AeroComp Service Evaluation Frequently Asked Questions

Who is running AeroComp?
AeroComp is run by a core team in collaboration with trainee research networks (TRNs) throughout the country. The Core Team is led by Dr Kariem El-Boghdadly, Consultant Anaesthetist at Guy's and St. Thomas' NHS Foundation Trust, London, UK. He is supported by Dr Imran Ahmad, Prof. Tim Cook, Dr John Cronin, Dr Justin Kua, Dr Eveliina Nurmi and Dr Danny Wong.

Where is the lead site?
The lead site is Guy's and St. Thomas' NHS Foundation Trust, London, UK.

When will the study take place?
The study duration will involve five days (patients will be enrolled over a 96 hour consecutive window with a further day of follow-up data collection). Individual sites are free to choose their own data collection window between 1st November and 3rd December 2021 as long as the 96 hour window commences at 07:30 on a Monday and closes at 07:29 on a Friday.

When will results be disseminated?
We are aiming to publish the results by June 2022.

What is the aim of the study?
AeroComp aims to explore the current perioperative incidence of airway complications amongst the adult population undergoing general anaesthesia for both elective and emergency procedures. The secondary aim is to identify if aerosol precautions such as personal protective equipment or modified anaesthetic techniques contribute to a higher risk of airway complications.

Which questions will be answered?
1. What is the perioperative incidence of airway complications in the current phase of the COVID-19 pandemic?
2. Which components of the aerosol precaution bundle (including PPE and anaesthetic techniques) are associated with a greater risk of airway complications?

How do I get involved?
Your local TRN has likely already made contact with your site, however if you have yet to hear anything, please contact the main project team by email to aerocompstudy@gmail.com and we can assist you in registering the project or put you in touch with people at your site who are already involved. We require at the bare minimum the names and email addresses of a lead trainee and lead consultant per site (i.e. hospital, not trust).

What acknowledgement will I receive?
All local investigators (lead trainees, lead consultants and other members of the local team, termed local investigators) will receive participation certificates at the end of the study. Additionally, everyone will be listed as a collaborator in all publications arising from the study. At the end of the study, the lead trainee will be invited to complete a list of all local investigators for their site to capture this information.

Can I be the lead at more than one site?
Yes. You can be either the trainee or consultant lead at more than one site. This typically occurs at trusts with multiple sites where the anaesthetists frequently visit both sites.

Can there be more than one trainee or consultant lead at each site?

We require the contact details of a single lead trainee and single lead consultant at each site for administration purposes. If two or more people truly share the lead role there is the option to acknowledge this when the final local investigator list is completed.

How many local investigators can be involved per site?
There is no hard and fast rule here. We expect all named local investigators to have had some involvement in running and administering the project locally, e.g. organised recruitment, advertised the project, distributed CRFs, added missing data and/or uploaded data to REDCap. We do not expect you to list every anaesthetist who has completed the CRF for their own patients. A reasonable maximum is one local investigator per 10 patients per day (e.g. if your site has 100 eligible patients a day then 10 local investigators would be reasonable) however if for good reasons you need more we will not prevent this.

Is patient consent required to collect the data?
No. AeroComp is registered at each trust as a service evaluation collecting anonymised data - no patient consent is required.

Is Good Clinical Practice (GCP) training required?
GCP is not required for local leads or local investigators.

Does AeroComp require Confidentiality Advisory Group Section 251 Clearance?
AeroComp only collects fully anonymized data and therefore does not require CAG Section 251 clearance as per the flowsheet https://s3.eu-west-2.amazonaws.com/www.hra.nhs.uk/media/documents/CAG_pre-application_checklist.pdf

Has AeroComp undergone Caldicott Guardian and Information Governance reviews?
Yes. AeroComp has received approvals from the Caldicott Guardian and Information Governance department at the lead site. These are available to sites upon request.

How do I register AeroComp locally?
AeroComp should be registered as a service evaluation with your local Clinical Governance department. It does not require Research and Development clearance.

How is the data uploaded?
All data is uploaded onto a secure data server based upon the REDCap platform. The lead trainee for each site will receive a log-in for this server once they forward local Clinical Governance approval to the project team at aerocompstudy@gmail.com. Three projects will be available: 1) Site Details, which needs completing before and after the study by the lead trainee, 2) Data Entry, which is the main data collected per patient, and 3) Investigator List, which needs completing after the study by the lead trainee. A training video on how to use REDCap is available on the website http://uk-plan.net/AeroComp

Can I get more log-ins for REDCap?
We acknowledge that some sites will recruit a lot of patients and this may be burdensome for a single person to upload. In this situation, the lead trainee will be able to request further log-ins by emailing the core team on aerocompstudy@gmail.com. Please do not share log-ins amongst yourselves.

When is the deadline for uploading information?
We appreciate it may take some time to upload the data but please aim to complete data uploads by 1 month after the last day of the particular project week you select. This is to ensure the data can be processed rapidly and the findings disseminated rapidly back to sites.

What if some data is missing on the case record form (CRF)?
Please try and ensure all data is complete. It is expected that in some cases the treating anaesthetist may not fully complete the CRF. In this case we hope the local investigators can retrospectively complete the CRF from available data. It is for this reason that the local ID field is included upon the CRF. In the very unlikely event you are unable to complete the CRF please obtain as much data as possible and flag this to the core team using the comments box at the bottom of the REDCap Data Entry project.

What is the "Study ID" on the paper CRF?
This is an ID generated by the REDCap Data Entry project when you begin uploading the data for each particular patient. When a new record is created on REDCap, it will have a Record ID number at the top which should be transcribed to the paper CRF as the Study ID. This ID takes the format "number *hyphen* number", e.g. "3-5". It is used in the situations where data upload for a particular patient is interrupted for any reason (you can go back and add more data later from the "Record Status Dashboard" on REDCap), as well as to allow the core team to contact you about a specific patient if we have any queries.

What is the "Local ID" on the paper CRF?
This is located on a tear-off strip on the right hand side of the CRF. It is optional and we expect sites to locally decide upon the best way to use it in conjunction with their Clinical Governance departments. The expected use is to provide a pseudoanonymised identifier for the particular patient which is then removed when data collection is complete. We expect the local teams to provide the appropriate number of CRFs to each theatre on each day of the study based upon published lists. These may be partially pre-populated by the local investigators to include e.g. age band and surgical specialty but please ensure the treating anaesthetist is able to identify which CRF goes with each patient they anaesthetise. The local ID also provides a means for the local investigators to retrospectively identify patients to complete any missing data in the CRF. The local ID must be detached from the CRF once all data for that patient has been captured and must not be uploaded to the REDCap data capture server.

What about emergency/out-of-hours cases?
AeroComp includes all patients and it may be difficult to capture data for emergency cases. We recommend that a stack of CRFs are provided in the emergency theatre(s) and that the local investigators the following day check the number completed against the theatre logs. In case of any missing data please try and collect as much as possible the following day from the notes and/or discussions with the treating anaesthetist. Robustly advertising the project in your department will help to ensure these overnight cases are not missed.

What is meant by "Study Day"?
There are four days included in the study: Monday, Tuesday, Wednesday and Thursday. For each, the actual study day runs from 07:30 in the morning to 07:29 in the following morning. Thus, a case undertaken at 04:00 on Friday morning should be recorded as having occurred on Thursday. This is to ensure concordance with shift working, i.e. the above example was undertaken by the team working the Thursday night shift.

What is meant by "total number of eligible patients" on the Site Details form?
We understand that despite the best efforts of the local investigators that some patients may not be included in the project. Examples include missed emergency cases and cases that occurred in remote sites with small numbers of cases. We require the lead trainee to also submit the total number of cases that were eligible for inclusion to identify the number of cases that were missed. This is important for manuscript submissions as we will be required to submit the capture rate.

Can private hospitals participate?
Only NHS hospitals are eligible to participate in AeroComp due to differing governance regulations pertaining to private hospitals.

What if I have a question that is not answered here?
Please review the other supporting documents on the project website http://uk-plan.net/AeroComp which includes the protocol and the "Running AeroComp at your Site" document. There are also videos linked that provide an overview of the project and how to use REDCap (for use at local governance days, for example). If you do not find an answer to your question there please let us know by email at aerocompstudy@gmail.com.