

Initials patient:

Patientnumber: -

Acute Kidney Injury – Epidemiologic Prospective Investigation (AKI-EPI)

Case Record Form



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A) Inclusion - Exclusion

1) Inclusion

- Patients \geq 18 year
- Informed Consent according to Local Ethics Committee

2) Exclusion

- Patients on chronic Renal Replacement Therapy (RRT)
- Patients admitted after recent kidney transplant (< 3 months)
- ICU discharge \leq 24H and alive
- Readmission to the ICU during the same hospitalization episode (Consider only the first admission to the ICU)

3) Informed Consent (according to local regulations)

- Explicit oral consent by patient or Legal Authorised Representative
- Written consent by patient or Legal Authorised Representative (+ form)

Date

// (ddmmyyyy)

Name and signature investigator:

.....

Initials patient: Patientnumber: -**B) Patient registration (see apendix)****1. Patient data:**Patient number: -Day of birth : // (ddmmyyyy) Age: yearAdmission Hospital: // (ddmmyyyy)Admission ICU: // (ddmmyyyy)Admission: Planned
Not planned Gender: male
female Intra hospital location before ICU: OR ER
Other ward Other ICU None Race: Caucasian Black Asian
Hispanic Other Weight: kgRepresentative Serum Creatinine: mg/dL μ mol/LRepresentative Serum Urea/BUN: mg/dL mmol/L

Initials patient: Patientnumber: -**2. Comorbidities (for SAPS 3 score) (see appendix)**

Cancer therapy	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>		
Cancer	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>		
Hematologic Cancer	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>		
Chronic heart failure (NYHA IV)	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>		
Cirrhosis	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>		
AIDS	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>		
Hypertension	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>		
COPD	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>		
Diabetes mellitus	No	<input type="checkbox"/>	Insulin	<input type="checkbox"/>	Non-insulin	<input type="checkbox"/>
Vasoactive drugs before ICU admission	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>		

Initials patient: Patientnumber: -**3. Reason for ICU admission** **CARDIOVASCULAR**Rhythm disturbances Yes No Hypovolemic shock Yes No Septic shock Yes No Anaphylactic, other shock Yes No **HEPATIC**Liver failure Yes No **DIGESTIVE**Severe acute pancreatitis Yes No Acute abdomen, other Yes No **NEUROLOGIC**Intracranial mass effect Yes No Focal neurologic deficit Yes No Seizures Yes No Coma/Stupor/Agitation/Confusion/
Delirium/Obtunded patient/ Vigilance
Disturbances Yes No

Initials patient: Patientnumber: -**4. Surgical status at admission**

Scheduled surgery Yes No

Emergency surgery Yes No

No surgery Yes No

5. Anatomical site of surgery

Transplantation surgery Yes No

Cardiac surgery without valve repair Yes No

Trauma Yes No

Neurosurgery Yes No

Other surgery Yes No

6. Acute infection at ICU admission

- Nosocomial (>48 h after hospital admission)
- Respiratory

7. Variables obtained within 1 h before or after ICU admission

Glasgow Coma Scale (estimated)		3-15
Total Bilirubin (highest value)		mg/dL $\mu\text{mol/L}$
Highest body temperature		$^{\circ}\text{C}$
Creatinine (highest value)		mg/dL $\mu\text{mol/L}$
Heart rate (highest value)		
Leucocytes (highest value)		$\times 1000 / \text{mm}^3$
pH (lowest value)		
Platelets (lowest value)		$\times 1000 / \text{mm}^3$
Systolic blood pressure (lowest value)		mmHg
Mechanical ventilation	Yes / No	
PaO ₂		mmHg kP
Oxygen saturation		
FiO ₂ *		

* For spontaneous breathing patients see Appendix 1

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B) Patient daily data entry

Date	/ /2010	/ /2010	/ /2010	/ /2010	/ /2010	/ /2010	/ /2010
RRT							
No							
CVVH							
CVVHD							
CVVHDF							
IHD							
PD							
Creatinine							
UO over 6h* (<0.5 m/kg over 6h)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
UO over 12h* (<0.5 m/kg over 12h)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
UO over 24h* (<0.5 m/kg over 24h)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Anuria over 12h	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
UO: incomplete 24 h collection/ mL	<input type="checkbox"/> /	<input type="checkbox"/> /	<input type="checkbox"/> /	<input type="checkbox"/> /	<input type="checkbox"/> /	<input type="checkbox"/> /	<input type="checkbox"/> /

RRT = renal replacement therapy, CVVH/HD/HDF=continuous veno venous hemofiltration / hemodialysis / hemodiafiltration, IHD=intermittent hemodialysis, PD=peritoneal dialysis, UO=urine output

*On the website, you will find the cut off urine output for this patient to fulfill the AKI criteria.

Initials patient: Patientnumber: -

C) AKI data entry form

You will be asked to fill out these data by the website when the patient meets AKI criteria.

Diuretic Therapy (24 h preceding AKI diagnosis)	<input type="checkbox"/>
Nephrotoxic Therapy (72 h preceding AKI diagnosis)	
Aminoglycosides	<input type="checkbox"/>
Amphotericin B	<input type="checkbox"/>
Radio-contrast media (iodinated)	<input type="checkbox"/>
Non steroidal anti-inflammatory drugs (NSAID's)	<input type="checkbox"/>
Angiotensin-converting enzyme inhibitors/angiotensin II receptor blockers (ACEI/ARB)	<input type="checkbox"/>
Etiology of AKI	
Drug induced (including radio-contrast)	<input type="checkbox"/>
Sepsis	<input type="checkbox"/>
Hypovolemia	<input type="checkbox"/>
Cardiogenic shock	<input type="checkbox"/>
Hepatorenal syndrome	<input type="checkbox"/>
Obstructive	<input type="checkbox"/>
Other	<input type="checkbox"/>

Initials patient: Patientnumber: -

SOFA score data (24h preceding AKI diagnosis)			
Serum Creatinine (highest value)			
Urine output (mL/day) (lowest value)			
Platelets (lowest value)			
Total Bilirubin (highest value)			
Mechanical Ventilation	No	Invasive	Non Invasive
PaO ₂ *			
FiO ₂ */**			
Mean Arterial Pressure (lowest value)			
Norepinephrine (µg/kg/min) (highest value)			
Epinephrine (µg/kg/min) (highest value)			
Dopamine (µg/kg/min) (highest value)			
Dobutamine (µg/kg/min) (highest value)			
Vasopressin (µg/kg/min) (highest value)			
Other vasoactive therapy (highest value)			
Glasgow Coma Scale(lowest value)			
Intra-abdominal pressure (highest value)			

* SOFA scores for the lowest PaO₂/FiO₂ ratio. Therefore, you should record the PaO₂ and FiO₂ that constituted the lowest PaO₂/FiO₂ ratio during the preceding 24h.

**For spontaneous breathing patients see Appendix 2

Initials patient: Patientnumber: -**D) Patient Discharge Data**

	Yes	No
Was there a decision to withhold or withdraw a life sustaining therapy?	<input type="checkbox"/>	<input type="checkbox"/>
Date (ddmmyyyy)		
ICU outcome		
Status: Alive	<input type="checkbox"/>	<input type="checkbox"/>
ICU discharge date (ddmmyyyy)		
Serum creatinine (enter most recent creatinine prior to ICU discharge)		
Renal Replacement Therapy at time of discharge. (enter the type even if the patient did not receive a treatment on the day of discharge)		
None	<input type="checkbox"/>	
CVVH	<input type="checkbox"/>	
CVVHD	<input type="checkbox"/>	
CVVHDF	<input type="checkbox"/>	
IHD	<input type="checkbox"/>	
PD	<input type="checkbox"/>	
Hospital outcome		
Status: Alive	<input type="checkbox"/>	<input type="checkbox"/>
Hospital discharge date (ddmmyyyy)		

Initials patient: Patientnumber: -

Serum creatinine (enter most recent creatinine prior to hospital discharge)	
Renal Replacement Therapy at time of discharge. (enter the type even if the patient did not receive a treatment on the day of discharge)	
None	<input type="checkbox"/>
IHD	<input type="checkbox"/>
PD	<input type="checkbox"/>

Initials patient: Patientnumber: -

Appendix 1: Definitions for patient registration

Missing data: in case of missing data or data that are out of normal range, the website will indicate this with a yellow flag. After reviewing and excluding a data entry mistake, you can enter again and the value will be recorded.

1. Patient data

Admission hospital (date): date of hospital admission. If the patient was admitted to more than one hospital before ICU admission, use the first hospital admission as the time of hospital entry.

Admission:

Planned: patients whose admission was planned at least 12 hours in advance.

Not planned: patients whose admission was unplanned or planned less than 12 hours in advance.

Intra-hospital location before ICU admission:

Ward: the patient was admitted to the ICU from a regular medical or surgical ward

Emergency room (ER): the patient was admitted to the ICU from the emergency room

Operative Room (OR): the patient was admitted to the ICU from the operative room.

Other ICU: the patient was admitted to the ICU from another ICU, located in the same hospital or in another hospital.

Representative serum creatinine/serum urea/BUN: a serum creatinine/urea/BUN concentration obtained within a 3-month period preceding ICU admission, considered representative for the baseline kidney function.

2. Comorbidities

Cancer therapy: - externally administered radiotherapy in the 6 months prior to admission. Excluding radiotherapy for non-invasive skin tumours, enteral or parenteral radioisotope therapy, radioactive implants, and radiotherapy for prevention of heterotopic bone formation.

- Chemotherapy administered in the 6 months prior to admission

Cancer: Any cancer, with or without metastasis

Hematologic cancer: lymphoma, acute leukaemia, or multiple myeloma

Chronic heart failure (NYHA IV): fatigue, dyspnoea or angina at rest or at minimum level of activity. Functionally, this patient cannot stand alone, walk slowly, or dress without symptoms.

Initials patient: Patientnumber: -

Cirrhosis: documented by biopsy or clinical symptoms of portal hypertension (gastric or oesophageal varices demonstrated by surgery, imaging or endoscopy, or the demonstration of retrograde splenic-venous blood flow by ultrasound, history of variceal bleeding or episodes of hepatic failure/encephalopathy/coma.

AIDS: Patient meeting the CDC/WHO definitions for AIDS, such as an HIV-positive patient with clinical complications such as *Pneumocystis carinii* pneumonia, Kaposi's sarcoma, lymphoma, tuberculosis or toxoplasma infection, or CD4 cells, if measured, are usually lower than 200.

Hypertension: history of systolic blood pressure equal to or greater than 160 mmHg and/or diastolic blood pressure equal to or greater than 95 mmHg, treated or not treated.

COPD: chronic obstructive pulmonary disease due to chronic bronchitis and/or emphysema

Diabetes Mellitus: - insulin dependent: patients needing daily injection(s) of insulin before ICU admission.

- Non-insulin dependent: patients with prior diagnosis of diabetes mellitus, controlled with diet and/or drugs. The patient does not need daily injection(s) of insulin before ICU admission.

Vasoactive drugs before ICU admission: dopamine equal or greater than 5 microgram/kg/minute or any dose of dobutamine, adrenaline, noradrenaline administered intravenously in continuous perfusion for more than 1 hour prior to ICU admission.

3. Reasons for ICU admission

Rhythm disturbances: due to heart rate or heart conduction disturbances

Shock: Defined by a systolic blood pressure (SBP) less than 90 mmHg or a drop in SBP from baselinewith presence of clinical signs of peripheral circulatory insufficiency (cold, moist, cyanosis) and organ hypoperfusion (oliguria, encephalopathy, metabolic acidosis) or use of intropic/vasopressor to maintain SBP at a level allowing organ perfusion (adrenaline, noradrenaline, dobutamine at any dose, dopamine >5 µg/kg/min).

- **Hypovolemic shock:** due to haemorrhage or other blood losses, or due to external fluid losses or internal sequestration.

Liver failure: hepatic failure inducing metabolic disturbances and/or encephalopathy.

Initials patient: Patientnumber: -

Acute abdomen: related to infection, ischemia, perforation, inflammation, either upper or lower gastrointestinal tract. Excludes severe pancreatitis.

4. Surgical status at admission

Scheduled surgery: patients undergoing a surgical procedure before ICU admission which was planned more than 24 hours in advance (including laparoscopic surgery).

Emergency surgery: patients undergoing a surgical procedure before ICU admission which was planned less than 24 hours in advance (including laparoscopic surgery).

No surgery: patients not undergoing surgery before ICU admission.

5. Anatomical site of surgery

Trauma: includes surgery on the

- **Brain:** surgery for subdural, epidural, intracerebral haematoma or skull fracture.
- **Thorax:** surgery for intrathoracic organs (either cardiac, respiratory or digestive tract) and vessels.
- **Abdomen**
- **Limp**
- **Multiple sites**

Cardiac surgery without valve repair: coronary artery by-pass grafting without valve repair

6. Acute infection at ICU admission

Describes the acquisition of an acute infection, present at ICU admission. Should only be displayed if there is an infection at ICU admission.

7. Variables obtained within 1 h before or after ICU admission

Glascow coma scale (GCS): for the SAPS 3 data we ask to record an estimated GCS, i.e. the GCS as it is estimated without sedation.

Initials patient: Patientnumber: -**B) Patient Daily data entry**

After entering the data the system will indicate if AKI occurred, and when AKI occurred you will be asked to fill out the AKI data web page.

Urine output:Incomplete UO collection

- Please indicate whether 24 h urine collection was complete, or on less than 24h. This may occur on the day a patient is admitted to the ICU, and at time of ICU discharge.
- When you indicate that UO data are on less than 24h, the patient cannot fulfill AKI criteria based upon the 24 h UO. The patient may still fulfill criteria based on creatinine criteria or the 6, 12, and 24 h 'check box' urine output criteria.
- It is important to check the check box before entering the urine output in mL.

Initials patient: Patientnumber: -**Appendix 2: FiO₂ for spontaneous breathing patients.**

100% O ₂ Flow rate (L/min)	FiO ₂	100% O ₂ Flow rate (L/min)	FiO ₂	100% O ₂ Flow rate (L/min)	FiO ₂
Nasal cannula		Oxygen mask		Non-rebreathing mask	
1	0.24	5-6	0.40	6	0.60
2	0.28	6-7	0.50	7	0.70
3	0.32	7-8	0.60	8	0.80
4	0.36			9	0.90
5	0.40			10	0.99
6	0.44				