Site_ID: __ __ __ __

Patient ID: __ __ __ __

- EPIS-AKI -

INTERNATIONAL OBSERVATIONAL STUDY TO EVALUATE THE EPIDEMIOLOGY OF SURGICAL-INDUCED ACUTE KIDNEY INJURY

CRF

INSTRUCTIONS FOR THE COMPLETION OF CASE REPORT FORMS

- Please use a black or dark-blue ballpoint pen to complete the case report form (CRF) and print legibly in English).
- In case of error, draw a single line through the incorrect entry, so the original entry is still visible and write the correct value next to it. Date and initial the correction.
- Dates must be entered in the order day / month / year. Write out the month using the first three letters
  Example: April 24th 2020 must be 1 8 / A P R / 2 0 2 0
  In case of unknown day or month for a date, please indicate "UK"
  Example: April 2020 must be U K / A P R / 2 0 2 0
- Times must be entered as 24-hour clock time. Valid times are: 0 0 : 0 0 to 2 3 : 5 9. Must use leading zeros.
- If a portion of an examination / module was not performed for any reason or the data is unobtainable, please cross out the section concerned and state the reason using the following abbreviations as appropriate:
  ND = not done **NA** = not applicable **UK** = unknown
  Example: Weight _ U K . _
- Please cross out unused repeating lines.
- ***** is equal to "**must provide value**"

Site_ID: __ __ __ __

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INCLUSION CRITERIA

The following must be answered with YES otherwise the subject is not eligible for the study

1. Age ≥ 18* ☐1yes ☐0no
2. Major surgeries with a duration of at least 2 h* ☐1yes ☐0no
3. Planned or unplanned admission to the ICU, IMC or PACU after surgery* ☐1yes ☐0no
4. Written informed consent /patient agreement* ☐1yes ☐0no

EXCLUSION CRITERIA *(inclusion only if none of the exclusion criteria are fulfilled)*

The following must all answered with NO otherwise the subject is not eligible for the study

1. Pre-existing Acute Kidney Injury* ☐1yes ☐0no
2. AKI within the last 3 months* ☐1yes ☐0no
3. End-stage renal disease requiring Renal Replacement Therapy* ☐1yes ☐0no
4. Kidney transplant* ☐1yes ☐0no

NEW PATIENT ENTRY

Admission date hospital*: __ __ /__ __ __ / __ __ __ __ [DD/MMM/YYYY]

Inclusion date*: __ __ /__ __ __ / __ __ __ __ [DD/MMM/YYYY]

Operation date*: __ __ /__ __ __ / __ __ __ __ [DD/MMM/YYYY]

Admission date ICU*: __ __ /__ __ __ / __ __ __ __ [DD/MMM/YYYY]

Site_ID: __ __ __ __

Patient ID: __ __ __ __

PATIENT DATA

Age*: __ __ [years]

Gender*: ☐1Male ☐2Female ☐999Unknown

Ethnicity*: ☐1Caucasian ☐2Black / African descent ☐3Asian ☐4Hispanic

☐5Other Specify: _____

Height*: __ __ __ [cm]

Weight*: __ __ __ [kg]

Creatinine baseline*: _____ ☐1mg/dL ☐2µmol/L ☐999Unknown

(known or presumed within 7 days prior surgery):

Site_ID: __ __ __ __

Patient ID: __ __ __ __

EPIS-AKI
Epidemiology of surgical induced acute kidney injury

MEDICAL HISTORY

COMORBIDITIES

Hypertension*: ☐1yes ☐0no

Atrial fibrillation/flutter*: ☐1yes ☐0no

Previous myocardial infarction*: ☐1yes ☐0no

Congestive heart failure*: ☐1yes ☐0no

If **yes**, please specify*: ☐1NYHA I ☐2NYHA II ☐3NYHA III ☐4NYHA IV

Diabetes*: ☐1yes ☐0no

If **yes**, please specify*: ☐1IDDM ☐2NIDDM

COPD* ☐1yes ☐0no

CKD [GFR < 60 mL/min]* ☐1yes ☐0no

If **yes**, please specify CKD stage*: ☐3 3 (eGFR 30-59 ml/min)

☐4 4 (eGFR 15-29 ml/min)

☐5 5 (eGFR < 15 ml/min) (= exclusion criterion)

Peripheral vascular disease*: ☐1yes ☐0no

Previous stroke*: ☐1yes ☐0no

ASA score*: ☐1ASA 1 ☐2ASA 2 ☐3ASA 3 ☐4ASA 4

MEDICATION

Aspirin (ASS)*: ☐1yes ☐0no

ACE inhibitors or ARBs*: ☐1yes ☐0no

Beta-blockers*: ☐1yes ☐0no

Diuretics*: ☐1yes ☐0no

NSAIDs (except ASS)*: ☐1yes ☐0no

Statins*: ☐1yes ☐0no

Vasopressors*: ☐1yes ☐0no

Use of contrast media one week prior to surgery*: ☐1yes ☐0no

Site_ID: __ __ __ __

Patient ID: __ __ __ __

INTRAOPERATIVE DATA

SURGICAL SPECIALTY (choose specialty responsible for surgical intervention)*

☐1Abdominal/General

☐2Cardiac

☐3Gynaecologic/Obstetric

☐4Neurosurgical

☐5Orthopaedic

☐6Thoracic

☐7Trauma

☐8Vascular

☐9Urologic

☐10Others: If **yes**, please specify: _____

TYPE OF SURGERY*

☐1Open surgery ☐2Non-robotic minimal invasive surgery

☐3Robotic surgery

☐4Planned combined minimal invasive and open surgery

☐5Unplanned combined minimal invasive and open surgery

SURGICAL PROCEDURE*

(See official website of International Classification of Health Interventions: https://www.mitel.dimi.uniud.it.ichi):

__ __ __. __ __ . __ __ (Example: laparoscopic appendectomy code: KBO.JK.AB)

__ __ __. __ __ . __ __ Please add up to three codes if there was more than one

__ __ __. __ __ . __ __ surgical procedure performed at the same time.

DURATION

Skin incision date/time*: __ __ /__ __ __ / __ __ __ __ [DD/MMM/YYYY] __ __ : __ __ [HH:MM]

Skin suture date/time*: __ __ /__ __ __ / __ __ __ __ [DD/MMM/YYYY] __ __ : __ __ [HH:MM]

Site_ID: __ __ __ __

Patient ID: __ __ __ __

If **CPB**, please specify*:

Total CPB time*: _____ min Total X-Clamp time*: _____ min

INTRAOPERATIVE DATA – CONTINUATION (Data from start of anesthesia until end of anesthesia)

FLUID INTAKE

Crystalloids*: __ __ __ __ __ [mL]

Colloids*: __ __ __ __ __ [mL]

Cell saver used*: ☐1yes ☐0no

(If a cellsaver is used please disregard the cell savers amount in the following and DO NOT include its volume in fluid intake/output calculations.)

EC*: __ __ __ __ __ [mL]

TC*: __ __ __ __ __ [mL]

FFP*: __ __ __ __ __ [mL]

OUTPUT

Total blood loss*: __ __ __ __ __ [mL]

Urine catheter used*: ☐1yes ☐0no

Total urinary output*:__ __ __ __ __ [mL]

EPISODES OF HYPOTENSION (MAP < 55 mmHg for more than 5 minutes)*: ☐1yes ☐0no

Application of vasopressors*: ☐1yes ☐0no

If **yes**, please specify*:
- ☐1Norepinephrine
- ☐2Epinephrine
- ☐3Dobutamine
- ☐4Vasopressin
- ☐5Other: _____

Application of nephrotoxic agents*: ☐1yes ☐0no

If **yes**, please specify*:
- ☐1ACEi/ARBs
- ☐2Aminoglycosides
- ☐3Amphotericin B
- ☐4Cyclosporine/Tacrolimus

☐5NSAIDs (except Aspirin/ASS)
☐6Radiocontrast agents
☐7Vancomycin
☐5Other: _____

Application of diuretics*: ☐1yes ☐0no

If **yes**, please specify*: _____

Intraoperative complications ☐1yes ☐0no

If **yes**, please specify*: ☐1CPR
☐2 Arrhythmias
☐3 Bleeding (Requiring at least one red blood cell unit)
☐4Pulmonal complications (e.g., aspiration, bronchospasm)
☐5Allergic reaction
☐6Other: _____

Site_ID: __ __ __ __

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EPIS-AKI
Epidemiology of surgical induced acute kidney injury

POSTOPERATIVE DATA (from end of anesthesia until end of postoperative day 3)

Start of Documentation date/time*: __ __ /__ __ __ / __ __ __ __ __ __ : __ __
(= end of anesthesia) [DD/MMM/YYYY] [HH:MM]

End of Documentation date/time*: __ __ /__ __ __ / __ __ __ __ __ __ : __ __
(= end of postoperative day 3) [DD/MMM/YYYY] [HH:MM]

APACHE II*: __ __ (Determined within 24 hours of admission to ICU)

SAPS*: __ __ __ (Determined within 24 hours of admission to ICU)

FLUID INTAKE (cumulative, i.v. and oral)

Crystalloids*: __ __ __ __ __ [mL]

Colloids*: __ __ __ __ __ [mL]

EC*: __ __ __ __ __ [mL]

TC*: __ __ __ __ __ [mL]

FFP*: __ __ __ __ __ [mL]

OUTPUT (cumulative)

Total blood loss*: __ __ __ __ __ [mL] (including drainages)

Total urinary output*:__ __ __ __ __ [mL]

Urine catheter removed*: ☐$_0$Immediately post-operative
☐$_1$Day 1 ☐$_2$Day 2 ☐$_3$Day 3
☐$_4$Removed later than day 3

DRUG APPLICATION

Application of vasopressors*: ☐$_1$yes ☐$_0$no

If **yes**, please specify*: ☐$_1$Norepinephrine
☐$_2$Epinephrine
☐$_3$Dobutamine
☐$_4$Vasopressin
☐$_5$Other: _____

Site_ID: __ __ __ __

Patient ID: __ __ __ __

Application of nephrotoxic agents*: ☐1yes ☐0no

If **yes**, please specify*:
- ☐1ACEi/ARBs
- ☐2Aminoglycosides
- ☐3Amphotericin B
- ☐4Cyclosporine/Tacrolimus
- ☐5NSAIDs (except Aspirin/ASS)
- ☐6Radiocontrast agents
- ☐7Vancomycin
- ☐8Other: _____

Application of diuretics*: ☐1yes ☐0no

☐0Post-OP ☐1Day 1 ☐2Day 2 ☐3Day 3

POSTOPERATIVE DATA CONTINUED (from end of anesthesia until end of postoperative day 3)

POSTOPERATIVE COMPLICATIONS*: ☐1yes ☐0no

If **yes**, please specify*:
- ☐1Hemodynamic instability (requiring new onset of vasopressor therapy or increase of norepinephrine/epinephrine ≥ 0.02µg/kg/min)
- ☐2Bleeding (requiring at least one red blood cell unit)
- ☐3Re-operation
- ☐4Pneumonia
- ☐5Sepsis
- ☐6Other: _____

KIDNEY FUNCTION:

Table 1. KDIGO criteria for diagnosis of AKI

Stage	Serum creatinine	Urine output
1	≥ 0.3 mg/dL (≥ 26.5 µmol/L) increase in 48 h *or* 1.5–1.9-times baseline within the last 7 days	< 0.5 mL/kg/h for ≥ 6 h
2	2.0-2.9-times baseline	< 0.5 mL/kg/h for ≥ 12h
3	3-times baseline *or* ≥ 4.0 mg/dL (≥ 353.6 µmol/L) increase *or* initiation of renal replacement therapy	< 0.3 mL/kg/h for ≥ 24 h *or* anuria for ≥ 12 h

Acute kidney injury (AKI)*: ☐1yes ☐0no

Severity of AKI (worst case)*: ☐1KDIGO 1 ☐2KDIGO 2 ☐3KDIGO 3

Occurrence*: ☐0Post-OP ☐1Day 1 ☐2Day 2 ☐3Day 3

Duration of AKI*: ☐1Transient (< 48h) ☐2Persistent (> 48h)

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Diagnosis (worst case AKI)*: ☐1SCr ☐2Urine output ☐3Both

Bladder catheter removed* ☐0Post-OP ☐1Day 1 ☐2Day 2 ☐3Day 3

(This is to evaluate whether AKI can only be diagnosed by creatinine)

Renal replacement therapy (RRT)*: ☐1yes ☐0no

If **yes**, start of RRT*: __ __/__ __ __ / __ __ __ __ [DD/MMM/YYYY]

Modality at time of initiation*: ☐1CRRT ☐2SLEDD ☐3IHD

Indication for initiation of RRT*: ☐1Lung edema ☐2Hypervolemia

☐3Electrolyte derangement

☐4Uremia ☐5Anuria ☐6Others

Site_ID: __ __ __ __

Patient ID: __ __ __ __

OUTCOMES

Date of ICU discharge*: __ __ /__ __ __ / __ __ __ __ [DD/MMM/YYYY]

Date of Hospital discharge*: __ __ /__ __ __ / __ __ __ __ [DD/MMM/YYYY]

Condition at hospital discharge*: ☐$_0$Alive ☐$_1$Death

Date of death*: __ __ /__ __ __ / __ __ __ __ [DD/MMM/YYYY]

Serum Creatinine

at ICU discharge*: _____ ☐$_1$mg/dL ☐$_2$µmol/L

at hospital discharge*: _____ ☐$_1$mg/dL ☐$_2$µmol/L

RRT at hospital discharge*: ☐$_1$Yes ☐$_0$No

If **yes***: Total days RRT __ __ __

DAY 90 FOLLOW UP

Index study date +90

Date of Follow Up*: _____ /_____ /_____ (DD/MMM/YYYY)

Condition*: ☐$_0$Alive ☐$_1$Death Date of death : __ __/__ __ __ / __ __ __ __ [DD/MMM/YYYY]

RRT*: ☐$_1$yes ☐$_0$no

Total days RRT (from hospital discharge until index study +90): _ _ _ ☐$_{999}$unknown

Serum Creatinine*: _____ ☐$_1$mg/dL ☐$_2$µmol/l ☐$_{999}$unknown