge and communication</i>			

	<i>skills of explaining reasons of surgery</i>									
<input type="checkbox"/>	Not observed or applicable	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7	<input type="checkbox"/> 8	<input type="checkbox"/> 9
8.	Explained procedure of surgery: <i>Demonstrates knowledge and communication skills of procedure of surgery</i>									
<input type="checkbox"/>	Not observed or applicable	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7	<input type="checkbox"/> 8	<input type="checkbox"/> 9
9.	Explained risks of Surgery: <i>Demonstrates knowledge and communication skills of all risks associated with procedure</i>									
<input type="checkbox"/>	Not observed or applicable	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7	<input type="checkbox"/> 8	<input type="checkbox"/> 9
10.	Explained benefits of surgery to Patient: <i>Demonstrates knowledge and communication skills regarding benefits of surgery</i>									
<input type="checkbox"/>	Not observed or applicable	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7	<input type="checkbox"/> 8	<input type="checkbox"/> 9
11.	Explain what will happen if the patient does not opt for surgery: <i>Demonstrates knowledge and communication skills to explain patient regarding what will happen if patient does not opt for surgery</i>									
<input type="checkbox"/>	Not observed or applicable	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7	<input type="checkbox"/> 8	<input type="checkbox"/> 9
12.	Explained other treatment options/surgery: <i>Demonstrates knowledge and communication skills regarding explaining other treatment options</i>									
<input type="checkbox"/>	Not observed or applicable	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7	<input type="checkbox"/> 8	<input type="checkbox"/> 9

13.	Ask Patient to repeat what he has understood about surgery: <i>Encourages the patient about clarity of procedure</i>								
<input type="checkbox"/> Not observed or applicable	<input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>	<input type="text" value="4"/>	<input type="text" value="5"/>	<input type="text" value="6"/>	<input type="text" value="7"/>	<input type="text" value="8"/>	<input type="text" value="9"/>
14.	Doubts & concern about confidentiality: <i>Provides reassurance and check discomforts concerns and complications.</i>								
<input type="checkbox"/> Not observed or applicable	<input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>	<input type="text" value="4"/>	<input type="text" value="5"/>	<input type="text" value="6"/>	<input type="text" value="7"/>	<input type="text" value="8"/>	<input type="text" value="9"/>
15.	Documentation: <i>Documents the whole informed consent including problems and complication, arranges & documents if any at risk consent</i>								
<input type="checkbox"/> Not observed or applicable	<input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>	<input type="text" value="4"/>	<input type="text" value="5"/>	<input type="text" value="6"/>	<input type="text" value="7"/>	<input type="text" value="8"/>	<input type="text" value="9"/>
Was the procedure completed satisfactorily				Yes			No		
Please note the focus of this discussion during this assesment (Refer to possible questions in the introduction									

Feedback	
Examples of what was done well	
Areas that needed supervisory input	
Suggestions for gaining greater independence	

Overall Performance of Procedure									
What Level of supervision did the trainee need for this procedure? (See Below)	Trainee needs assessor with the patient			Trainee needs assessor nearby			Trainee could take informed consent independently and did not require any supervision		
	1	2	3	4	5	6	7	8	9
<ol style="list-style-type: none"> 1. Not comfortable leaving trainee unsupervised for any period of time. 2. Comfortable to leave trainee briefly i.e. take a brief call 3. As in 2, but comfortable staying away for a bit longer 4. Happy to leave the area, but remain immediately available in the hospital. Feels the need to check in on the trainee at regular intervals. 5. Happy to leave the area but remain immediately available in the hospital e.g. not take on another case themselves 6. As in 5 but happy to take on another case themselves 7. Could potentially be off-site but would want to talk with the trainee before the trainee started the procedure. 8. Supervisor Off-site. Confident that trainee can do the procedure but want to be notified that they are doing it. 9. Trainee could complete the procedure as a consultant. Appropriate if they don't contact supervisor. 									
Does another DOPS needs to be completed for this type of Clinical case	Yes	If Yes Why							
Trainee Comments	No								
Date of Assessment									
Trainee Name				Trainee Email					
Assessor Name				Assessor Email					

ANNEXURE-II

Feedback Questionnaires for intern- Mark ✓ in the appropriate box in front of the statement. Please mark only one answer (SD- Strongly Disagree; D- Disagree; N –neutral; A- Agree; SA- Strongly Agree)

S.No	Statement	SD	D	N	A	SA
1.	DOPS was a feasible exercise					
2.	The process was too long					
3.	It should be incorporated as a means of assessment in the curriculum					
4	It made me confident in taking informed consent.					
5	It helped me in improving my communication skills					
6	It is satisfactory method of assessing capabilities					
7	It will help in achieving good attitudinal and communication skills					
8	This program should be continued					
9	This assessment tool was an effective tool					
	for feedback.					

Any comments –

ANNEXURE: III

Feedback Questionnaires for faculty- Mark ✓ in the appropriate box in front of the statement. Please mark only one answer (SD- Strongly Disagree; D- Disagree; N – neutral; A- Agree; SA- Strongly Agree)

S. No	Statement	SD	D	N	A	SA
1.	DOPS was a feasible exercise					
2.	It's a satisfactory method of assessing competency in interns					
4	This assessment tool was an effective tool for feedback.					
5	It makes interns confident					
6	It helps in improving the communication skills of interns					
7	DOPS should be used for assessing other competencies as well					
8	It will help in achieving good attitudinal and communication skills					
9	This program should be continued					

Any Comments-