



Instructions to complete the CRFs

Participants should register online on our webpage (www.intensive.org). Please enter the mailing address clearly. Providing a valid email is mandatory to facilitate correspondence during the study. Please inform us of any changes in your mailing address/email.

Upon completion of the online registration form, each investigator will receive login information to our secured website, where all the data should be electronically entered. Each center (ICU) will be assigned a code (i.e., center number, from 1 to 1000). Please use your center number in all correspondence with the coordinating center. We invite the investigators to take some time in exploring the data entry area before the start of the study. Please feel free to contact the coordinating centre in case of any questions.

Center Inclusion (Form 1)

This should be completed and submitted electronically within one week after starting enrollment. In cases where several ICUs are involved in the same hospital, each ICU should complete and submit a separate form.

- Institution: Name of the hospital and the ICU involved.
- Type of ICU: The ICU is classified according to the majority (> 60 %) of regular admissions. Please indicate whether your ICU is open or closed.
- ICU specialty: The most appropriate choice must be marked. This should be based on the majority of admissions (> 60%). A free text can be filled in for other specialties if applicable.
- Staffed ICU beds: This refers to the number of beds available for admissions. In other words, closed beds due any reason (shortage of staff, technical problems, etc....) are not counted.
- Nursing status: Please indicate the number of nurses during these periods.

Enrollment (Form 2)

This form consists of two sections:

1. patient enrollment demography, and
2. Infection on the study day (May 8)

- Center nr.:** Center number provided by the coordinating center.
- Patient nr.:** Please enter sequential numbers from 1 to n for your center.
- Date of admission:** The format day/month/year should be used.
- Age:** Patient's age (in years) at their last birthday.
- Type of admission:** Surgical - defined as having surgery in the 4 weeks preceding admission . Elective surgery is defined as surgery scheduled > 24 hours in advance and emergency surgery as that scheduled within 24 hours of operation. Trauma is defined as ICU admissions directed related to, or as a complication of, a traumatic event in the 30 days preceding admission. Both trauma and surgical admissions could be chosen simultaneously if a trauma patient was operated on. All other admissions are considered medical. Codes for site of surgery are listed separately (up to 3 sites are possible)
- Admission source:** Only one choice is possible.
- Primary diagnosis:** The main reason for admission to the ICU. Only one primary diagnosis should be entered (see codes).
- Secondary diagnoses:** Defined as associated acute conditions on admission. Up to 6 secondary diagnoses are possible (see codes). If no relevant secondary diagnoses, please leave blank.
- Comorbidities:** Chronic diseases present prior to admission. More than one could be chosen according to the following definitions:
 - Metastatic cancer:** Metastases proven by surgery, computed tomography or magnetic resonance scan, or any other method.
 - Hematologic malignancy:** Lymphoma, acute leukemia, or multiple myeloma.
 - HIV infection:** HIV positive patients with clinical complications such as Pneumocystis pneumonia, Kaposi's sarcoma, lymphoma, tuberculosis, or toxoplasma infection.
 - Chronic renal failure:** Defined as the need for chronic renal support or history of chronic renal insufficiency with a serum creatinine over 3.6 gm/dL (300 µmol/L).
 - Immunosuppression:** Administration in the 6 months prior to ICU admission of steroid treatment (at



- least 0.3 mg/kg/day prednisolone for at least one month), severe malnutrition, congenital immunohumoral or cellular immune deficiency state.
- **Chemotherapy/radiotherapy:** In the 6 months prior to ICU admission.
 - **Insulin dependent diabetes mellitus:** The need, prior to ICU admission, for insulin injections to control blood sugar levels.
 - **Infection diagnosis:** The definitions proposed by the International Sepsis Forum (Calandra and Cohen, Critical Care Medicine 33:1538-1548, 2005) will serve as a frame for infection diagnosis (see below for details).
 - Clinical infection is defined a probable or possible infection, which may not be microbiologically documented if the culture remains sterile due to antibiotic therapy.
 - Please introduce the appropriate code for the site of infection and microorganism(s) (see below). Only pathogenic microorganisms are to be considered with the most relevant microorganism for each site of infection to be recorded.
 - Antibiotic administration may be prophylactic or therapeutic, please make the appropriate choice.

Enrollment (Form 3)

- **Center nr.:** Center number provided by the coordinating center.
- **Patient nr.:** Please enter sequential numbers from 1 to n for your center.
- Potential interference should be avoided when recording these values (during bedding, procedures, etc.....).
- If the values are collected retrospectively (randomization after 24 hrs of admission), missing values are left blank, otherwise, the values should be measured and recorded.
- **Min** refers to the lowest value and **max** to the highest value. Both min and max values are required when indicated. If only one value is recorded it should be considered for both fields (min & max).
- Please choose the **appropriate unit** when applicable.
- **Vasopressor doses** are calculated in $\mu\text{g}/\text{kg}/\text{min}$. Patient weight can be estimated.
- In patients without respiratory support, FiO_2 could be estimated using the provided guidelines (listed separately at the end of this document)
- **$\text{PaO}_2/\text{FiO}_2$** should be recorded simultaneously and the lowest value during the day is reported. In absence of respiratory support, use the provided guidelines to estimate the FiO_2 and/or PaO_2 . Artifacts should be avoided (transient decrease during pneumothorax.....etc).
- **Respiratory support** refers to any form of mechanical ventilatory aid (including continuous positive airway pressure (CPAP)).
- If the patient dies within the first 24 hours, the **urine output** should be estimated for the 24 hour period (for example, if the patient dies after 8 hours and had 500 ml of urine during his ICU stay, the urine output would be 1.5 L).
- Continuous **hemofiltration** refers to any forms of continuous renal therapy (CVVH, CVVHD, etc.) whereas **hemodialysis** refers to iterative hemodialysis.
- We will record only the "assumed" **Glasgow coma score**. In other words, a patient who is in deep coma only because he is being treated with high doses of sedative agents should be considered to have a Glasgow coma score of 15.

Follow-up (Form 4)

This form should be completed and submitted before July 31, 2007.

General comments:

- The paper form allows additional annotations if required.
- For any queries, do not hesitate to contact us (email: jlvincen@ulb.ac.be, fax: +32.2.555.4555).