AUDIT ON VALIDITY AND ADEQUACY OF CONSENT FORMS FOR OPHTHALMOLOGY LASER PROCEDURES AND ANGIOGRAPHY IN A TERTIARY HOSPITAL

Tham ZK[1], Mohd Taufik SA[1], Ong EZ[1], and Ramli N[1].
[1]University Malaya Eye Research Centre, Department of Ophthalmology, Faculty of Medicine, University of Malaya, 50603 Kuala Lumpur, Malaysia

Correspondence:
Tham Zen Kuang,
University Malaya Eye Research Centre,
Department of Ophthalmology,
Faculty of Medicine,
University of Malaya, 50603 Kuala Lumpur, Malaysia.
Email: danielthamzk@gmail.com

Abstract

The importance of complete and valid written consent for medical procedure is indisputable. Written consent forms for ophthalmology related laser procedures and angiography were audited against guidelines regarding validity and adequacy. A full cycle clinical audit was carried out at a tertiary hospital providing ophthalmology service. A pre-intervention audit was performed in 2018 where consent forms of all ophthalmology related laser procedures and angiography were reviewed. Multiple interventions were taken to improve the adherence in obtaining a valid and adequate written consent prior to the post intervention audit. Standards of practice were compared to 'Guidelines for Consent for Treatment of Patients by Registered Medical Practitioners' by Malaysian Medical Council (MMC), and 'Consent Forms in Ophthalmic Practice' by Dr. Amit Khosla. A total of 412 consent forms were reviewed in the pre-intervention audit of 2018. Adherence to standard was 37.14%. In the post intervention audit, 256 forms were reviewed, and the adherence improved to 85.94%. Interventions taken include briefing to stakeholders, formulating a standardized risks checklist and multiple checks were done to ensure the interventions were adhered to by the doctors. The significant improvement in adequacy and validity of consent taking for ophthalmology related laser procedures and angiography showed that the interventions taken, were indeed useful. However, continuous effort in maintaining the standard is crucial for patient care and safety.

Keywords: Clinical Audit, Consent Forms**,** Laser Procedures**,** Risks and Complications**,** Angiography

Introduction

An informed consent is acquired when the patient has been thoroughly educated about the risks, procedures, and benefits of an operation. When medical and surgical procedures are proposed, ethical principles and the law both require discussion between physician and patient of the significant associated risks. If a patient is too young to legally consent to treatment or lacks the capacity to comprehend and decide independently, the informed consent must be obtained from a surrogate who is legally entitled to provide consent on the patient's behalf. The same procedure for explaining the rationale, risks, benefits, and alternatives should be followed with a guardian or surrogate (1).

In general, only fully certified medical practitioners may get a patient's consent for a procedure, examination, surgery, or therapy. The practitioner obtaining consent and conducting the procedure, examination, surgery, or treatment must be able to explain all information of the procedures to the patient. According to Malaysian Medical Council (MMC) guideline on consent for treatment of patients by registered medical practitioners, a valid consent is defined as the voluntary agreement by an individual to a proposed procedure, given after appropriate and reliable information about the procedure, including the potential risks and benefits, has been conveyed to the individual (2).

There are currently no known standardized criteria regarding specific risks that must be communicated while obtaining consent for ophthalmic operations, there is a manual available titled 'Consent Forms in Ophthalmic Practice' by Bhavna Chawla (Rajendra Prasad Centre for Ophthalmic Sciences) which is highly effective in helping ophthalmic medical practitioners in providing thorough and proper informed consent (3).

The importance of complete and valid written consent for medical procedures is indisputable, as it ensures that patients fully understand the potential risks and benefits

of the procedure, and that their consent is obtained in a legally and ethically appropriate manner. The objective of this audit is to ensure that written consent forms for ophthalmology related laser procedures and angiography meet the guidelines for validity and adequacy. To achieve this objective, the written consent forms for ophthalmology-related laser procedures and angiography will be audited against established guidelines.

A pre-interventional audit on adequacy and validity of consents taken for ophthalmology related laser procedures and angiography was carried out at a tertiary hospital providing ophthalmology service. The auditor used both MMC Guidelines for Consent for Treatment of Patients by Registered Medical Practitioners and 'Consent Forms in Ophthalmic Practice' by Bhavna Chawla as the audit guidelines. The pre-intervention audit results concluded that the consents taken in ophthalmology clinic did not fully meet the standard national guideline. To improve the validity of consents taken, multiple interventions were taken to improve the adherence in obtaining a valid and adequate written consent prior to the post intervention audit.

Materials and Methods

Sample collection

The audit was conducted from July 1st to September 30th, 2021, with the aim of completing the cycle of the previous audit conducted from January 1st to March 31st, 2018. Prior to the re-audit, interventions were implemented from June 1st to June 30th, 2021. The interventions taken include:

1. Doctors were briefed individually regarding the standards for a valid consent.
2. An example of filled consent form was placed in the procedure room.
3. A designated area was created for placement of the laser and angiography consent forms.
4. A new checklist of standardized risks according to the audit standards was formulated (Table 1)

Data of patients who underwent ophthalmology laser and angiography procedure were collected from the entries recorded by the doctors in the census book. The consent forms were then traced according to the patient's registration number and the dates which the procedure has been done via the electronic medical records (EMR).

Inclusion criteria include all consent forms which were uploaded into the EMR for patients who listed in the census book within the mentioned period, who had undergone Panretinal photocoagulation (PRP), Grid/Focal laser, Nd:YAG capsulotomy (Nd:YAG), Peripheral Iridotomy (PI), fundus fluorescein angiography (FFA) and indocyanine green angiography (ICG). Exclusion criteria include procedures listed in the census book but were abandoned due to various reasons as well as procedures that are not frequently performed such as Yag-vitreolysis, selective laser trabeculoplasty (SLT), argon laser trabeculoplasty (ALT) and barricade laser procedures.

"Malaysian Medical Council Guidelines for Consent for Treatment of Patients by Registered Medical Practitioners" was used as the standards to assess the validity of the consent forms. According to the guideline, the standard consent form should contain:

i. Patient identification data: name, identification card number.
ii. Name of procedure to be performed in full.
iii. Name of registered medical practitioner performing the procedure.
iv. Signature or thumbprint of patient and date.
v. Signature of practitioner, name stamp and date.
vi. Signature, name of witness and date.
vii. A statement to the effect that the person who is performing the procedure has explained to the patient (or next-of-kin) the nature of the procedure and the potential material risks.
viii. A statement to indicate that the Patient has received and read additional Explanatory Notes.

Consent forms that meet all the criteria outlined above will be considered valid, while those that do not meet all of the criteria will be considered invalid.

The next stage of the audit focused on evaluating the adequacy of risks disclosed in the consent form. To determine the adequacy of risks, we referred to the 'Consent Forms in Ophthalmic Practice' guidelines by Bhavna Chawla as our audit standard. Table 1 presents a comprehensive list of standard risks that should be included for various ophthalmology-related laser procedures and angiography.

Table 1: The standard risks that should be mentioned for various ophthalmology laser and angiography procedures.

No.	Procedure	Risks Involved
1	Panretinal Photocoagulation	Pain
		Transient vision loss post procedure
		Reduced night vision
		Reduced Peripheral Vision
		Scotoma
		Vitreous Hemorrhage
		Tractional Retinal Detachment
		Accidental Fovea Burn
		Aim is to prevent worsening of Diabetic Retinopathy
		Takes more than 1 session if Full PRP
2	Focal or Grid	Transient vision loss post procedure
		Scotoma
		Retinal or choroidal detachment
		Choroidal neovascular membrane
		Vitreous Hemorrhage
		Prevent worsening of maculopathy
3	Peripheral Iridotomy	Transient vision loss post procedure
		Epithelial defect
		Cornea burn
		Intraocular inflammation
		Post laser intraocular pressure (IOP) spike
		Late iridotomy closure
		Bleeding and hyphema
		Cataract
		Cystoid Macula Edema
		Retina burns
4	Nd:YAG capsulotomy	Cornea edema
		Intraocular lens (IOL) Pitting
		IOL Subluxation
		Failure requiring retreatment
		Post laser IOP Spike
		New floaters
		Cystoid Macula Edema
		Retinal detachment
5	FFA/ICG	Discomfort from needle or flash of camera
		Nausea/vomiting
		Allergic reaction including urticarial or anaphylaxis
		Skin and urine stain yellow for 36 hours

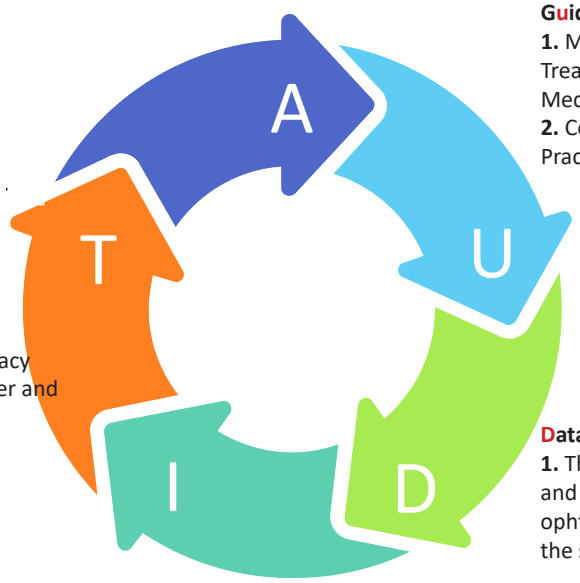
A consent form will be considered adequate if all the standard risks are clearly communicated to the patient. However, if any of the standard risks are not disclosed, the consent form will be considered inadequate.

A consent form will be considered "complete" only when both adequacy and validity criteria are met; otherwise, it will be labeled as "incomplete." For consent forms that were not available in the electronic medical record (EMR), they were categorized as "missing consent" or "consent not taken."

The overview of the audit can be illustrated using Figure 1.

AUDIT LOOP OVERVIEW (Figure 1)

Acknowledging Problem:
1. Incomplete consent form.
2. Missing consent.
3. Risks explained are not adequate.



Guidelines/ Standards:
1. MMC Guidelines for Consent for Treatment of Patients by Registered Medical Practitioners.
2. Consent Forms in Ophthalmic Practice' by Bhavna Chawla.

Results of re-audit:
1. Significant improvement in adequacy and validity of consent taking for laser and angiography procedures.

Data from previous audit:
1. The consents taken for laser and angiography procedures in ophthalmology clinic did not fully meet the standard national guideline.

Intervention:
1. Medical officers were briefed individually regarding the standards for a valid consent.

2. An example of complete filled consent form was pasted in the procedure room for reference.

3. A tray was placed in the procedure room and labeled as (CONSENT FORM).

4. A new checklist of standardized risks according to the audit standards was formulated.

Results

According to the census book, there were a total of 256 patients who had undergone laser treatment and FFA/ICG from July till September 2021. The commonest procedure done was Panretinal Photocoagulation (sectoral, scatter or full) as many as 192 patients (75%), followed by Nd:YAG capsulotomy 28 patients (10.94%), Peripheral Iridotomy 14 patients (5.47%), Grid/Focal laser 10 patients (3.91%), Barricade laser 9 patients (3.51%), and FFA/ICG 3 patients (1.17%)(Table 2).

Generally, the overall number of patients who undergone the procedures was greatly reduced compared to the previous audit as we had to cut down the number of patients during the COVID pandemics.

Table 2: Laser and angiography procedures done in laser room 27.

Procedures done	January- March 2018	July – September 2021
PRP	248 (69.09%)	192 (75%)
Nd:YAG capsulotomy	47 (11.65%)	28 (10.94%)
Grid/ focal	45 (11.17%)	10 (3.91%)
FFA / ICG	45 (10.92%)	3 (1.17%)
PI	18 (4.37%)	14 (5.47%)
Barricade	9 (2.18%)	9 (3.51%)
Total	412 (100%)	256 (100%)

Out of 256 patients, 220 patients' (85.94%) consent forms were complete, 33 consent forms were incomplete (12.89%), and there were 3 patients (1.17%) which had no consent form found in the EMR (Table 3). There is an increase in trend for complete consent form by 48.80% and number of missing and incomplete consents forms have been tremendously reduced by 34.44% and 14.36% respectively.

Table 3: Consent form status

Consent form status	January- March 2018	July– September 2021	Trend	Comments
Complete	153 (37.14%)	220 (85.94%)	↑48.80%	Increasing trend for complete consent form.
Incomplete	195 (47.33%)	33 (12.89%)	↓34.44%	Number of missing and incomplete consents have been tremendously reduced.
Absent	64 (15.53%)	3 (1.17%)	↓14.36%	

In post-intervention audit, the part of the form that was most frequently left empty was the date in 17 patients (6.64%), followed by the name and signature of the witness in 10 patients (3.91%), the stamp of the doctor and patients' identification number in 6 patients (2.34%), and the other parts were all below 2% respectively. There is generally a reduction in percentage of parts that were frequently left empty for 5 parts of the consent form, ranging from 4.59% to 9.94% (Table 4).

Table 4: Parts of consent form which were frequently left empty

Parts of consent form	January- March 2018	July – September 2021	Trend
Date	54 (13.11%)	17 (6.64%)	↓6.47%
Name of doctor in charge	49 (11.89%)	5 (1.95%)	↓9.94%
Name of witness	44 (10.68%)	10 (3.91%)	↓6.77%
Stamp of doctor	40 (9.71%)	6 (2.34%)	↓7.37%
Signature of witness	35 (8.50%)	10 (3.91%)	↓4.59%
NRIC	5 (1.21%)	6 (2.34%)	↑1.13%
Signature of patient	4 (0.97%)	3 (1.17%)	↑0.20%
Signature of doctor	3 (0.73%)	5 (1.95%)	↑1.22%
Name of procedure	1 (0.24%)	3 (1.17%)	↑0.93%
Identification Sticker not pasted on form	1 (0.24%)	3 (1.17%)	↑0.93%

Out of the 256 consent forms, 216 forms (94.14%) had the procedure risks stated. By comparing with the results for January-March 2018, it had shown a 38.31% increased in number of consent form with risk stated (Table 5).

Table 5: The number of consent form with risk stated

	January- March 2018	July – September 2021	Comments
Consent form with risk stated	230 (55.83%)	241 (94.14%)	38.31% Increase in number of consent forms with risk stated.

Table 6 shows the types of risks written and informed according to procedures as measured against the audit standard 'Consent Forms in Ophthalmic Practice' by Bhavna Chawla, it's compared with the results for January-March 2018. The improvement has been across the board, with the majority of divisions show increasing in numbers of risk written and informed to patient.

Table 6: Types of risk written and informed according to procedures (the checklist)

Name and risks of procedure	Procedure with Risks Informed/ total = 230 forms (n/%) (January- March 2018)	Procedure with Risks Informed/ total = 241 forms (n/%) July- September 2021
Panretinal Photocoagulation	Panretinal Photocoagulation (138/60.00%)	Panretinal Photocoagulation (181 /75.10%)
Pain	25 (18.12%)	↑178 (98.34%)
Transient vision loss post procedure	8 (5.80%)	↑175 (96.69%)
Reduced night vision	86 (62.31%)	↑175 (96.69%)
Reduced Peripheral Vision	91 (65.94%)	↑178 (98.34%)
Scotoma	4 (2.90%)	↑172 (95.03%)
Vitreous Hemorrhage	57 (41.30%)	↑174 (96.13%)
Tractional Retinal Detachment	74 (53.60%)	↑176 (97.24%)
Accidental Fovea Burn	18 (13.04%)	↑173 (95.58%)
Aim is to prevent worsening of Diabetic Retinopathy	5 (3.62%)	↑171 (94.48%)
Takes more than 1 session if Full PRP	0 (0.00%)	↑172 (95.03%)
Focal or Grid	Focal or Grid (27/11.74%)	Focal or Grid (10 /4.15%)
Transient vision loss post procedure	0 (0.00%)	↑8 (80%)
Scotoma	1 (3.70%)	↑9 (90%)
Retinal or choroidal detachment	5 (18.52%)	↑9 (90%)
Choroidal neovascular membrane	1 (3.7%)	↑8 (80%)
Vitreous Hemorrhage	5 (18.52%)	↑9 (90%)
Peripheral Iridotomy	Peripheral Iridotomy (8/3.48%)	Peripheral Iridotomy (12/4.98%)
Transient vision loss post procedure	0 (0.00%)	↑11 (91.67%)
Cornea burn	1 (12.50%)	↑12 (100%)
Intraocular inflammation	2 (25.00%)	↑12 (100.00%)
Post laser IOP spike	5 (62.50%)	↑11 (91.67%)
Late iridotomy closure	0 (0.00%)	↑11 (91.67%)
Bleeding and hyphema	6 (75.00%)	↑12 (100%)
Cataract	3 (37.50%)	↑12 (100%)
Cystoid Macula Edema	0 (0.00%)	↑11 (91.67%)
Retina burns	0 (0.00%)	↑12 (100%)
Nd:YAG capsulotomy	Nd:YAG capsulotomy (26/11.30%)	Nd:YAG capsulotomy (27 /11.20%)
Cornea edema	6 (23.08%)	↑23 (85.19%)
IOL Pitting	17 (65.38%)	↑26 (96.30%)
IOL Subluxation	5 (19.23%)	↑26 (96.30%)
Failure requiring retreatment	3 (11.54%)	↑23 (85.19%)
Post laser IOP Spike	9 (34.62%)	↑27 (100%)
New floaters	2 (7.69%)	↑23 (85.19%)
Cystoid Macula Edema	10 (38.46%)	↑26 (96.30%)
Retinal detachment	12 (46.15%)	↑24 (88.89%)
FFA/ICG	FFA/ICG (31/13.48%)	FFA/ICG (2 /0.83%)
Discomfort from needle or flash of camera	4 (12.9%)	↑2 (100%)
Nausea/vomiting	14 (45.16%)	↑2 (100%)
Allergic reaction including urticarial or anaphylaxis	29 (93.55%)	↑2 (100%)
Skin and urine stain yellow for 36 hours	12 (38.71%)	↑2 (100%)

Discussion

The importance of valid consent is indisputable, whereby poor quality of consenting can cause serious medico-legal issues and impact the quality of care provided to patients, therefore interventions were taken to improve the consenting process. This audit had successfully demonstrated that there is significant improvement in adequacy and hence validity of consent taking for ophthalmology laser and angiography procedures. Improvement is seen in terms of significant increment in percentages of completed consent forms. For consent forms which were incomplete, the key areas of improvement include an overall trend of reduction in percentages of parts that were left empty and an increase in documentation of risks associated with different procedures. Despite a few parts that were left empty had shown an increment, the percentage of increment was small, ranging from 0.2% to 1.22%.

This audit has several strengths. First, this study has a relatively large sample size as compared to other similar audit study (4-9). Study with a larger sample size allows generation of more representative and generalizable results. This audit also included a wide range of laser and angiography procedures. The results obtained from this audit are noteworthy as there is no previous study specifically done for ophthalmology laser and angiography procedures, hence providing empiric data for future reference. Furthermore, the pre and post intervention audit were carried out by 2 different auditors, same methodology had been employed and duration used for data collection was the same (3 months period), hence reducing possibility of any bias in obtaining the results.

An interventional study which was done by Leng and Shama (5), highlighted the deficiencies identified from initial audit, subsequently implemented a structured consultant- led teaching for all new junior doctors of the department on a six-monthly basis, had shown improvement in their accuracy in completing consent forms. Based on our literature review on similar studies, the results of the initial audit reported that only one-third of written consent forms were adequately documented (6, 10). Similarly in our study, the pre-intervention audit revealed that only 37.14% of patients had a fully completed written consent form, showing that there were considerable inadequacies in consent taking. This could jeopardize the excellent level of patient care that we all strive for and at the same time, expose the clinicians to legal ramifications.

A few studies have shown that uses of hospital standardized consent forms for various surgical procedures carried a high variability and failure in documenting potential key complications (11-14). As a results, Isherwood et al. (12) created a "complications sticker" that listed all the specific complication associated with that particular procedure to improve documentation of consent forms for total hip replacement procedures. As for our study, we have created a new checklist of standardized risks associated with the laser and angiography procedures (Table 1), and it's attached with the consent form for patient to sign upon giving consent. This measure had greatly increased the validity and adequacy of our consent forms.

The reasons for incomplete and missing consent form are likely to be multifactorial. First and foremost, the consent form used was in paper based form and was scanned into EMR system by medical record department. Hence, absence of consent form could be attributed to lacking consensus on proper placement of forms leading to misplacement and no counter check on the total number of consent form collected with the total number of procedures recorded in the census book prior sending to the medical record department.

Poorer consent practice may be a result of time constraints and work stress with burnout brought on by a heavy patient load and a busy clinic. Some medical practitioners may have discussed the risks with the patients, but due to time constraints, they have forgotten to document down. In view of varying level of experience of the doctors, those less experienced may be unaware of what is a valid consent form and what risk need to be mentioned for a specific procedure, to be deemed as adequate. Another common error is that risk factors that are deemed "generic" or "obvious" for any type of surgical procedures such as pain may be discussed via verbal consent rather than documented, this is shown in the initial audit, for Pan retinal photocoagulation procedure, pain which is one of the most common risk was only documented in 18.12% of cases.

Although progress has been made following the first audit, there is still room for improvement to ensure that we are conforming to the national guidelines. We have devised the following recommendations to help improve documentation of the consent process:

We recommend to continually assess consent forms taken, the best is to re-audit quarterly or at least annually if restricted by limited manpower. The audit results should be conveyed to each team member during the departmental meeting session to enable identification of problem and allow timely intervention to be carried out.

In view of the possibility for modest discrepancies in experience and seniority among the practicing doctors, we should brief all the newcomers of the department regarding the standard guidelines of consent for treatment and provide consistent reinforcement course to all clinicians on a regular basis. This can also provide all clinicians opportunity to clarify any doubts in consent taking with the consultants.

If delivering regular courses on consent taking is too challenging due to lack of manpower, we can design an online course on consent taking and ask all the clinicians to complete the online course on a regular basis. Virtual self-directed learning would reduce the great demand of staff to deliver talks or teachings while at the same time, improve clinicians' recall of the proper consent taking procedure. We believe that proper consent taking, and documentation

is something that every medical practitioner, regardless of seniority, can and should strive to do, provided they have been adequately briefed.

We can also place an example of filled consent form in the procedural room for reference and as refreshment, particularly for procedures that are less frequently performed such as peripheral iridotomy.

Consent forms themselves should be improved as well. We should get departmental approval to formally implement the accredited checklist of standardized risk of different laser procedures. This acts as a reminder to medical practitioners of the important risks to discuss during the consent taking process. The checklist form is simpler to complete which can save up time spent to complete paperwork, and it is clear and legible.

We should adopt usage of electronic consent forms, so that the consent can be recorded directly into the electronic system, reducing likelihood of the consent forms went missing or not uploaded. This would ensure legibility of the form as well. It would also assist with the problem of needing to find consent forms in paper-form which may be difficult at times.

However, this study does carry a few limitations. Certain procedures that are not frequently performed such as Yag-vitreolysis, SLT, ALT, barricade laser procedures were excluded in this study. Moreover, the audit only covered laser and angiography procedures that were performed in the eye clinic's procedure room, excluding any other laser procedures that were performed elsewhere such as Transscleral Cyclophotocoagulation (TSCPC), light indirect ophthalmoscope (LIO) and laser for retinopathy of Prematurity (ROP). This is due to difficulty in tracing the consent forms taken as there is no record or census book available for this purpose. Finally, only the forms scanned into the EMR were included in this audit, therefore those which are not available in the system were considered either missing or consents not taken.

More research may be done in the future, by conducting the audit in multicenter. Another area for further research could be to assess recall of risks by patients who have been consented, to ascertain how much they have actually understood and how effective is the consent taking procedure, despite proper documentation.

Conclusions

The significant improvement in adequacy and validity of consent taking for laser and angiography procedures in ophthalmology clinic showed that the interventions taken were indeed useful. However, consistent efforts will need to be in place, to fully meet the standard national guideline. After all, valid and adequate consents are important for patient care and safety.

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Not applicable.

Competing interests

The authors declare that they have no competing interests.

Ethical clearance

Formal ethical approval was not necessary because this was a clinical assessment of existing service provision. The study was registered with the eye department of the corresponding university, and audit and information governance standards were adhered to. Although written consent was not obtained, patients were verbally informed regarding the audit.

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