Study title: Airway Terminology and Outcome Measures (ATOM): A core outcome set development process

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Invitation and brief summary

General anaesthesia allows patients to be treated in a state of controlled unconsciousness – the term 'asleep' is increasingly used to describe this state. A continuous supply of oxygen to the lungs is vital to life and this needs to be maintained as part of having a general anaesthetic. This is achieved by using an airway device which is placed in, or above, the trachea (windpipe)—a process known as airway management. The airway device is connected to an anaesthetic machine to ensure that oxygen is supplied to the lungs. There are a variety of airway devices and differing methods used by anaesthetists to manage the airway, so clinical/medical studies are continually being made to assess which methods work best. In this study, we are seeking your participation to understand better some of the technical aspects of airway management, such as whether there was difficulty in using the equipment or how long it took to place the airway device. The study will also focus on more patient-centred issues, such as the severity of a sore throat or a change in voice following general anaesthesia, as well as the more serious complications that can occur as part of airway management. The term 'outcome' is used to describe how something turns out, whether this is positive and as expected, or negative and not as planned. In the Airway Terminology and Outcome Measures (ATOM) study, we are asking patients who have had or will have, airway management and clinicians, researchers and other stakeholders with experience or insights in airway management to decide on which outcomes should be included in a core outcome set for airway management research.

What would taking part involve?

The way that clinical outcomes are reported can vary significantly meaning that it is difficult to make accurate comparisons of studies undertaken by different research groups. There is a need to identify a core outcome set which will be an agreed list of the important outcomes that should be measured in all studies in airway management.

In the ATOM study, we are asking patients, doctors and health care professionals, researchers and other interested parties to decide on which important outcomes should be included in a core outcome set for airway management research. We are looking for patients who are about to undergo planned airway management during general anaesthesia or using an awake technique. We are also looking for patients who have previously undergone airway management in the emergency setting and required a stay in the intensive care unit. We will be inviting clinicians who are regularly involved in airway management procedures, and researchers in the area of airway management, guideline developers, and prospective funders and publishers of research.

Do I have to take part?

No, it is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. Deciding not to take part or withdrawing from the study will not affect the healthcare that you receive, or your legal rights.

What would taking part involve?

We will ask you to review the information sheet then complete an e-consent form either by scanning a quick-response (QR) code or visiting the link from our website: www.airway-management.org. These will take you to the study website and allow you to do the survey. This can be done at any time as long as the survey is open and you have had airway management experience.

Once this has been done, we will ask you to complete 2 or 3 questionnaires using a computer, these will be circulated about 3 months apart. These will take about 30 minutes to complete. In the first questionnaire you will be presented with a list of outcomes that relate only to patient outcomes which might be important in future airway management research. We will ask you to score each outcome based on how important you may think it is on a 9-point scale. We will give you an opportunity to provide any additional outcomes that you feel may have been missed.

Once the first round of questionnaires has been completed, we will remove the outcomes that most people agreed are not important, and put the most important outcomes everyone agreed on in the core outcome set. The second and third round of questionnaires will address the remaining outcomes, to be looked at again. This time, participants will be able to see the average scores given to each outcome from the previous round.

Finally, we will give all participants an opportunity to take part in an online discussion about what we have found. This will be available if you indicate that you would like to participate in this exercise on the initial e-consent form. This online discussion should last for about two hours. The information gathered at the online discussion will involve discussions and coming to a consensus agreement to decide which outcomes to include in the core outcome set, and what tools we should use to measure them.

What are the possible benefits of taking part?

You would not benefit directly from participating in this study. The information you provide us with will help inform the development of a list of outcomes, which will in turn aid future research in the field of airway management.

What are the possible disadvantages and risks of taking part?

You will be asked to complete two or three questionnaires. This means being involved in the study over a period of up to 6-12 months and being contacted by us more than once. To minimise any disturbance, we will send you up to one reminder at each stage if we fail to hear from you. There is a small chance that if you have had a bad experience with airway management in the past, some elements of the survey could trigger a memory of these events. If you are distressed by any element of this survey, please contact the anaesthetic team responsible for your airway management, or if unavailable, please contact the research team at 07500062989 (Monday to Friday 0900–1700).

Further supporting information

If you would like to participate, please visit the link listed in your information sheet or scan the QR code therein with your phone.

go.airway-management.org/survey

• What will happen if I don't want to carry on with the study?

If you start the survey or complete it then decide you no longer wish to take part, you do not need to continue.

• What will happen to the results of this study?

The results of the study will be available on the ATOM website once completed www.airway-management.org

• Who is organising and funding this study?

The study is funded by the National Institute of Academic Anaesthesia (NIAA).

• How have patients and the public been involved in this study?

A member of the public has been part of the Steering Committee and has helped to design the study and will support its implementation.

Information on the Use of Data

How will we use information about you?

We will need to use information from you for this research project.

This information will include your initials and name. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure. Data will be retained for 5 years.

As Sponsor Guy's and St Thomas' NHS Foundation Trust (GSTT) has a responsibility to keep information collected about the patient safe and secure, and to ensure the integrity of research data. Specialist teams within Guy's and St Thomas' NHS Foundation Trust continually assess and ensure that data is held in the most appropriate and secure way. For this study the research team will use REDCap which is hosted on Amazon Web Services and is a GSTT contracted general data protection regulation (GDPR) compliant third-party storage provider within Europe (London) region. This third-party storage provider will not have access to any data that could directly identify the patient.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from: www.guysandstthomas.nhs.uk/research/patients/use-of-data.aspx (For GSTT)
- by asking one of the research team (contact details included below)
- by contacting the Data Protection Officer: (For GSTT: Nick Murphy-O'Kane DPO@gstt.nhs.uk; For Kig's College London (KCL): Olenka Cogias info-compliance@kcl.ac.uk)

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions [insert Principal Investigator name, telephone number and e-mail address]. If you remain unhappy and wish to complain formally, you can do this through the Guy's and St Thomas' Patients Advice and Liaison Service (PALS) on 020 7188 8801, pals@gstt.nhs.uk. The PALS team are based in the main entrance on the ground floor at St Thomas' Hospital and on the ground floor at Guy's Hospital in the Tower Wing.

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for legal action for compensation against [name of Sponsor Organisation, NHS Trust, Private Clinic] but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

Who is organising the study?

The study has been organised by Theatres, Anaesthesia and Perioperative Medicine (TAP) department at Guy's and St Thomas' NHS Foundation Trust. The study is funded by the NIAA

Who has reviewed the study?

The study/trial has been reviewed by the Research Ethics Committee (REC) and Health Research Authority (HRA) (as appropriate) and has been reviewed by patient panel member on the Steering Committee.

Contacting the team

If you would like to find out more about this study, please contact the investigators:

Prof Kariem El-Boghdadly
E-mail: info@airway-management.org

Thank you for taking the time to read this information sheet and please keep a copy for your records.