European Surgical Outcomes Study
(EuSOS)

Frequently Asked Questions

To be used together with the EuSOS study protocol and case record forms

For the latest study documents, further information or to contact us please visit http://eusos.esicm.org
EuSOS Operating Room CRF FAQs

When is the EuSOS study cohort week?
The cohort week begins at 09:00 on 4th April 2011 and ends at 08:59 on 11th April 2011. Every eligible patient who has surgery during the cohort week should be included. Patients should be followed up until hospital discharge or for a maximum of 60 days whichever is shorter. We will complete the critical care CRF for the first admission to critical care during the follow-up period.

Which patients should we include in the study?
Every adult patient aged 16 years or older who undergoes non-cardiac surgery which starts (ie induction of anaesthesia) during the seven day cohort week and is planned to stay overnight in hospital. This will include minor, intermediate and major surgery but we will not collect data on day-case (ambulatory) surgery even if they have an unplanned overnight stay in hospital. We will not collect data on patients who have cardiac surgery, neurosurgery, obstetric or radiological procedures.

Is thoracic surgery included?
Yes. Patients who have thoracic surgery are eligible. Cardiac surgery is excluded.

Neurosurgery is excluded – does this include spinal surgery?
Neurosurgical procedures involving the brain and cervical spine are excluded. Surgery on the thoracic and lumbar spine is included and is classed as orthopaedic in the CRF.

Does this mean we should aim to recruit every patient who fits these criteria?
Yes, we want you to collect data describing young fit patients as well as older ones. We need to find out more about the whole surgical population to understand what happens to the patients at high risk of complications. This means we need to aim to collect data on every patient who fits the criteria.
It seems like a lot of work to collect data on every patient?
We realise taking part in EuSOS involves a lot of work and we are very grateful to all the investigators for your support. We have carefully balanced collection of important data against the work this involves. The data sheets (CRFs) are very short compared to other studies of this type. The study cohort week lasts only seven days and over 90% of patients will require completion of the operating room CRF only.

In my hospital the standard of peri-operative care is very good. Will data on our patients help?
Yes. We know very little about the epidemiology of non-cardiac surgery but it does appear that survival varies for similar patients in different hospitals. We need to know more about the care in hospitals with good results so we can understand what types of care are most effective.

Will my work be recognised?
Yes. All local investigators who take part in the study are members of the EuSOS study group and will be publicly listed on the website. All EuSOS publications will be published on behalf of the EuSOS study group which means all study group members can list these in their publications.

Does the cohort week start time vary with international time zones?
No. The start will be 09:00 in your time zone and the finish time will be 08:59 in your time zone. This does mean there will be a one hour difference between the start and finish times between some countries.

What if a patient has surgery twice during the seven day cohort week?
Patients should only be included in the study once. Repeat surgery should only be included if the first procedure took place before the EuSOS study week began.
How should we decide the American Society of Anesthesiologists (ASA) score?
I  A normal healthy patient
II  A patient with mild systemic disease which does not limit physical activity
III A patient with severe systemic disease which limits physical activity
IV  A patient with severe systemic disease that is a constant threat to life
V   A patient who is not expected to survive for 24 hours without the operation

Why do you ask about my patient’s ethnicity?
We need to know whether a patient is black (Afro-Caribbean descent) in order to calculate estimated glomerular filtration rate (eGFR) using the MDRD equation. This equation was developed in North America where eGFR was 21% higher for any given creatinine.

What shall I do if my patient has important medical problems which aren’t listed in the chronic co-morbid disease section of the Operating Room CRF?
We realise that some patients may have important data which we do not ask for. The Operating room CRF in particular, has been designed to request only a small amount of the most important patient data.

What are the definitions for the chronic co-morbid diseases?
We have not made any definitions for these diseases. We realise that many anaesthetists will not have time to read an extensive definition manual. We simply want doctors to give what they believe is the most appropriate answer. If the patient probably has the disease then tick the box if they probably do not then leave it blank.

Some patients will not have any blood tests requested (eg creatinine). Should we take blood samples so we can run these tests just for the study?
No. We do not want you to make any changes to the diagnostic tests or clinical treatment your patients would normally receive. If blood results are not available, please leave this domain empty.
How is anaesthetic technique defined?

**General anaesthesia:** Pharmacologically induced state of unconsciousness in order to facilitate surgical procedure

**Sedation:** Pharmacologically induced reduced level of consciousness during which verbal contact is maintained

**Spinal anaesthesia:** injection or infusion of a clinically effective dose of local anaesthetic and / or opioid drugs into the cerbro-spinal fluid in order to provide clinically effective anaesthesia

**Epidural anaesthesia:** injection or infusion of a clinically effective dose of local anaesthetic and / or opioid drugs into the epidural space in order to provide clinically effective anaesthesia

**Other regional anaesthesia:** injection or infusion of a clinically effective dose of local anaesthetic and / or opioid drugs into the region of a major nerve plexus in order to provide clinically effective anaesthesia

**Local anaesthesia:** injection of a clinically effective dose of local anaesthetic into the tissues at the site of surgery in order to provide clinically effective anaesthesia

How do I find out the unique EuSOS identifier code for my patient?

A unique code is created for each patient but not until you enter the data onto the internet based electronic case record form (eCRF). The ID code generator is hosted on the main EuSOS website. Once a paper CRF is complete (and not before), the patient name and date of birth can be removed. However, the unique patient EuSOS ID still links the electronic data to the paper CRF stored in your hospital. This allows us to ask questions about possible errors in the data you have submitted without knowing the patient’s name. In this way the EuSOS data set is anonymous.

When should I remove the patient name and date of birth from the paper CRF?

Only remove these details when the paper CRF is as complete as possible. We recommend this is removed when the patient data is uploaded onto the internet based eCRF.
What do you mean by the ‘most senior’ surgeon or anaesthetist?
We have decided to ask about the most senior staff member who is involved in the case and are present in the operating room. The most senior surgeon may not perform the operation themselves but watch a junior colleague do this. However, they are still the most senior surgeon in the operating room and could, for example, assist if something went wrong. The most senior surgeon may not be present in the operating room throughout the entire procedure. The same principles apply to anaesthetists. A junior surgeon or anaesthetist is defined as having less than three years experience in the specialty but may have been a doctor for longer than this. An attending (senior or consultant) surgeon or anaesthetist is a senior doctor who has completed their training and been appointed to an attending (consultant) post. Middle grade doctors are all those in between regardless of the number of years experience or whether they are training to be an attending (senior or consultant) anaesthetist or surgeon.

What is the difference between laparoscopic and laparoscopic assisted surgery?
In laparoscopic surgery, the incision made is only big enough to remove the specimen that is being (or planned to be) resected. In laparoscopic assisted surgery, a laparoscope is used for some of the procedure but there is also a larger incision to allow the surgeon more access to see or operate.

What do you mean by a cardiac output monitor?
Any technology which provides a value for cardiac output. This would include oesophageal Doppler, pulmonary artery catheter and arterial waveform analysis (eg LiDCO, PiCCO, Vigileo-Flotrac) but not devices which only estimate arterial pressure variability and cannot provide a value for cardiac output.

How is urgency of surgery defined in the EuSOS study?
Elective: Not immediately life saving; planned within months or weeks.
Urgent: Planned surgery within hours or days of the decision to operate.
Emergency: As soon as possible; no delay to plan care; ideally within 24 hours.
What do you mean by severity of surgery?
This is the category of surgery which indicates a combination of complexity and amount of tissue injury.

Minor surgery would include procedures lasting less than 30 minutes performed in a dedicated operating room which would often involve extremities or body surface or brief diagnostic and therapeutic procedures eg arthroscopy without intervention, removal of small cutaneous tumour, diagnostic proctology, biopsy of small lesions, etc.

Intermediate procedures are more prolonged or complex that may pose the risk of significant complications or tissue injury. Examples include laparoscopic cholecystectomy, arthroscopy with intervention, bilateral varicose vein removal, tonsillectomy, inguinal hernia repair, breast lump resection, haemorrhoidectomy, appendicectomy, partial thyroidectomy, cataract surgery, uvuloplasty, minimally invasive repair of vaginal prolapse, vaginal hysterectomy, tendon repair of hand, fixation of mandibular fracture, etc.

Major surgical procedures are expected to last more than 90 minutes and include major gut resection, major joint replacement, mastectomy, extensive head and neck tumour resection, abdominal aortic aneurysm repair, major vascular bypass procedure, procedures involving free flap to repair tissue defect, amputation, total thyroidectomy, cystectomy, trans-urethral resection of prostate, resection of liver tumour, carotid endarterectomy, nephrectomy, total abdominal hysterectomy, spinal discectomy, etc.

How should we estimate blood loss during surgery?
There many ways of calculating such an estimate of blood loss. This cannot be accurately measured and it would be too complex to standardise this. Instead we ask you to provide an estimate you believe to be reliable regardless of method.

How is end of surgery defined in the EuSOS study?
The time at which the patient leaves the operating room.
How do you define Post-anaesthetic recovery unit?
A post-anaesthetic recovery unit is dedicated facility for the care of all patients following surgery under anaesthesia. This does not include units which routinely care for invasively ventilated patients overnight. These will be defined as critical care units for this study. Duration of stay is the time from arrival to departure measured in minutes.

How is duration of hospital stay defined in the EuSOS study?
Duration of hospital stay is defined as time in days from the day of surgery to the day the patient leaves hospital. This will not be adjusted for delays relating to provision of social care in the community.

What about patients who are still in hospital many months after surgery?
This will happen for a small number of patients. Because we need complete data returned quickly, we have decided to censor follow-up at sixty days. So all patients are followed until hospital discharge or for sixty days after surgery whichever is the shortest. There is a specific question for this on the critical care CRF. In the unusual event that a patients is not admitted to critical care at any stage but still remains in hospital after 60 days, please tick ‘yes’ to survived to hospital discharge and enter the date for day 60 after surgery in the hospital discharge date section.

What if the data requested is not available?
It is likely that some data such as blood results will not always be available. In other cases, an interpretation can be made. For example, where blood loss is described as minimal this could be entered as zero.
EuSOS Critical Care CRF FAQs

How is critical care defined in the EuSOS study?
We have defined a critical care unit as a facility routinely capable of admitting patients who require invasive ventilation overnight. Definitions vary from country to country but we must use one standard for all patients included in the EuSOS study. This is different to the definition of a post-anaesthetic recovery unit which has the primary purpose of providing care for all patients after anaesthesia regardless of organ support.

Which patients should we complete the critical care CRF for?
Firstly, only patients who have surgery which starts between **09:00 on 4th April 2011 and 08:59 on 11th April 2011** should be included. Each of these patients should be followed until hospital discharge up to a maximum of 60 days. A critical care CRF should be completed for the patients first admission to critical care at any time after surgery even if this is after the seven day cohort week has ended.

What if a patient is only admitted to critical care for a short time?
Many patients will be discharged from critical care in less than 48 hours. In this case, please leave the remaining pages of the CRF empty.

What if a patient is admitted to critical care twice during the follow-up period?
A critical care CRF should only be completed for the first admission admission to critical care. The critical care CRF is not completed for subsequent critical care admissions.

What about patients who are admitted to critical care more than once?
A critical care CRF should only be completed for the first critical care admission even if this is only very short. The first admission to critical care is the most important.
What shall I do if my patient has important medical problems which aren’t listed in the chronic co-morbid disease section of the Critical Care CRF?

We realise that some patients may have important data which we do not ask for. The Critical Care CRF has allows us to collect more information than the Operating room CRF but we still recognise that some teams will not have time to collect more than this.

Are there chronic co-morbid disease definitions for the Critical Care CRF?

No, we have not provided definitions for these diseases. We simply want doctors to give what they believe is the most appropriate answer. If the patient probably has the disease then tick the box if they probably do not then leave it blank.

How should we measure core temperature?

It will be impossible to standardize measurements like this. Please use the most reliable available method.

In the critical care CRF, what do you mean by major therapeutic limitation?

A patient for whom treatment is withheld because they have a poor chance of survival.

How do we complete the CRF for patients who are alive at 60 days but still in hospital?

There is a specific question for this on the critical care CRF. In the unusual event that a patients is not admitted to critical care at any stage but still remains in hospital after 60 days, please tick 'yes' to survived to hospital discharge and enter the date for day 60 after surgery in the hospital discharge date section.

Remember the EuSOS FAQs will be updated on a regular basis. Please check the EuSOS website to make sure you have the latest version of the study documents.