

| | |
|---|---|
| FULL/LONG TITLE OF THE STUDY | Anaesthetic pre-operative Assessment of the adult Airway and Non-Specialist video Assessment: a method-comparison study |
| SHORT STUDY TITLE / ACRONYM | AAANSA |
| PROTOCOL VERSION NUMBER AND DATE | Version 1.1 19th April 2021 |
| IRAS Number: | 294205 |
| SPONSORS Number: | 2021 - 2671 |
| Chief Investigator | Dr Thomas Woodland |

LIST of CONTENTS

| GENERAL INFORMATION | Page No. |
|---|----------|
| HRA PROTOCOL COMPLIANCE DECLARATION | i |
| TITLE PAGE | ii |
| RESEARCH REFERENCE NUMBERS | ii |
| SIGNATURE PAGE | iii |
| LIST OF CONTENTS | iv |
| KEY STUDY CONTACTS | v |
| STUDY SUMMARY | v |
| FUNDING | vi |
| ROLE OF SPONSOR AND FUNDER | vi |
| ROLES & RESPONSIBILITIES OF STUDY STEERING GROUPS AND INDIVIDUALS | vi |
| STUDY FLOW CHART | vii |
| SECTION | |
| 1. BACKGROUND | |
| 2. RATIONALE | |
| 3. THEORETICAL FRAMEWORK | |
| 4. RESEARCH QUESTION/AIM(S) | |
| 5. STUDY DESIGN/METHODS | |
| 6. STUDY SETTING | |
| 7. SAMPLE AND RECRUITMENT | |
| 8. ETHICAL AND REGULATORY COMPLIANCE | |
| 9. DISSEMINATION POLICY | |
| 10. REFERENCES | |
| 11. APPENDICES | |

| KEY STUDY CONTACTS | |
|--------------------------------|---|
| Chief Investigator | <p>Dr Thomas Woodland Academy Office Great Western Hospital Marlborough Road Swindon SN3 6BB thomas.woodland@nhs.net 01793 604020</p> |
| Study Co-ordinator | Dr Thomas Woodland |
| Sponsor | <p>University of Bristol research-governance@bristol.ac.uk</p> <p>Sponsor representative: Adam Taylor</p> <p>Sponsor contact: Adam Taylor Head of Research Governance Research Governance Team Research & Enterprise Division University of Bristol One Cathedral Square, Trinity Street, College Green, Bristol BS1 5DD T: 01173940177 M: 07773 816495 adam.taylor@bristol.ac.uk General Enquiries: research-governance@bristol.ac.uk</p> |
| Joint-sponsor(s)/co-sponsor(s) | N/A |
| Funder(s) | This study is funded internally by Great Western Hospital Academy |
| Key Protocol Contributors | Dr Thomas Woodland |

| STUDY SUMMARY | |
|--|---|
| Study Title | Anaesthetic pre-operative Assessment of the adult Airway and Non-Specialist video Assessment: a method-comparison study |
| Internal ref. no. (or short title) | AAANSA |
| Study Design | Method-Comparison Study |
| Study Participants | Attending a pre-operative remote video assessment clinic prior to an operation under general anaesthesia |
| Planned Size of Sample (if applicable) | 200 patients |
| Follow up duration (if applicable) | N/A |
| Planned Study Period | Estimated duration for the main protocol (e.g. from start of screening to last subject processed and finishing the study) is approximately 1 year |
| Research Question/Aim(s) | <p>Primary aim:</p> <p>To determine whether non-specialist remote video assessment of the airway is comparable to in-person anaesthetic assessment of the airway</p> <p>Secondary aims:</p> <ol style="list-style-type: none"> 1) To determine how the quality of remote video airway assessment can be optimised 2) To determine which elements of the airway assessment can be adequately assessed remotely |

| FUNDING AND SUPPORT IN KIND | |
|--|---|
| FUNDER(S) | FINANCIAL AND NON-FINANCIAL SUPPORT GIVEN |
| Dr Kevin Jones Great Western Hospital Academy Marlborough Rd Swindon SN3 6BB | Providing financial support for the study |

ROLE OF STUDY SPONSOR AND FUNDER

Study sponsor: University of Bristol

Role of study sponsor: assuming overall responsibility for the initiation and management of the study. The University of Bristol will provide support in the form of advice on study design, conduct, data analysis and interpretation. They will review the IRAS application for Health Research Authority ethical approval.

PROTOCOL CONTRIBUTORS

The protocol was conceived and designed by Dr Thomas Woodland (lead investigator).

The University of Bristol Research Governance Team provided advice on:

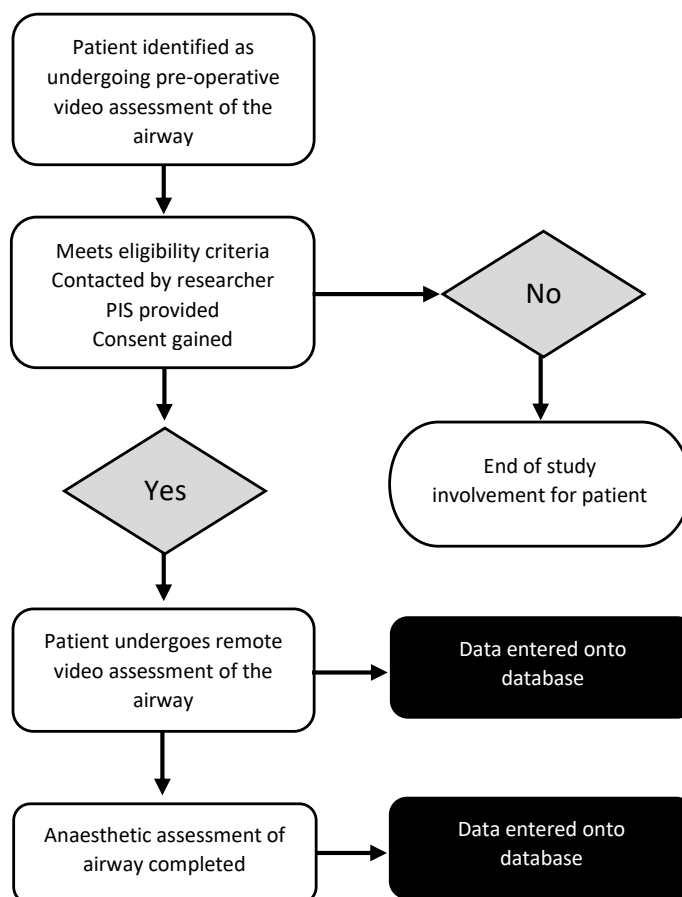
- Study design
- Conduct
- Supporting the application for IRAS ethical approval

Great Western Hospital Academy, the study funder, will not control study design, analysis, interpretation or manuscript writing.

KEY WORDS:

Anaesthetic airway remote video assessment
telemedicine

STUDY FLOW CHART



| Abbreviations | |
|---------------|--|
| CRF | Case Report Forms |
| GWH | Great Western Hospital |
| HRA | Health Research Authority |
| IRAS | Integrated Research Application System |
| NHS | National Health Service |
| PIS | Patient Information Sheet |
| REC | Research Ethics Committee |

STUDY PROTOCOL

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

1 BACKGROUND

For patients undergoing general anaesthesia, anaesthetists attempt to predict difficult tracheal intubation using a variety of anatomic predictors and bedside tests^[1]. When difficulty is suspected, these predictions should be used to inform the clinician's approach to airway management, including a 'rescue' approach, should difficulty be encountered^[2]. Airway assessment also helps to determine if additional precautions are needed prior to starting intubation of the airway^[2].

Meta-analysis has given clinicians insight into which assessments help to predict difficult tracheal intubation, and how successful they are at doing so^[1]. However, the evidence base for remote video assessment of the airway is lacking^[3]. A single study, published in 2013, suggested similar sensitivity in predicting difficult tracheal intubation between remote and in-person airway assessment^[4]. However, this study used tele-medicine technology, which consisted of non-portable, high-definition, video-streaming equipment with dedicated lighting. This represents a very different method of assessment to what is being utilised by many NHS hospitals during the SARS-CoV-2 outbreak.

Since the onset of the pandemic, face-to-face assessments have been largely replaced by virtual clinics^[5]. As Cook (2021) points out, this has the potential to reduce the opportunities to perform airway assessment, and to impact on the accuracy of the assessment itself. In our hospital's pre-operative department, patients are now invited to a remote video consultation with a nurse practitioner or healthcare assistant. Patients that are due to undergo an operation under general anaesthesia, are invited to a video consultation using a text messaging service. This results in the patient joining the consultation using the front-facing camera of their mobile phone device. We believe our experiences of pre-operative assessment reflect the wider picture across the United Kingdom^[6]. This rapid and unprecedented change away from traditional in-person assessment is yet to be properly studied, and many questions remain unanswered.

We will assess remote video airway assessment by non-specialist healthcare providers and compare the results to a face-to-face assessment. We also aim to determine the common limitations to remote assessment, in order to issue recommendations for optimising the consultation.

2 RATIONALE

2.1 Primary question:

- Is pre-operative non-specialist remote video assessment of the adult airway comparable to in-person assessment of the airway?

The primary aim is to determine if the findings from the remote video non-specialist airway assessment correlate with the results of an in-person anaesthetic assessment. A literature review of telemedicine anaesthetic assessment by Bridges et al. in 2020 revealed a single randomised controlled trial that compared remote airway evaluation to in-person assessment. The findings suggested comparable sensitivities, but the study was performed using non-portable, high-definition, video-streaming equipment with dedicated lighting. This limits the generalisability of the findings to our patient population, who are using mobile phone devices to connect to the videocall.

2.2 Secondary question(s):

- How can the quality of remote video airway assessment be optimised?

This question looks to determine how often video assessment is unacceptable, what factors make the assessment unacceptable, and what recommendations can be drawn from these findings to optimise the assessment.

- Which elements of pre-operative airway assessment can be adequately assessed remotely?

This question will help determine whether some of the traditional anatomic markers and tests can be easily assessed using remote video consultation. There are practical considerations when undertaking mobile device videocalls that may impact the adequacy of the assessment. For example, assessment of the mouth may be frequently impaired by inadequate lighting.

3 THEORETICAL FRAMEWORK

Airway assessment and the management of the difficult airway has consistently been a topic of interest in anaesthesia research and in clinical practice guidelines. The SARS-CoV-2 pandemic has caused a significant shift away from face-to-face consultations and towards virtual assessment. This has the potential to impact upon the accuracy of difficult airway prediction and which could ultimately lead to detrimental patient outcomes.

“Optimising the quality of remote airway assessment and exploring whether it correlates with face-to-face assessment” was an area identified as worthy of research in the Association of Anaesthetists COVID-19 airway management guidance^[5].

We theorise that virtual airway assessment can be used as a valid tool to provide comparable results to in-person anaesthetic assessment. We will collect and collate data to establish the reality using quantitative methods, comparing the results using kappa analysis^[11].

Furthermore, we will enquire on the limitations of virtual assessment by using a qualitative, interpretative approach whereby we find meaning from the personal experience and perspectives of the assessors^[12].

Hypotheses:

- Video assessment of the airway will provide comparable results to in-person assessment of the airway for the following measurements:
 - Mallampati score
 - Upper lip bite test
 - Lower jaw protrusion

- Video assessment of the airway will provide discordant results to in-person assessment of the airway for the following measurements:
 - Mouth opening
 - Thyromental distance
- Technical limitations experienced during the video assessments are likely to have a greater impact on the adequacy of certain airway measurements than others

4 RESEARCH QUESTION/AIM(S)

Aim:

The aim of the study is to evaluate the use of non-specialist remote video assessment of the adult airway in the pre-operative environment

4.1 Objectives

The study's objectives are:

- Compare the results of non-specialist remote video assessment of the adult airway to in-person anaesthetic assessment
- Identify common problems that impair the quality of remote video airway assessment
- Identify the frequency with which airway assessment tests fail to be adequately assessed remotely

4.2 Outcome

The study outcomes are:

- To determine whether remote video assessment of the adult airway is a suitable alternative to in-person anaesthetic assessment
- Formulate recommendations that may help with optimising future remote video airway assessments

5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYSIS

This is a single centre, method-comparison study that does not involve an intervention, but does involve the gathering and comparison of patient data. Patients that meet the eligibility criteria will be contacted by researchers using their telephone number. The participants will be provided with a participant information sheet via email, and given time to read the information. This will include information on the nature, significance, implications and risks of the trial and the participant will have the right to withdraw from the trial at any time. The researcher will then give the participant the opportunity to ask questions regarding the study. If the participant agrees to take part in the study, they will be sent an electronic consent form for them to record their consent. Consenting patients will be given a unique study identifying number which will be recorded on a password-protected database held on Great Western Hospital's servers.

Data collection

The study design will be a method-comparison study. This will involve the collection of the patient's airway data via two separate methods, and compare the results. Healthcare professionals working

within the pre-operative assessment clinic at Great Western Hospital are already completing remote video assessments of the airway. As part of the study, they will collect additional data on airway assessment tests and anatomical markers. The data collection points used for airway assessment will be based on the current literature evidence base. The meta-analysis published by Roth et al.^[1] identified the following bedside airway assessment tests with an underlying evidence base:

- Modified Mallampati^[7]
- Thyromental distance^[8]
- Mouth opening^[9]
- Upper lip bite test^[10]

The following tests were identified from the British Journal of Anaesthesia review on predicting difficult intubation^[13]:

- Neck movement
- Lower jaw protrusion

The healthcare professional conducting the assessment will also be asked to record any technical problems or limitations that impeded their assessment of the airway.

The results will be recorded using paper forms designed by the researcher, which will be stored within a locked cabinet on NHS premises until it is entered onto a password-protected database on the hospital's servers. This will happen as soon as possible and the database will only be accessible to the research team. The unique study identifier will be linked to the individuals' personal data on a separate password-protected database held on the hospital's servers.

No video footage or still images will be stored or recorded.

The data will be archived according to the Sponsor's standard operating procedure.

Patients' demographics will be described using frequency and proportion for categorical data and means and standard deviations for continuous data. A comparison between the results of the two airway assessments made by the non-specialist and the anaesthesiologist will be conducted on each of the airway measurements using kappa analysis.

6 STUDY SETTING

The study will take place at Great Western Hospital, Swindon, and is a single centre study.

Participants will be identified via the Great Western Hospital Pre-Operative Assessment Clinic. Potential participants will be contacted by the researcher via telephone prior to their attendance at the pre-operative clinic in-order to provide the participant information (via email), check eligibility criteria and gain electronic consent using the Microsoft Forms online platform. Microsoft forms is compliant with GDPR and the Data Protection Act (2018). The consent forms will be password protected, with access granted on an individual basis to select members of the research team.

Prior to recruitment start, staff will undergo the relevant training and receive the necessary information, either remotely, or face-to-face. Pre-operative assessment staff already perform remote video airway assessments as part of their day-to-day job. Data will be collected in the pre-operative assessment clinic and in the operating theatre for the remote video assessment and the in-person assessment respectively. Both data sets will initially be recorded onto paper forms and then transcribed to a secure database, as outlined in section 5. Any paper forms will immediately be disposed of in-keeping with the hospital confidential waste policy.

Participants will be considered eligible for enrolment into this study if they fulfil all of the inclusion criteria and none of the exclusion criteria as defined in section 7.

Using Great Western Hospital is an appropriate setting for this study as it already has an operational video-calling system in place that adheres to the principles of GDPR and meets the necessary data security standards. The hospital also has a research and innovation department that is willing to review the study protocol and support the study through local feasibility approval processes.

7 SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria

The study will recruit adult patients that are attending a remote video consultation with a healthcare professional from the pre-operative assessment clinic at Great Western Hospital, Swindon. This will include male and female participants. The study will aim to recruit patients that meet the inclusion criteria and will exclude patients that meet the exclusion criteria.

Patients that are deemed to be high-risk for difficult intubation or airway management by the pre-operative assessment staff are sometimes referred to a senior anaesthetist for in-person assessment. This is a decision that is made by the pre-operative staff, often in conjunction with senior anaesthetists, and is based on their clinical reasoning. These patients will be included in the study.

7.1.1 Inclusion criteria

Potential participants must satisfy the following criteria to be enrolled in the study:

- Age ≥ 18
- Attending a pre-operative remote video assessment clinic prior to an operation under general anaesthesia
- Owns a mobile phone device with the ability to video call

7.1.2 Exclusion criteria

Potential participants meeting any of the following criteria will be excluded from study participation:

- Age < 18
- Lacking capacity to give consent
- Unwilling to give consent
- Pregnancy
- Prisoners
- Prior participation in the study
- Patient does not have access to a mobile smartphone device
- Does not speak English
- Difficulty understanding verbal or written instructions

7.2 Sampling

7.2.1 Size of sample

A sample size calculation has been performed so that the study has a stated probability of detecting a statistically significant kappa coefficient^[11]. We used an a priori calculation with the assumption that a kappa of ≥ 0.7 could be considered good agreement. Assuming that the average proportion of positive ratings on a dichotomous question is 0.7, that the assessors are unbiased, that the two-tailed null value is 0.5, and that the pairwise kappa we wish to detect is 0.7, we would need 173 subjects. To correct for possible systemic biases, we plan to recruit 200 subjects.

7.2.2 Sampling technique

A convenience non-consecutive sampling technique will be employed with participants identified through the Great Western Hospital pre-operative clinic. Once ethical and final sponsorship approval has been granted, patient pre-operative clinic lists will be screened by the researchers. Patients that meet the inclusion criteria will be contacted by telephone to confirm inclusion/exclusion criteria, provide information, given the opportunity to ask questions and gain electronic consent.

There will be an estimated delay between the two airway assessments of several weeks (time taken from pre-operative video airway assessment to operation). However, given that anatomical changes to patient airways do not tend to occur acutely in a stable outpatient population this is unlikely to affect results.

Generalisability

As patients are being recruited through outpatient elective pre-operative lists, the findings may not be generalisable to unwell or unstable inpatients undergoing tracheal intubation. However, the researchers do not foresee this subgroup of patients to be the focus of future remote video airway assessments, as inpatients have the opportunity for a face-to-face assessment by an anaesthetist.

7.3 Recruitment

Patient recruitment will only commence once evidence of the following approval / essential documents are in place:

- Research Ethics Committee (REC) approval (via IRAS platform)
- Final sponsorship permissions
- Great Western Hospital Feasibility approval

7.3.2 Consent

Patients that meet the eligibility criteria will be contacted by the Principal Investigator, or an appropriately trained member of the team, via telephone, prior to their attendance at the pre-operative assessment clinic. Potential participants will be provided with an electronic Participant Information Sheet (PIS) via email, and given time to read the information and to consider their participation in the study. This will include information on the nature, significance, implications and risks of the trial and will have been approved by the REC. Participants will be given the opportunity to ask any questions they may have. If the participant would like further information, they may also talk to an independent

person that is aware of the study protocol but is not directly involved, for example, a member of the anaesthetics department.

The patient will be informed that their medical records are subject to review by representatives of the sponsor as necessary and that data will be collected and processed in accordance with the Data Protection Act 2018. Each patient will be advised that data collected may be published or presented at scientific meetings and may also be subject to audit procedures from Regulatory Authorities. All such personally identifiable data will be pseudo-anonymised to maintain patient confidentiality.

If new information results in significant changes to the risk–benefit assessment, the consent form will be reviewed and updated if necessary. All participants, including those already being treated, will be informed of the new information, given a copy of the revised consent form and asked to re-consent if they choose to continue in the study.

Due to the perceived low risk, burden and minimally invasive nature of the study, consent will be sought on the day of contact from the researcher. Patients that confirm their willingness to take part in the study over the phone will be sent an electronic consent form. This will be in keeping with the guidance published by the Health Research Authority entitled “Joint statement on seeking consent by electronic methods, September 2018, HRA and MHRA” which is available here:

<https://www.hra.nhs.uk/about-us/news-updates/hra-and-mhra-publish-joint-statement-seeking-and-documenting-consent-using-electronic-methods-econsent/>

The electronic consent form will consist of tick-box declarations and a typewritten signature. Completion of the form will indicate that the participant agrees to be included in the study. The participant will have the right to withdraw from the trial at any time. Potential participants will be made aware that their care will not be affected in any way if they decide not to take part.

The consent form will ask the participant for confirmation that they have read the Participant Information Sheet (PIS) and will include the document version. If the PIS is updated, the consent form will be updated centrally to amend the version number. Should a situation arise where a patient has delayed in consenting and the PIS they received was an older version, the patient will be contacted and asked to read the updated PIS before consenting.

8 ETHICAL AND REGULATORY CONSIDERATIONS

The study will be conducted in compliance with the protocol as agreed by the Sponsor and which will need to be given favourable opinion by the Research Ethics Committee (REC) and Health Research Authority (HRA) before proceeding.

Within 90 days after the end of the study, the Chief Investigator and Sponsor will ensure that the REC is notified that the study has finished by completing the Sponsor’s ‘End of Study Declaration’. The CI will supply an End of Study report of the clinical study to the REC within one year after the end of the study. If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination.

8.1 Assessment and management of risk

The study is perceived low risk, due to its minimally invasive nature and low burden placed on patients and staff. All participants will already be undergoing pre-operative remote video assessment of the airway and will likely receive some form of inpatient airway assessment when they attend for their planned operation. The study will elaborate on these assessments, ensuring that more in-depth data is collected to enable detailed comparison of the two means of assessment.

If the research team identify concerns regarding potential harm to the patient or to others e.g. concerns regarding the participant's mental health, then these will be discussed with the research team clinician (Dr Thomas Woodland) and appropriate action taken.

8.2 Research Ethics Committee (REC) and other Regulatory review & reports

Before the start of the study, a favourable opinion will be sought from an appropriate REC for the study protocol, informed consent forms and other relevant documents e.g. Participant Information Sheet.

- Substantial amendments that require review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to implement at site.
- It is the Chief Investigator's responsibility to produce the annual reports and submit the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended.
- The Chief Investigator will notify the REC of the end of the study within one year after the end of the study.
- If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination.

Regulatory Review & Compliance

Before Great Western Hospital can enrol patients into the study, the Chief Investigator/Principal Investigator or designee will ensure that appropriate local approvals are in place. Specific arrangements on how to gain approval from participating organisations are in place and comply with the relevant guidance.

Amendments

For any amendment to the study, the Chief Investigator or designee, in agreement with the sponsor will submit information to the appropriate body in order for them to issue approval for the amendment. The Chief Investigator or designee will work with sites (R&D departments at GWH site as well as the study delivery team) so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

If the sponsor wishes to make a substantial amendment to the REC application or the supporting documents, the sponsor must submit a valid notice of amendment to the REC for consideration. The REC

will provide a response regarding the amendment within 35 days of receipt of the notice. It is the sponsor's responsibility to decide whether an amendment is substantial or non-substantial for the purposes of submission to the REC.

If applicable, other specialist review bodies (e.g. Confidentiality Advisory Group (CAG)) need to be notified about substantial amendments in case the amendment affects their opinion of the study.

8.3 Peer review

The research proposal (protocol) has been peer reviewed through the funder, GWH academy. They have been able to offer independent, proportionate advice on the research proposal's scientific quality.

8.4 Patient & Public Involvement

The study is low risk, minimally invasive and places a low burden on patients. Due to this, patients or members of the public have not been involved in shaping the research protocol.

8.5 Protocol compliance

Protocol deviations, non-compliances, or breaches are departures from the approved protocol. Accidental protocol deviations can happen at any time. All protocol deviations must be adequately documented and reported to the Chief Investigator and Sponsor immediately. Deviations from the protocol which are found to frequently recur are not acceptable, will require immediate action and could potentially be classified as a serious breach.

8.6 Data protection and patient confidentiality

All data will be handled in accordance with the Data Protection Act 2018 (UK implementation of the EU General Data Protection Regulation (GDPR)).

Forms completed by the pre-operative assessment staff will contain similar data to what is already being collected by the service. Basic participant demographic data (e.g. gender, age) will also be recorded. Data will be recorded on paper Case Report Forms and will be stored in a locked cabinet in the pre-operative assessment clinic, which is only accessible to delegated members of the research team. This data will then be transcribed onto a pseudo-anonymised password-protected database on the Hospital's servers, using the patient's unique study identifier. This will happen as soon as possible and the database will only be accessible to the research team. The unique study identifier will be linked to the individuals' personal data on a separate password-protected database held on the hospital's servers.

Data collected regarding the patient's in-person anaesthetic airway assessment will be recorded on paper Case Report Forms that will only include the patient's unique study identifier. This data will also be added to the password-protected database on the Hospital's servers, as above. The data will be processed in compliance with the Sponsor's data handling policy. No video footage will be stored or recorded.

Consent forms will be issued and returned electronically. This will be done using the Microsoft Forms online service which is compliant with the Health Insurance Portability and Accountability Act (HIPAA)

and with GDPR. The consent forms will only be accessible to delegated members of the research team.

Participants' airway data (transcribed from Case Report Forms) and consent forms will be stored for up to 12 months after study completion. This is to allow processing of the airway data which will form the final dataset. Once the final dataset has been transferred to Bristol University, all personal data will be deleted.

The final dataset will be uploaded to the Bristol Research Data Service and will be accessible via the Bristol Research Data Repository (<https://data.bris.ac.uk/data/>). The data will be anonymised and stored for 10 years to allow further analysis. After this period the data will be deleted. Participants will be informed of this intention via the PIS and will be required to consent to this to be included in the study.

8.7 Indemnity

The University of Bristol has arranged Public Liability insurance to cover the legal liability of the University as Research Sponsor in the eventuality of harm to a research participant arising from management of the research by the University. This does not in any way affect an NHS Trust's responsibility for any clinical negligence on the part of its staff (including the Trust's responsibility for University of Bristol employees acting in connection with their NHS honorary appointments).

Great Western Hospital NHS Foundation Trust is party to NHS Litigation Authority (NHSLA) / NHS Resolution. As an NHS body it is liable for clinical negligence and other negligent harm to individuals covered by their duty of care. NHS Institutions employing researchers are liable for negligent harm caused by the design of studies they initiate.

The University of Bristol holds Professional Negligence insurance to cover the legal liability of the University, for harm to participants arising from the design of the research, where the research protocol was designed by the University.

8.8 Access to the final study dataset

Members of the research team will have access to the full dataset. Patients will be consented for possible secondary analysis through possible future research projects.

9 DISSEMINATION POLICY

9.1 Dissemination policy

Publication: "Any activity that discloses, outside of the circle of trial investigators, any final or interim data or results of the Trial, or any details of the Trial methodology that have not been made public by the Sponsor including, for example, presentations at symposia, national or regional professional meetings, publications in journals, theses or dissertations."

All scientific contributors to the Trial have a responsibility to ensure that results of scientific interest arising from Trial are appropriately published and disseminated. The Sponsor has a firm commitment to publish

the results of the Trial in a transparent and unbiased manner without consideration for commercial objectives.

To maximise the impact and scientific validity of the Trial, data shall be consolidated over the duration of the trial, reviewed internally among all investigators and not be submitted for publication prematurely. Lead in any publications arising from the Trial shall lie with the Sponsor in the first instance.

9.2 Authorship eligibility guidelines and any intended use of professional writers

The Chief Investigator shall liaise with all investigators and strive to consolidate data and results and submit a manuscript for peer-review with a view to publication in a reputable academic journal or similar outlet as the Main Publication.

- The Chief Investigator shall be senior and corresponding author of the Main Publication.
- Insofar as compatible with the policies of the publication outlet and good academic practice, the other Investigators shall be listed in alphabetic order.

10 REFERENCES

1. Roth, D., Pace, N.L., Lee, A., Hovhannisyan, K., Warenits, A.M., Arrich, J. and Herkner, H. (2019), Bedside tests for predicting difficult airways: an abridged Cochrane diagnostic test accuracy systematic review. *Anaesthesia*, 74: 915-928. <https://doi.org/10.1111/anae.14608>
2. Law, J.A. and Duggan, L.V. (2019), The airway assessment has come of age—or has it? *Anaesthesia*, 74: 834-838. <https://doi.org/10.1111/anae.14658>
3. Bridges, K.H., McSwain J.R., Wilson P.R. (2020) To Infinity and Beyond: The Past, Present, and Future of Tele-Anesthesia. *Anesth Analg.*, 130(2):276-284
<https://doi.org/10.1213/ane.0000000000004346>
4. Applegate, R.L., Gildea B., Patchin R., Rook J.L., Wolford B., Nyirady J., Dawes T.A., Faltys J., Ramsingh D.S., Stier G. (2013) Telemedicine pre-anesthesia evaluation: a randomized pilot trial. *Telemed J E Health.*,19(3):211-6
5. Cook, T.M., McGuire, B., Mushambi, M., Misra, U., Carey, C., Lucas, N., O'Sullivan, E. and Harrop-Griffiths, W. (2021), Airway management guidance for the endemic phase of COVID-19. *Anaesthesia*, 76: 251-260. <https://doi.org/10.1111/anae.15253>
6. Stokel-Walker, C., (2020) Why telemedicine is here to stay. *BMJ*, 2020;371:m3603
<https://doi.org/10.1136/bmj.m3603>
7. Samsoon, G. L. T., & Young, J. R. B. (1987). Difficult tracheal intubation: a retrospective study. *Anaesthesia*, 42(5), 487-490.
8. Lewis, M., Keramati, S., Benumof, J. L., & Berry, C. C. (1994). What is the best way to determine oropharyngeal classification and mandibular space length to predict difficult laryngoscopy?. *The Journal of the American Society of Anesthesiologists*, 81(1), 69-75.

9. Calder, I., Picard, J., Chapman, M., O'Sullivan, C., & Crockard, H. A. (2003). Mouth opening: a new angle. *The Journal of the American Society of Anesthesiologists*, 99(4), 799-801.
10. Khan, Z. H., Kashfi, A., & Ebrahimkhani, E. (2003). A comparison of the upper lip bite test (a simple new technique) with modified Mallampati classification in predicting difficulty in endotracheal intubation: a prospective blinded study. *Anesthesia & Analgesia*, 96(2), 595-599.
11. Sim, J., & Wright, C. C. (2005). The kappa statistic in reliability studies: use, interpretation, and sample size requirements. *Physical therapy*, 85(3), 257-268.
12. Thorne, S., (2000). Data analysis in qualitative research. *Evidence-Based Nursing*, 3, 68-70.
13. Crawley, S.M., Dalton, A.J. (2015) Predicting the difficult airway. *BJA Education*, 15(5) 253–257.

11. APPENDICIES

11.1 Appendix 1- Required documentation

[Patient Information Sheet](#)

11.2 Appendix 3 – Amendment History

| Amendment No. | Protocol version no. | Date issued | Author(s) of changes | Details of changes made |
|---------------|----------------------|-------------|----------------------|-------------------------|
| | | | | |