SECURE

Service Evaluation of Cross-Specialty
UK Rapid Sequence Intubation Events

FAQs

Where can I find materials for the study?

All materials will be uploaded to our website - https://www.raftuk.org/raft-5-secure

What is a site?

For SECURE, a site is defined as a single physical hospital. Therefore, a single NHS trust will often contain more than one site.

What is a site lead?

Site leads coordinate data collection for their particular site. Each site must have at least one resident Site Lead, however Site leads may choose to coordinate data collection for multiple sites, for example where these are within one NHS trust.

Do we always need a consultant advocate?

For governance purposes, SECURE cannot be delivered at a site without a named consultant advocate for that site. For larger sites there should be a designated site lead for each specialty as well as consultant advocates for each specialty, as shown in the flowchart in the regional lead guide. In smaller sites, it may be appropriate to have less than 3 site leads. For example, the ICM and anaesthetic site lead may be the same person, with one consultant advocate for both as well.

How will the Site Leads & Local Investigators be recognised?

All regional leads and site leads will be PubMed-indexed collaborators in any relevant SECURE publication, as will any local investigators nominated by the site leads with significant involvement in the study. Anyone filling out a site survey form will be included as a PubMed-indexed collaborator. All these people will be awarded certificates in recognition for their contribution.

We have a list of regional leads and site leads already. The site survey provides the SECURE team with information on who filled out the form by allowing for the input of two named investigators and their emails. Any local investigators who have contributed significantly whilst working alongside site leads need to be identified by site leads and names need to be emailed to the SECURE team.

Members of the intubating team who fill out a single activity survey form do not get collaborator status- although we are grateful for their contribution and the project would not be possible without their participation.

What is a regional lead?

Regional leads work with their local research network to coordinate data collection across an area. Their main job is to support the site leads across their network. The regional research networks should be able to support them with questions, however if there are any which are not covered then they can contact the main secure team on secure@das.uk.com where a team member will try to respond to the query within 7 days.

What happens at study sites where trainees rotate through from multiple deaneries/schools?

For consistency, we suggest to use school/deanery boundaries for anaesthetics and if anaesthetic residents from both deaneries go to that site then to have a discussion with regional leads across the border and see what works best (for instance if the resident willing to act as site lead is from one deanery then it may make sense to stay with the RRN of that deanery). As we don't know all the regions well, we have allowed a degree of autonomy to neighbouring regional leads to reach an agreement. Please ensure you discuss with your neighbouring RLs early in this situation to avoid confusion, and please email the RAFT email if you require the email details of neighbouring RLs.

Who will have access to the RedCap database?

Only named investigators will have access to the database. The steering committee is not all based at UHBW but are all NHS clinicians and they will have access to the database as required. No patient identifiable information is uploaded to the database.

Site leads will not have access to the database and are not required to sort any data or identify duplicate entries etc.

There will not be any log in details- anyone can log in a CRF.

Do you have an anticipated date for destruction of the dataset after research has been completed?

We anticipate a destruction date after 5 years as per standard UHBW guidelines.

Is SECURE registered for the Associate PI scheme?

Unfortunately, SECURE is not eligible for the Associate PI scheme.

Do local investigators need to do GCP?

Because SECURE is a service evaluation and not research, you do not need GCP certification to contribute.

Are RSIs on the ward included?

Yes, inclusion criteria are all patients 18and above having an intubation that is deemed by their team to be an RSI or modified RSI, anywhere in the hospital grounds, excluding those intubations carried out in patients in cardiac arrest. Please do include those intubations carried out after return of spontaneous circulation in patients who had cardiac arrest.

What will the QR code for the activity survey link to?

The QR code will link directly to the REDCap CRF form.

Will there be paper forms for the site survey and activity survey?

Yes, these will be on the website as PDF CRFs. We encourage use of paper forms initially for the site survey to allow you to have time to fill it out and come back to it if

necessary, before uploading the information to the electronic CRF. REDCap database will not allow you to save progress.

For the activity survey we will provide a paper CRF if you feel you need it but encourage the intubating team to log on directly to the REDCap electronic database in the first instance to minimise workload.

When should the activity survey be filled in?

The activity survey should be filled as close in time to the RSI event as possible and ideally by a member of the intubating team, or by a member of the intubating team working with a local investigator.

When will publicity material become available?

We will be providing a template presentation set to allow for site leads to present the project to their departments and spread awareness, particularly ahead of the chosen window for the activity survey. This will be available on the website by the 23rd of February.

Posters and QR codes will be uploaded to the website as they become available.

Will sites have access to their activity survey data?

After data collection sites can request a report of their RSI activity survey from the SECURE team. We will endeavour to make this available to you after the end of the study to allow for local review and quality improvement projects. This will be on a restricted basis and individual hospital data will not be available for public viewing.

How do site leads know which specific clinical areas the site survey should target?

Depending on services available the study site, Site Leads will complete the Site Survey **once for each of the following clinical areas**:

1. **Operating theatres** (theatre area in which the majority of general RSIs are performed)
2. **Obstetric theatres** (dedicated obstetric theatre area in which the majority of obstetric RSIs are performed)
3. **Critical care** (ICU area in which the majority of RSIs are performed)
4. **Emergency department** ('ED resus' area in which the majority of RSIs are performed)

For each clinical area, a single survey will be completed **for the main high-acuity location where RSI is performed most frequently,** especially if there are split clinical areas (e.g. multiple theatre complexes, separate obstetric theatres, remote anaesthetic locations, multiple critical care areas, multiple ED areas). Investigators will be asked to document the **typical provision of resources for that area**.