USI Guidelines for the conduct of live operative workshops (Under USI, Zonal or Section or Subsidiaries or affiliated bodies' banner)

Version: Sunday, 6 January 2024

Status: Approved by USI council

Guideline statement

Methodology

USI had decided to formulate the guidelines for Live operative workshops (LOW). Accordingly in the first week of July 2023, USI appointed a committee headed by Dr Prashant Mulawkar (as chairman) and Dr Sujata Patwardhan (as co-chairman). The USI office bearers gave some guidelines and suggested to formulate a committee comprising of above two persons, secretaries of sections and one representative from each zone with Dr GG Laxman Prabhu as the ex-officio member. The list of members is annexed at the end of this document. A WhatsApp group was formed, and draft statement was posted on 23 July 2023. The group members interacted on the various clauses of the document. Second version was posted on 31 July 2023. The group members interacted on this and the third version was circulated on 7 Sep 2023. A zoom meeting of the group was convened on 7 Sep 2023. This meeting convened with one week notice so that all members can spare time for it. The committee members deliberated on zoom and the final version of guideline statement was submitted to the USI legal cell for opinion. Their suggestions are incorporated in this guideline statement. Revised document was submitted on 15 Oct 2023. Suggestions received after this are incorporated in this document. The guidelines were submitted to the USI council on 31 Dec 2023. USI council unanimously approved these guidelines during the executive council meeting held on 6 Jan 2024.

Why these guidelines?

Most of the urological conferences include one or two days of Live operative workshops (LOW) wherein an experienced surgeon demonstrates his operative techniques to an audience sitting in another hall. There have been concerns about the patient safety and ethical issues about these LOWs. Hence USI council has decided to formulate these guidelines.

Scope of the guidelines

These guidelines are applicable to LOW conducted under the banner of USI, its zones, or sections, or subsidiaries (like WoU, YoU, ISU), or local bodies affiliated with USI irrespective of the financial contribution or financial involvement. Any event wherein logo of USI or its sister concerns mentioned above is displayed on the flyer, brochure or website of the event would be considered as an event where these guidelines are applicable. The guidelines are only for the conduct of the LOWs by USI and its subsidiaries keeping safety, ethical, medicolegal and personnel related factors in mind. The

logistics of organising and registration process of the LOW is outside the scope of this document. The financial arrangements in organising and sharing is outside the scope of this document.

Do we need operative workshops?

With varying curriculum of urology courses across the country and need for the continued education, the committee feels that the LOW form an important medium for knowledge dissipation and should be continued within some regulatory framework.

Measures for patient safety

Patient safety must be the first priority in conduct of LOW.

Consent

- Patients should have the right to make an informed decision about the surgical procedure being performed. The patients should be aware of the implications of the surgery being performed and should be aware about the alternative approaches. They should not be coerced into agreeing to the procedure(1).
- The patients should be explicitly made aware about their participation in LOW. They should be made aware that the surgery would be watched by a large audience. Patients should be given adequate time to take an informed decision.
- The consent form should mention the risks posed by live surgery, and presence of an audio-visual team in the OR.
- Whenever patient's history is presented, it desirable to mention that proper consent is obtained. But for obvious reasons, the consent form should not be displayed.
- Patients must be asked, well in advance, for their permission to partake in a live surgical event and must suffer no disadvantage if they decline.
- The standard consent for participation in the LOW is annexed with this document.
- The patient must be made aware by a signed document informing the patient that visiting operating faculty will be offering their services under the overall supervision of a local expert.

Privacy

During the LOW, patient's history is shared with a large audience. Every attempt should be made that patient's dignity, confidentiality, and privacy is not compromised. The committee would recommend following points.

- As far as possible, patient's face should be covered. Exception can be oral mucosa harvest for reconstructive procedure. If patient's face cannot be covered for anaesthesia related monitoring, a screen between surgical and anaesthesia team should be used.
- All radiological investigations wherein patient's identifying features are visible should be deidentified. All radiological investigations with DICOM compatibility have this feature. Appropriate help can be obtained from concerned radiology department.
- All the high-end Endo cameras have feature of recording patient's details at the start of the procedure. If such feature is used, deidentification should be practiced with the help of technical guys from concerned camera company.
- It is advisable not to declare past history which is irrelevant to the procedure being shown .

- Urological operations involve exposure of the genitals. The operating team should take utmost care to respect the privacy of the patients with modesty. However, it is made clear, that it may not always be possible.

Duties of the Local organizing committee (LOC)

- The LOC must define the educational goals of the LOW clearly.
- The LOC should designate one program director who will look after the requirement of compliances of LOW. LOC program director should be willing to handle legalities.
- The LOC should ensure that there is no undue delay in performing the surgery and should adjust the NBM status accordingly. It is not advisable to keep the patient under anaesthesia for prolonged time because screen is not available.
- If some intra-operative delays are expected due to the relay procedure, preference should be given to a patient with co-morbid condition that would impact the outcome related to prolonged anaesthesia time and surgical time.
- During case selection due weightage should be given in selecting the best candidate for the indicated procedure which would provide the best possible outcome(2).

- LOC should ensure that there would be no delay of the patient's treatment (for example upstaging of the pathology and similar outcomes) because of agreement to a live surgical procedure.
- LOC should also see that they have kept some reserve patients. These patients should be appropriately counselled.
- The LOC should be aware that anything that is published on web, YouTube, zoom etc is permanent. It is accessible to anyone on this planet. And its use is beyond anyone's control(3)
- COI and financial arrangements disclosure must be collected by the organisers under the responsibility of the director of the Live Surgery Event and kept in hospital file.
- There should be no extra financial burden on the patient on account of consent to undergo a new procedure, its recording and transmission of surgery.
- Faculty of LOC under whom the patient is admitted will be responsible for the peri operative care. There would be no liability of the operating surgeon for the postoperative outcomes. This should be vetted by the local team. The operating surgeon, although is an expert in the field, has no control on the system of the hospital. The onus of patient care and outcome would be the LOC.
- Any suit for negligence is responsibility of Local hospital, LOC, program director and surgeon under whom patient is admitted. This is specifically mentioned in temporary permission for foreign doctors to practice medicine in India which clearly states that the sponsoring authority and concerned doctor in India shall be responsible for all the medicolegal aspects concerned with the practice of medicine by foreign visiting doctor.
- Even if the operating surgeon is experienced, it is always nice for the operating surgeon to be in the comfort of his own regular operating place. With technology, it is very easy for live transmissions to be relayed, from any place to any place in the country . On this ground, if any complex or high-risk procedure is to be included in LOW, option of semi-live video or direct relay from the home institute of the surgeon should be given a thought for while planning LOW event. It minimises stress, contains legal liabilities, and contains costs. In addition, the operating surgeon would have full control over the post-op care.
- The LOC should, whenever possible, undertake proper insurance and indemnify the operating surgeons.

- LOC should arrange an interpreter for a guest faculty who are non-English speaking.
- LOC should see that sponsoring companies are not permitted to exert any influence on the surgical procedure. Standard cases rather than extremes are preferable and recommended.
- LOC should be able to handle severe complications either intra-op or post op and should be able to handle the other issues also, like social and media reactions after an unfavourable event.
- LOC should see that the patient is admitted under program director or local operating surgeon, because visiting operating surgeon neither has control over local logistics nor over the local system.
- In case of some complication the LOC should take over to the management of case or other social issues and take to its logical conclusion without any obligation to the USI.
- LOC should inform the outcome of LOW to the USI office within 4 weeks. This report should include short term outcome including histopathology report.

Duties of Operating surgeon

- The operating surgeon should ensure that they are qualified and legally privileged to perform the said surgery in India. They should have a valid registration with national medical council (erstwhile MCI).
- If any innovative surgery or modification is being demonstrated, the operating surgeon should ensure that it is properly documented in existing literature. The surgeon should ensure that the surgery or modification does not pose undue risks towards patient safety apart from well known and documented adverse effects of the procedure.
- Narrating the operative procedure during LOW may put some stress on the surgeon and may act as distraction. The operating surgeons should make themselves comfortable with audio-visual equipment and if they feel distracted, they should choose to hand over the microphone to another expert in the operating room(4).
- As far as possible the surgeon or their assistants should get familiarised with the operating equipment, facilities, or environment. If such a thing is not possible a local team member should brief the surgeon about these(2).
- If any complex steps need demonstration, the surgeon should think if a pre-recorded surgical video would be a better alternative.
- If any sponsored equipment is being demonstrated, the surgeon should make them familiarised with the equipment or technology.
- The operating surgeon should make sure that they are capable of handling severe intra-operative complications.
- For guest surgeons: Definition of Guest Surgeon: A surgeon who has expertise and experience in the domain in which the proposed procedure falls but is not associated with the institute where the operation is being carried out. Any guest surgeon(s) must be invited preferably to arrive the day before surgery, at a time which allows for a proper briefing before surgery. The guest surgeon should have recovered from jet lag. This should be followed if technically feasible.
- The operating surgeon should review all patient records and imaging before Anaesthesia (preferably examine and counsel the patient in person) to satisfy oneself for the appropriateness of diagnosis, sufficiency of investigations, pre-op preparation, and corresponding plan of surgery.

- The guest surgeon may reserve the right to decline to operate, and contingency plans should be in place for this eventuality.
- For RMP registered with any state medical council performing operative procedure in another state: The different states have different rules. Some state medical councils recommend registration with the particular state council. Whereas some state councils honour registration with NMC (erstwhile MCI) making one privileged to practice medicine in India. Registration with multiple state councils is possible and legally allowed in India. It is not clear if no objection certificate is needed from parent state medical council while registering with another state medical council. In this situation, the laws prevailing the state where LOW is being organised should be followed.
- To practice medicine which falls within the purview of THOA act and PCPNDT act, special registration is definitely required.

Special Procedures for LOW of Kidney Transplant (KT) Operations

- Registration with the respective state medical council is essential.
- The hospital where KT is to be done, must inform the Appropriate Authority for Kidney Transplant in the state, about the faculty doing KT in the hospital.
- The patient should be informed in no uncertain terms about the credentials of the faculty and special consent for operation to be done by the faculty shall be obtained from the patient.
- The post operative care shall be taken by the local KT team of the hospital where KT is being done.
- There shall be no professional charges paid for the KT done in the LOW, to the visiting faculty.
- The financial aspects of the KT procedure done in LOW, shall be strictly within the domain of the hospital, patient and the primary consultants (the original KT team of the hospital) under whose care patients shall be admitted.
- The faculty must meet the patient and the donor and ensure for himself the appropriateness of the procedure.
- The faculty and the LOC must ensure that all the provisions of the TOHA and rules are followed in each and every case to be operated upon.
- All the documents pertaining to the legal aspects of the said KT shall be always available for everyone's reference and assurance.
- Identity of the recipient and donor shall not be revealed during the procedure and ensured that it is not revealed during the recording, transmission and telecast. Privacy of the donor and the recipient shall always be respected and protected.
- There always should be a provision of an expert rescue team in case of a surgical complication.
- The visiting faculty in communication with the LOC must ensure that the instruments, equipment, imaging, disposables and the OT teams and infrastructure are adequate for a successful outcome and should they feel so, be allowed to make available such additional resources (including manpower and assistants) as may be necessary. These aspects must be clearly communicated between the visiting faculty and LOC in order to serve the patients the best that is available.

- If possible, it is advisable to have a live transmission from the centre which has the authorization and wishes to educate

Patients' advocate or ombudsman or Moderator in Operating Room / Discretion during transmission

In each LOW, there should be one senior independent urologist with no conflict of intertest. They should be inside the OT but not demonstrating surgery themselves. Their job is to safeguard interest of the patient. They should ensure that patient's best interests are maintained. If things are not going smoothly, they should be empowered to terminate the live relay or the entire operation or suggest changing the surgical approach. The ombudsman should also be empowered to depute the most competent person available in the system to take over the management of the case if the things are not going smoothly.

Measures to be adopted While doing Live Relay from Surgeon's Parent Hospital

- The operating team should ensure that the surgery being relayed meets educational goals of the LOW.
- All measures regarding patient safety and privacy mentioned above should be followed.
- The indication and appropriateness of the procedure should be looked after by the operating team or hospital.
- All the laws of the land where the procedure is being undertaken would be the responsibility of the operating team and hospital.
- The responsibility of the pre-operative, intra-operative and post-operative care would be with the operating team or hospital from where the surgery is being streamed live and organisers of LOW would have no role in this regard.

General measures/ Discipline in the theatre

- The WHO surgical check list must be used and contributed to by all involved personnel in the operating room.
- All personnel in the operating room including (but not limited to) patients, surgeons, anaesthesiologists, nurses, assistants, audio-visual team should be wearing OT scrubs. This includes OT dress, cap and mask. There should be no one moving around in civil clothes.
- Patients should also be given OT clothes.
- Representatives of industry should only be in the operating room if their presence is mandatory, and they should be appropriately registered for the event and wearing ID badge for the event. Their presence in the operating room should be certified by the host hospital or LOC.
- All procedures should preferably under general anaesthesia.
- Unnecessary movements should be avoided.
- Entry should be restricted to those who are absolutely necessary for the procedure, Ombudsman, those assisting the relay.
- No procedure should be placed in the web platforms without patients consent. This can be incorporated in the comprehensive consent taken for the procedure.

- Copyright of the educational videos generated from LOW should be determined beforehand and transferred accordingly.
- The LOW should not be used to commercially promote the centre where it is conducted.
- Patients submitting themselves for LOW should not be financially exploited for revenue generation on the pretext of treatment is given by experts in the field.
- Patient's relatives, attendants should not be allowed entry to the auditorium where the surgery is being relayed.
- Media personnel should not be allowed entry to the auditorium where the surgery is being relayed.

Next step in the guidelines

Executive summary of the guidelines should be published in the Indian Journal of Urology

Annexure

Supplementary Material1:

Addendum to patient's consent

(Standard list of complications should be included in the consent, in addition following points should be added)

Informed consent should not be demoralising.

I give consent for the surgical procedure to be recorded / shown live during the surgery for the purpose of training other doctors and to highlight the surgical technique.

I am aware that my right to refuse is intact. I am aware that I have the opportunity to withdraw at any stage pre-operatively and I will not suffer any disadvantage if I do so.

I am aware that operations on urinary tract involve exposure of the genital organs. I have been assured that my anonymity and dignity will be respected.

I am aware that the surgical clips / video recording to be used in the digital media like Facebook, Whatsapp, Google, YouTube, website etc. and in CME, workshop or conference as a part of the lecture / training for other doctors.

I am aware that the surgical clips and video recordings of the operation and my clinical data would be used for medical publications.

The visiting operating surgeon's name (Dr XXXX) credentials have been explained to me by the LOC. (Dr YYYY) / I have met the surgeon (Dr XXXX or YYYY) .

I have had the opportunity to ask questions.

My pre-operative care and post-operative care is to be undertaken by the local surgical team in conjunction with the guest surgeon and a local expert in the field.

My preoperative care, operation and the post operative care might be held in different hospital for logistics reason, but I am aware that the LOC team looking after me would be same.

Potential complications of the procedure as contained in the hospital consent form have been explained to me.

I understand that the procedure is novel.* (if applicable)

I understand that new equipment will be used during the operation.* (if applicable)

I am aware that the anaesthetic and surgical time may be longer because the surgery is being observed.

I understand that at present there is no evidence that live surgery can impact on outcomes or increase the possibility of infection.

The consent form should be signed by local expert looking after the care of the patient or a member of local organising team delegated by the organisers as is the case with surgeries performed in a surgical unit in all training institutes in India.

Supplementary Material 2

Form for temporary registration of the foreign faculty

https://www.nmc.org.in/MCIRest/open/getDocument?path=/Documents/Public/Portal/ApplicationForm/Pdf/Temporary_Registration_Non-Schedule-7A-FTP.pdf

Supplementary Material 3: Guideline Committee

Dr Prashant Mulawkar, Chairperson

Dr Sujata Patwardhan, Co-chairperson

Dr GG Laxman Prabhu, Ex-officio member

Members

Dr M S Ansari, Secretary, Paed Urology

Dr Vineet Malhotra, Secrtetary Andrology

Dr Pawan Vasudeva, Secretary FFUS

Dr Ajay Oswal, Secretary Renal transplant

Dr Harpreet Singh, Secretary Urolithiasis

Dr Ravimohan Mavuduru, Secretary Uro-oncology

Dr Rishi Nayyar, NZ representative

Dr Pankaj Joshi, WZ representative

Dr Nischit D Souza, SZ representative

Dr Rohit Upadhyay, EZ representative

Legal cell:

Dr Lalit Shah, Legal cell chairman

Dr Ashok Kumar Sharma, Legal cell member

Dr Gaurang Rameshchandra Shah, Legal cell member

References

1. Palep J. Commentary: Live telecast surgery on shaky ground. Indian J Med Ethics. 2011;8(4):245.

2. Philip-Watson J, Khan SAA, Hadjipavlou M, Rane A, Knoll T. Live surgery at conferences – Clinical benefits and ethical dilemmas. Arab J Urol. 2014 Sep;12(3):183–6.

3. Rouprêt M, Morgan TM, Bostrom PJ, Cooperberg MR, Kutikov A, Linton KD, et al. European Association of Urology (@Uroweb) recommendations on the appropriate use of social media. Eur Urol. 2014 Oct;66(4):628–32.

4. Cameron D. Surgery as Spectacle. [cited 2023 Jul 23]; Available from: https://www.ctsnet.org/article/surgery-spectacle

https://maharashtramedicalcouncil.in/Files/final%20FAQ.pdf

https://qr.ae/pKtwki