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Study title:

Anaesthetic pre-operative Assessment of the adult Airway and Non-Specialist video Assessment: a method-comparison study (AAANSA)

Invitation:

We invite you to take part in the AAANSA study, a research project being run at Great Western Hospital, Swindon.

Adults that are due to undergo an operation under general anaesthesia attend a pre-operative assessment clinic which involves performing some simple measurements of the airway, such as looking into your open mouth. At the start of your operation the anaesthetist will insert a small breathing tube (called an endotracheal tube), to allow a machine to breath for you. Performing the airway measurements in the pre-operative clinic helps to inform the anaesthetist of any potential difficulties that might be encountered.

The COVID-19 pandemic has resulted in many face-to-face consultations moving to virtual (video) clinics. This includes the pre-operative assessment of the airway. We want to find out more information about how these changes are impacting our assessments of the airway, and what can be done to improve the information we gather.

What is the purpose of this study?

When you attend your pre-operative video clinic consultation, the healthcare professional will already record some information about your airway, such as the view of the back of your mouth, how easy it is for you to open your mouth wide and what your neck

movements are like. We would like to perform a more detailed assessment with a few additional measurements, such as your ability to move your lower jaw. We would like to record and store this data so it can be compared with a face-to-face assessment performed by an anaesthetist on the day of your operation.

It is currently not known how reliable airway assessments carried out using video calls are, what parts of the assessment work well or what parts are difficult to accurately measure. We hope to use this study to answer these questions, so we can improve future video calls for our patients.

What is patient data?

When you go to your GP or hospital, the doctors and others looking after you will record information about your health. This will include your health problems, and the tests and treatment you have had. They might want to know about family history, if you smoke or what work you do. All this information that is recorded about you is called patient data or patient information.

When information about your health care joins together with information that can show who you are (like your name or NHS number) it is called identifiable patient information. It's important to all of us that this identifiable patient information is kept confidential to the patient and the people who need to know relevant bits of that information to look after the patient. There are special rules to keep confidential patient information safe and secure.

What would taking part involve?

When you have agreed to take part in the study, the research team may look at your medical history and ask you questions to see if you are suitable for the study. When you attend the pre-operative clinic video assessment, the healthcare professional will ask you to perform several simple tasks such as opening your mouth as wide as possible. If you agree to take part in the study, the only change will involve recording a few additional measurements such as extending your lower jaw. When you attend for your operation, an anaesthetist will see you on the morning of your surgery. They will perform the same assessment of your airway that was carried out on the video call and the data will be recorded by a researcher.

The research team will record this data in special forms and combine it with the information from everyone else in the study. This recorded information is research data.

Taking part will not result in any change to the care you receive whilst you are an inpatient.

Why does health and care research use information from patients?

In clinical trials, the researchers are collecting data that will tell them whether one treatment is better or worse than another. The information they collect will show how safe a treatment is, or whether it is making a difference to your health. Different people can respond differently to a treatment. By collecting information from lots of people, researchers can use statistics to work out what effect a treatment is having.

Other types of research will collect data from lots of health records to look for patterns. It might be looking to see if any problems happen more in patients taking a medicine. Or to see if people who have screening tests are more likely to stay healthier.

Some research will use blood tests or samples along with information about the patient's health. Researchers may be looking at changes in cells or chemicals due to a disease.

All research should only use the patient data that it really needs to do the research. You can ask what parts of your health records will be looked at.

How does research use patient data?

If you take part in some types of research, like clinical trials, some of the research team will need to know your name and contact details so they can contact you. Researchers must always make sure that as few people as possible can see this sort of information that can show who you are.

In lots of research, most of the research team will not need to know your name. In these cases, someone will remove your name from the research data and replace it with a code number. This is called coded data, or the technical term is pseudonymised data. For example, your airway data will be labelled with your code number instead of your name. It can be matched up with the rest of the data relating to you by the code number.

When there is no information that could show who you are, this is called anonymous data.

Why have I been invited?

You have been invited because you are attending a pre-operative video assessment clinic before you undergo an operation under general anaesthesia.

You must own a mobile phone device that is capable of receiving a video call to participate in the study.

Do I have to participate?

No, it is entirely up to you whether you would like to participate in this study. We will describe the study and go through this information sheet with you. If you agree to take part, we will then ask you to sign a consent form. You are free to withdraw at any time without giving a reason. This will not affect the standard of care you receive.

Inclusion criteria

To take part in the study you must:
• Be aged ≥18
• Be due to attend a pre-operative remote video assessment clinic at Great Western Hospital prior to an operation under general anaesthesia
• Own a mobile phone device with the ability to video call

Exclusion criteria

Unfortunately, you will not be able to take part in the study if you:
• Aged <18
• Lack capacity to give consent or are unwilling to give consent
• Are pregnant
• Are a prisoner
• Have already participated in the study
• Do not have access to a mobile smartphone device
• Do not speak English
• Have difficulty understanding verbal or written instructions

What do I have to do if I take part?

If you would like to take part, you will need to complete an electronic consent form. This will be sent to you using the email address you gave the researcher in order to receive this Participant Information Sheet.

Are there any benefits to taking part?

There are no direct benefits to taking part in the study, but by taking part you will be helping us to better understand how comparable video airway assessment is to face-to-face assessment, and what we can do to improve the assessment.

Are there any risks to participating in this study?

There are no specific risks to your health or wellbeing as the only change will be to collect more information regarding your airway assessment. Data will be collected and stored following strict security and confidentiality guidelines that include anonymising data, encrypting data and limiting access to select members of the research team. All data will be stored on NHS hospital computer servers and will not leave the Great Western Hospital site.

Do I get paid for doing this?

We appreciate the time you will be dedicating to reading this information and completing the consent form, but we cannot offer any payment for your participation.

What are my choices about my patient data?

You can stop being part of a research study at any time, without giving a reason, and the research team will delete the data that they already have. This will not affect your healthcare or legal rights. You can find out what would happen with your data before you agree to take part in a study.

Researchers need to manage your records in specific ways for the research to be reliable. This means that they won't be able to let you see or change the data they hold about you.

Where will my data go?

Sometimes your own doctor or care team will be involved in doing a research study. Often, they will be part of a bigger research team. Great Western Hospital is the only hospital involved in this research study, but we are working with the University of Bristol. The coded data will be stored on Great Western Hospital computers. The final anonymised data will be transferred to the University of Bristol.

What happens to my research data after the study?

Once they have finished the study, the research team will keep the coded data for 12 months, in case they need to check it. This data will be stored securely on Great Western

Hospital computers. Any information that could show who you are will be held safely with strict limits on who can access it. All the computers storing patient data must meet special security arrangements.

The data will be analysed to determine how comparable the two different methods of airway assessment are. The intention of the researchers is to write a report on the study that will be published in a medical journal. Researchers must make sure they write the reports about the study in a way that no-one can work out that you took part in the study.

The final dataset will be fully anonymised; no individual participant will be identifiable from the data. This anonymised data will be kept for 10 years on University of Bristol computers to allow further analysis, and will then be deleted.

If you agree to take part in a research study, you will be agreeing to give your research data from this study for future research. This future research will use research data that has had your name and NHS number removed. Once your details like your name or NHS number have been removed, other researchers won't be able to contact you to ask you about future research. This anonymised data will be stored for 10 years on University of Bristol computers. Your data will not be used to sell you anything. It will not be given to other organisations or companies except for research.

Will the use of my data meet GDPR rules?

GDPR stands for the General Data Protection Regulation. In the UK we follow the GDPR rules and have a law called the Data Protection Act. All research using patient data must follow UK laws and rules.

Universities, NHS organisations and companies may use patient data to do research to make health and care better.

When companies do research to develop new treatments, they need to be able to prove that they need to use patient data for the research, and that they need to do the research to develop new treatments. In legal terms this means that they have a 'legitimate interest' in using patient data.

Universities and the NHS are funded from taxes and they are expected to do research as part of their job. They still need to be able to prove that they need to use patient data for the research. In legal terms this means that they use patient data as part of 'a task in the public interest'.

If they could do the research without using patient data they would not be allowed to get your data.

Researchers must show that their research takes account of the views of patients and ordinary members of the public. They must also show how they protect the privacy of the people who take part. An NHS research ethics committee checks this before the research starts.

Who can I contact if I have a complaint?

If you want to complain about how researchers have handled your information, you should contact the research team. If you are not happy after that, you can contact the Data Protection Officer. The research team can give you details of the right Data Protection Officer.

Swindon Great Western Hospital Patient Advice and Liaison Service (PALS) can be contacted should you wish to make a complaint and are independent of the research team. Their contact details are: Telephone: 01793 604031 or Email: gwh.pals@nhs.net

If you are not happy with their response or believe they are processing your data in a way that is not right or lawful, you can complain to the Information Commissioner's Office (ICO) (www.ico.org.uk or 0303 123 1113).

Further information and contact details

If you would like further information or have any questions about this research study, please send an email to: thomas.woodland@nhs.net

We are happy to answer any questions you have.

We thank you for taking the time to read this information sheet and considering to participate in this research study.