Frequently Asked Question

How will ISOS work?

ISOS will run along very similar lines to the previous EuSOS study. Each hospital will collect data on every eligible patient who has surgery during the study week and follow them until they leave hospital to collect further data on complications after surgery. Data will be collected on paper and then entered onto a secure website. Analysis will then start once data collection is complete.

Are there any differences to the previous EUSOS study?

The most obvious difference is that all countries will be eligible to take part worldwide. In this study we will only collect data on elective surgery. We have learned some important lessons from EuSOS which will greatly improve the experience of investigators during ISOS. We have developed a data entry website especially for the project to make this process quicker, simpler and more accurate. A key difference is that patient, hospital and national level data will be anonymised with comparisons made across international regions. Once your data is uploaded and confirmed as complete and accurate, you will be automatically provided with a spreadsheet of the data for your hospital.

Can anyone take part?

We would welcome as many hospitals as possible from around the world. However, to take part, each country must include at least ten hospitals. Only those hospitals which include more than 20 patients will be included in the data analysis.

When is the ISOS study cohort week?

The cohort week will be slightly different in each participating country to avoid national holidays and other events which may affect patient recruitment. Each national group will choose a week between April and June 2014. The seven day recruitment period will begin at 08:00 local time on the Monday of this week and ends at 07:59 on the following Monday.

Which patients should we include in the study?

Every adult patient aged 18 years or older who undergoes elective 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 radiological procedures. Patients should be followed up until hospital discharge or for a maximum of 30 days whichever is shorter.

Do we include patients who have emergency surgery?

No. We have decided to include only elective surgical patients in the ISOS study to make data collection easier for investigators.

Are cardiac and thoracic surgeries included?

Yes. Patients who have either cardiac or thoracic surgery are eligible. This is a change to the previous EuSOS study.

Does this mean that 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 ISOS 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.

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 surgery and we need to make sure the findings of ISOS are relevant to as many different hospitals as possible 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 ISOS study group and will be publicly listed on the website. All ISOS publications will be published on behalf of the ISOS study group which means all study group members can list these in their curriculum vitae or resume. All 2000 investigators on the previous EuSOS study were listed on Pubmed.

Does the cohort week start time vary with international time zones?

No. The seven day recruitment period will begin at 08:00 local time on the Monday of this week and ends at 07:59 on the following Monday.

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 ISOS study week began.

How should we decide the American Society of Anaesthesiologists 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.

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 CRF has been designed to request only the most important patient data.

What are the definitions for the chronic co-morbid disease?
We have not made any definitions for these diseases. We realise that many doctors 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.
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.

Is spinal surgery listed as neurosurgery or orthopaedic surgery?
Either is acceptable. Use the primary specialty of the operating surgeon.

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

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 entry quickly, we have decided to censor follow-up at thirty days. So all patients are followed until hospital discharge or for thirty days after surgery whichever is the shortest. If a patient remains in hospital after 30 days, please tick ‘alive’ to status at 30 days after surgery If the patient was discharged alive before day 30 please tick ‘alive’ and record number of days in hospital after the surgery. Day of surgery is a day zero, for instance if patient has had a surgery on Monday and was discharge on Wednesday, the total number of hospital stay after surgery is two.

What if the data requested is not available?
It is likely that some data such as blood results will not always be available. You should not order additional tests unless they are required for clinical reasons.

How is elective surgery defined in ISOS?

Elective surgery is not immediately life-saving and is usually planned over a period of weeks or months before the procedure.

How is critical care defined in the ISOS 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 ISOS 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.

How do I find out the unique ISOS 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).

How is the data protected?
All identifiable data collected, processed and store for the purpose of the project will remain confidential at all times and comply with Good Clinical Practice for research (GCP) guidelines and the principles of the Data Protection Act 1998 (UK). Data will be anonymised prior to transfer to the ISOS study management group except where the patient has given written informed consent to allow transfer of identifiable data. Access to the data entry system will be protected by username and password delivered during the registration process for individual local investigators. All electronic data transfer between participating centres and the co-ordinating centres will be encrypted using SSL/TLS protocol (HTTPS).

How do I record the duration of stay in Post-Anaesthetic Care Unit on the Case Report Form if patient was there only e.g. 10 minutes?
The length of Post-Anaesthetic Care Unit stay should be rounded up to nearest whole hour.