EAU POLICY STATEMENT ON LIVE SURGERY EVENTS

The EAU endorses the use of live surgery* as a technique for dissemination of surgical knowledge, and does so provided that it is organised within the following regulatory framework. The over-riding principle is that patient safety must take priority over all other considerations in the conduct of live surgery.

EAU endorsed live surgical events** must be organised under the auspices of a specifically identified local organising committee with a designated director. This committee will report to, and act under the auspices of the EAU Live Surgery Committee who will endorse the event when the following requirements are met:

A) The EAU code of conduct for live surgery is followed
B) Structured organisational requirements are followed
C) An Application & Procedure Checklist for live surgery is completed and submitted prior to the event
D) A specific Patient Consent Addendum is used and retained in the patient’s medical records
E) A pre-determined protocol of immediate post-operative care is followed
F) 90-days and 1 year outcomes and complication data must be entered into the EAU web-based Live Surgery Registry
G) For complications reporting the amended Clavien-Dindo grading system is used

This policy represents the consensus views of an expert panel assembled to advise the EAU. It will be revisited regularly, and by a reiterative process of prospective continuous evaluation and research into all aspects of live surgery, will be updated on a regular basis.

* Live surgery is any surgical procedure conducted in real time and observed for educational purposes.

** A live surgery event is any surgical procedure organised for a dedicated audience, conducted in real time and observed for educational purposes.

LOCAL ORGANISING COMMITTEE

- The local organisers will appoint a medical lead clinician (director of the live surgery event) for the event who will be responsible for the optimal patient care and safety, the faculty involved, the supporting staff, appropriate disinfection, and appropriately experienced nursing staff.
- The local organising committee will nominate an experienced urologist who is not involved in, or part of the local organising committee, whose responsibility will be at all times to look after the patient’s best interests (patient advocate). In the event of multiple, simultaneous, Live Surgery procedures conducted in different hospitals a patient advocate should be appointed in each hospital.
- By submitting an application and completed checklist the director of the event agrees to follow the EAU code of conduct and assure follow-up data.
- The director will be the responsible individual in direct contact with the EAU Live Surgery Committee. Contact: e.robijn@uroweb.org
- The educational objectives of the live surgery event have to be pre-determined.
THE EAU LIVE SURGERY CODE OF CONDUCT

• The educational goals of the live surgical event must be defined and included in the application to the EAU Live Surgery Committee.

• The role and responsibilities of all participants including the director of the Live Surgery event, the local onsite surgeon, the guest surgeon, the moderator, and all other staff members must be clearly defined.

• The director of the Live Surgery Event, the operating surgeon, all members of the operating team, and the sponsors must complete and submit a conflict of interest disclosure (COI) which is to be kept in hospital file.*

• All funding must be transparent and all financial arrangements fully disclosed in advance.*

• Sponsoring companies are not permitted to exert any influence on the surgical procedure.

• Patient dignity, anonymity and confidentiality must be maintained at all times.

• Any guest surgeon(s) must be invited to arrive the day before surgery, at a time which allows for a proper briefing before surgery

• The Patient Consent Addendum must be completed and retained in the patient’s medical records.

• All decisions must be taken in the best interest of the patient, and the patient’s advocate must be identified.

• The highest professional standards must be followed and sensationalism must be avoided.

• Post-evaluation must follow local standardised protocols.

• All outcomes and complications should be reported to the EAU Live Surgery Committee using a standardised proforma and submitted to the central EAU Live Surgery Committee registry.

• Submission of data must be done online by the director of the live surgery event, using his/her MyEAU secured Live Surgery Portfolio.

• The EAU Live Surgery Committee can, at a later stage, request disclosure of any documents kept on record by the director of the Live Surgery Event (COI, financial arrangements and Patient Consent Addendum) for assessment purposes.

* 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.
STRUCTURED ORGANISATIONAL REQUIREMENTS FOR AN EAU ENDORSED LIVE SURGERY EVENT

All statutory procedures which apply in different countries and hospitals must be followed.

1. PREPARATION

1.1 Selection of Surgeons

- The guest surgeon is to be proposed and credentials and Curriculum Vitae reviewed by the director of the Live Surgery Event.
- The local organisers should ensure that the surgeon holds operating privileges in a hospital in his/her country of origin and is granted privileges in the host unit.
- Both personal and hospital indemnity insurance must be explicitly arranged prior to the event.
- It must be explicit whether the guest surgeon is the primary surgeon or not.
- The guest surgeon must be named on the Patient Consent Addendum.

1.2 Selection of Patients

- The local organising committee is responsible for the selection of patients for the Live Surgery Event.
- Standard cases rather than extremes are preferable and recommended.
- Patient selection must reflect the pre-determined educational objectives of the event.
- 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.
- There must be no delay of the patient’s treatment as a consequence of agreement to a live surgical procedure.
- Reserve patients should be available and appropriately counselled.

1.3 Theatre Team Preparation

- The operating surgeon is requested to submit in advance a detailed list of preferences which should include:
  1. Instruments, specific disposables and devices;
  2. Patient, surgeon and scrub nurse positioning;
  3. Preferred assistant(s).
- Any language difficulties should be foreseen and where possible avoided.
- Nominated assistant(s) should be appropriately registered and suitably experienced.
- Anaesthesiologists must be involved in planning the procedure.

1.4 Pre-operative Surgical Checks

- The medical history, test results and images of the selected patient should be sent to the guest surgeon for review well in advance, preferably with an opportunity for discussion with the host surgical team.
- The surgeon should be invited to arrive at the host unit the day before the surgery.
- The guest surgeon may reserve the right to decline to operate, and contingency plans should be in place for this eventuality.
1.5 Preparation of the Patient

A standard consent to surgery used by the hospital must be signed and retained in the patient’s medical records. Patients should also give specific consent to a live link during the operation (Patient Consent Addendum). Patients should have the opportunity to withdraw at any stage pre-operatively and must suffer no disadvantage if they do so. If there is a guest surgeon, patients must meet the guest surgeon in a calm environment the day before surgery.

2. THE SURGICAL PROCEDURE

- The WHO surgical check list must be used, and contributed to by all involved personnel in the operating room.
- Additions and modifications to fit local practice may be required.
- All involved personnel must be briefed about the event by the director.
- Unnecessary personnel and equipment should not be present in the operating room.
- Representatives of industry should only be in the operating room if their presence is mandatory, and they should be appropriately registered and certified by the host hospital.
- Cases must be digitally recorded.
- Any significant delay purely for the conduct of the live proceedings is not acceptable, and must be avoided.
- The presence of a local experienced urologist, acting as the patient’s advocate in theatre, is mandatory.
- The use of one or more moderators is highly recommended.

(The role of good moderator(s) can be critical: filtering irrelevant questions, guiding to more important steps, helping the surgeon in teaching, raising the occasionally unasked interesting questions, feeling the tension in the operating theatre, minimizing distractions to the surgeon, recognising difficult moments of surgery, interrupting the teleconference to quietly handle arising complications).

The recommended set up is: one moderator in the operating room, and one or more moderators (a panel) in the audience room.

3. POST-OPERATIVE CARE

- There must be dedicated on call personnel throughout the patient’s hospital stay including general and open surgical teams.
- The postoperative follow-up under the direction of the local surgeon and team must comply with the standard protocol of the host hospital.
- The guest surgeon must be informed of and, where possible, be involved in all decisions about post-operative patient care even if not still in the unit. Regular post operative ward rounds are mandatory and the guest surgeon must be kept informed of all deviations from the care plan.
- All complications must be documented, and outcomes and complications submitted to the EAU Live Surgery Committee registry.
EAU LIVE SURGICAL EVENT APPLICATION FORM & PROCEDURE CHECKLIST

Event Title: 

Event Venue: 

Event Date: 

Event Audience: 

Organization Body: 

Director: 

Institution: 

Patient advocate
Live Surgery Event*

* In the event of multiple, simultaneous, Live Surgery procedures conducted in different hospitals a patient advocate should be appointed in each hospital.

Please describe the planned surgical procedure(s):


Please describe the educational value of the Live Surgery Event:


Local Surgeon(s):       Guest Surgeon(s):
**PROCEDURE CHECKLIST**

The director hereby agrees to follow the Code of Conduct as determined by the EAU Live Surgery Committee and assures that follow-up data will be provided 90 days and 1 year after the Live Surgery Event.

I AGREE □

**Initial Steps (Tick to confirm)**

- Detailed proposal for approval to the EAU live surgery committee submitted.
- Outline of the educational objectives of the live surgery event prepared.
- Conflicts of Interest of all participants disclosed.
- Disclosure of financial arrangements made.
- No influence of sponsoring companies confirmed.
- Patient Advocate(s) identified and informed.

**Selection of Surgeons (Tick to confirm)**

- Surgeon’s CVs and credentials submitted, reviewed and approved by director of the Live Surgery Event.
- Operating privileges in host hospital granted to guest surgeon(s) and documented by hosting hospital.
- Personal/hospital insurance indemnity of guest surgeon(s) formally checked.
- Guest surgeon(s) to be listed as the primary surgeon in the operating records.
- Guest surgeon(s) named on the Patient Consent Addendum.
- Guest surgeon(s) confirmed acceptance of the proposed cases.

**Selection of Surgeons (Tick to Confirm)**

- Standard cases rather than extremes selected.
- Reserve patient(s) identified.
- Patient’s permission to partake in Live Surgery Event obtained.
- Informed consent of the patient taken and filed.

**Selection of Surgeons (Tick to confirm)**

- Mandatory and preferred instruments, disposables and devices list received.
- Written instructions on all positioning, and steps of the procedure received.
- Preferred assistant(s) identified.
- Any language difficulties anticipated and catered for.
- Chosen assistant(s) registered and of adequate expertise.
- Anaesthesiologists involved in planning the procedure.
### Pre-Operative Surgical Checks (Tick to confirm)

<table>
<thead>
<tr>
<th>Item</th>
<th>Confirmation</th>
</tr>
</thead>
<tbody>
<tr>
<td>All statutory regulations and procedures in the host hospital and country adhered to.</td>
<td></td>
</tr>
<tr>
<td>Medical history, test result and images of the selected patient sent to guest surgeon(s) for review in advance.</td>
<td></td>
</tr>
<tr>
<td>Guest surgeon(s) to arrive the day before the surgery.</td>
<td></td>
</tr>
<tr>
<td>Guest surgeon(s) to be involved in post operative patient care.</td>
<td></td>
</tr>
</tbody>
</table>

### Preparation of Patient (Tick to confirm)

<table>
<thead>
<tr>
<th>Item</th>
<th>Confirmation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard consent to surgery signed and retained in patient’s medical records.</td>
<td></td>
</tr>
<tr>
<td>Consent to live-link obtained.</td>
<td></td>
</tr>
<tr>
<td>Patient(s) informed that they may decline participation at any time with no detriment to them.</td>
<td></td>
</tr>
<tr>
<td>Counselling of patient(s) included all criteria in the Patient Consent Addendum.</td>
<td></td>
</tr>
<tr>
<td>Patient(s) will be available the day before surgery.</td>
<td></td>
</tr>
<tr>
<td>Pre-operative meeting with guest surgeon(s) scheduled.</td>
<td></td>
</tr>
</tbody>
</table>

### Surgical Procedure (Tick to Confirm)

<table>
<thead>
<tr>
<th>Item</th>
<th>Confirmation</th>
</tr>
</thead>
<tbody>
<tr>
<td>WHO Surgical Checklist or local adaptation used.</td>
<td></td>
</tr>
<tr>
<td>Live Surgery briefing by director.</td>
<td></td>
</tr>
<tr>
<td>Restriction placed on personnel present in operating room.</td>
<td></td>
</tr>
<tr>
<td>Only necessary representatives of industry present in operating room.</td>
<td></td>
</tr>
<tr>
<td>Digital recording of the surgical procedure in place.</td>
<td></td>
</tr>
<tr>
<td>A local urologist (Patient Advocate) representing the patient present in operating room(s).</td>
<td></td>
</tr>
<tr>
<td>Moderator present in the operating room.</td>
<td></td>
</tr>
<tr>
<td>One or more moderators (a panel) in the audience room.</td>
<td></td>
</tr>
</tbody>
</table>

### Post-Operative Care (Tick to confirm)

<table>
<thead>
<tr>
<th>Item</th>
<th>Confirmation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standardised postoperative care plan agreed with the operating surgeon.</td>
<td></td>
</tr>
<tr>
<td>Dedicated on call general and open surgical teams available for at least 48hr.</td>
<td></td>
</tr>
<tr>
<td>Regular post operative ward rounds planned.</td>
<td></td>
</tr>
<tr>
<td>Guest surgeon(s) to be informed of all deviations from the care plan.</td>
<td></td>
</tr>
<tr>
<td>Outcomes to be entered into the standardised EAU Live Surgery registry.</td>
<td></td>
</tr>
</tbody>
</table>
PATIENT CONSENT ADDENDUM (To be retained in patient’s medical records)

In addition to the host hospital’s consent form, this addendum is to be signed by the patient, local surgeon and guest surgeon(s) and independent witnesses, and retained in the patient’s medical records. The information imparted to the patient must be honest, and unbiased.

The patient must be specifically informed about the following items, and understand that by signing the form the patient agrees that:

1. The educational purpose of live surgery event and the type of audience has been clearly explained to me.
2. My anonymity and dignity will be respected.
3. The visiting operating surgeon’s credentials have been explained and I have met the surgeon and have had the opportunity to ask questions.
4. My pre-operative care and post-operative care is to be undertaken by the local surgical team in conjunction with the guest surgeon.
5. Potential complications of the procedure as contained in the hospital consent form have been explained to me.
6. I understand that the procedure is novel.*
7. New equipment will be used during the operation.*
8. The anaesthetic and surgical time may be longer because the surgery is being observed.
9. I understand that at present there is no evidence that live surgery can impact on outcomes or increase the possibility of infection.

(*Delete as necessary)

Signed: ____________________________ (Patient)
Name: ____________________________ Date: __________________

Signed: ____________________________ (Local surgeon)
Name: ____________________________ Date: __________________

Signed: ____________________________ (Guest surgeon[s])
Name: ____________________________ Date: __________________

Signed: ____________________________ (Witness)
Name: ____________________________ Date: __________________
CONFLICT OF INTEREST INFORMATION
To be retained in hospital file

The EAU wishes to promote independence, objectivity, scientific rigor and a fair balance of representation, in all its activities, including Live Surgery Events.

In order to ensure this, individuals participating in Live Surgery Events are expected to disclose their financial or in-kind relationships both with health industry that develop, manufacture, distribute or sell health care materials or services, or other organizations that could represent a potential conflict of interest. Such relationships exclude personal or family medical care.

EAU recognizes that these relationships do not necessarily imply bias or decrease the value of participation in professional activities.

Disclosure of these relationships is necessary for the Live Surgery director to make an informed decision about the impact of the disclosed relationship. Recognition of potential COI will allow the Live Surgery director in question to take this into account in the decision making process.

Each individual participating in a Live Surgery Event is requested to complete this form. All relationships over the previous two calendar years and the current year (including future commitments which are foreseen over the coming year) must be disclosed.

Use the following list to declare your existing or known future financial relationships or commercial affiliations. Indicate the name of the company by entering the name in one of the six fields per category.

If you do not have any conflicts of interest to disclose please check the appropriate box.

Live Surgery Event: 

Given Name (First Name): 

Surname (Last Name): 

Date:
<table>
<thead>
<tr>
<th>Company Name</th>
<th>Company Name</th>
<th>Company Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Equity interests</td>
<td>Equity interests</td>
<td>Equity interests</td>
</tr>
<tr>
<td>Director or employee</td>
<td>Director or employee</td>
<td>Director or employee</td>
</tr>
<tr>
<td>Owner enterprise</td>
<td>Owner enterprise</td>
<td>Owner enterprise</td>
</tr>
<tr>
<td>Ownership of patent(s)</td>
<td>Ownership of patent(s)</td>
<td>Ownership of patent(s)</td>
</tr>
<tr>
<td>Royalties</td>
<td>Royalties</td>
<td>Royalties</td>
</tr>
<tr>
<td>Company consultant</td>
<td>Company consultant</td>
<td>Company consultant</td>
</tr>
<tr>
<td>Company speaker honorarium</td>
<td>Company speaker honorarium</td>
<td>Company speaker honorarium</td>
</tr>
<tr>
<td>Trial participation</td>
<td>Trial participation</td>
<td>Trial participation</td>
</tr>
<tr>
<td>Fellowship, travel grants</td>
<td>Fellowship, travel grants</td>
<td>Fellowship, travel grants</td>
</tr>
<tr>
<td>Research grants</td>
<td>Research grants</td>
<td>Research grants</td>
</tr>
<tr>
<td>Other – please indicate</td>
<td>Company</td>
<td>Conflict Type</td>
</tr>
<tr>
<td></td>
<td>Company</td>
<td>Conflict Type</td>
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<td></td>
<td>Company</td>
<td>Conflict Type</td>
</tr>
</tbody>
</table>
CHARLSON COMORBIDITY INDEX

(ftp://www.fpnotebook.com/prevent/Exam/ChrlsnCmrbdtyIndx.htm)

Aka: Charlson Comorbidity Index, Comorbidity-Adjusted Life Expectancy

1. **Indication**
   1. Assess whether a patient will live long enough to benefit from a specific screening measure or medical intervention

2. **Scoring: Comorbidity Component (Apply 1 point to each unless otherwise noted)**
   1. Myocardial Infarction
   2. Congestive Heart Failure
   3. Peripheral Vascular Disease
   4. Cerebrovascular Disease
   5. Dementia
   6. COPD
   7. Connective Tissue Disease
   8. Peptic Ulcer Disease
   9. Diabetes Mellitus (1 point uncomplicated, 2 points if end-organ damage)
   10. Moderate to Severe Chronic Kidney Disease (2 points)
   11. Hemiplegia (2 points)
   12. Leukemia (2 points)
   13. Malignant Lymphoma (2 points)
   14. Solid Tumor (2 points, 6 points if metastatic)
   15. Liver Disease (1 point mild, 3 points if moderate to severe)
   16. AIDS (6 points)

3. **Scoring: Age**
   1. Age <40 years: 0 points
   2. Age 41-50 years: 1 point
   3. Age 51-60 years: 2 points
   4. Age 61-70 years: 3 points
   5. Age 71-80 years: 4 points

4. **Interpretation**
   1. Calculate Charlson Score or Index (i)
      1. Add Comorbidity score to age score
      2. Total denoted as ‘i’ below
   2. Calculate Charlson Probability (10 year mortality)
      1. Calculate Y = e^[(i * 0.9)]
      2. Calculate Z = 0.983^Y
      3. where Z is the 10 year survival

5. **References**
## CLAVIEN-DINDO GRADING SYSTEM FOR THE CLASSIFICATION OF SURGICAL COMPLICATIONS

<table>
<thead>
<tr>
<th>Grades</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade I</td>
<td>Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic and radiological interventions. Allowed therapeutic regimens are: drugs as antiemetics, antipyretics, analgetics, diuretics and electrolytes and physiotherapy. This grade also includes wound infections opened at the bedside.</td>
</tr>
<tr>
<td>Grade II</td>
<td>Requiring pharmacological treatment with drugs other than such allowed for grade I complications. Blood transfusions and total parenteral nutrition are also included.</td>
</tr>
<tr>
<td>Grade III</td>
<td>Requiring surgical, endoscopic or radiological intervention.</td>
</tr>
<tr>
<td>Grade III-a</td>
<td>Intervention not under general anesthesia.</td>
</tr>
<tr>
<td>Grade III-b</td>
<td>Intervention under general anesthesia.</td>
</tr>
<tr>
<td>Grade IV</td>
<td>Life-threatening complication (including CNS complications: brain haemorrhage, ischaemic stroke, subarachnoid bleeding, but excluding transient ischaemic attacks) requiring IC/ICU management.</td>
</tr>
<tr>
<td>Grade IV-a</td>
<td>Single organ dysfunction (including dialysis).</td>
</tr>
<tr>
<td>Grade IV-b</td>
<td>Multi-organ dysfunction.</td>
</tr>
<tr>
<td>Grade V</td>
<td>Death of a patient.</td>
</tr>
<tr>
<td>Suffix ‘d’</td>
<td>If the patients suffers from a complication at the time of discharge, the suffix “d” (for ‘disability’) is added to the respective grade of complication. This label indicates the need for a follow-up to fully evaluate the complication.</td>
</tr>
</tbody>
</table>

For more information, visit http://www.surgicalcomplication.info/templates_download.html
ECOG PERFORMANCE STATUS

These scales and criteria are used by doctors and researchers to assess how a patient’s disease is progressing, assess how the disease affects the daily living abilities of the patient, and determine appropriate treatment and prognosis. They are included here for health care professionals to access.

<table>
<thead>
<tr>
<th>Grades</th>
<th>ECOG</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Fully active, able to carry on all pre-disease performance without restriction.</td>
</tr>
<tr>
<td>1</td>
<td>Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work.</td>
</tr>
<tr>
<td>2</td>
<td>Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours.</td>
</tr>
<tr>
<td>3</td>
<td>Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours.</td>
</tr>
<tr>
<td>4</td>
<td>Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair.</td>
</tr>
<tr>
<td>5</td>
<td>Dead.</td>
</tr>
</tbody>
</table>

* As published in Am. J. Clin. Oncol.:

The ECOG Performance Status is in the public domain therefore available for public use. To duplicate the scale, please cite the reference above and credit the Eastern Cooperative Oncology Group, Robert Comis M.D., Group Chair.
AMERICAN SOCIETY OF ANESTHESIOLOGISTS (ASA)
ASA Physical Status Classification System

**ASA Physical Status 1** - A normal healthy patient.
**ASA Physical Status 2** - A patient with mild systemic disease.
**ASA Physical Status 3** - A patient with severe systemic disease.
**ASA Physical Status 4** - A patient with severe systemic disease that is a constant threat to life.
**ASA Physical Status 5** - A moribund patient who is not expected to survive without the operation.
**ASA Physical Status 6** - A declared brain-dead patient whose organs are being removed for donor purposes.

These definitions appear in each annual edition of the ASA Relative Value Guide.® There is no additional information that will help you further define these categories.
The Logo

The EAU endorses the use of live surgery as a technique for dissemination of surgical knowledge, and does so provided that it is organised within this regulatory framework. The over-riding principle is that patient safety must take priority over all other considerations in the conduct of live surgery.

Disclaimer

The European Association of Urology (EAU) Live Surgery Committee expressly disclaim all responsibility for any act of omission or commission on the part of the Event Organiser, Institution, operating surgeons and any or all other individuals undertaking any live surgical procedure under the auspices of the EAU. No liability is accepted for any delays, damages, personal injury or death linked to the live surgery event.