

Title: intubateCOVID

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Lead site: Guy's and St Thomas' NHS Foundation Trust, London, UK

Design: Service Evaluation

Registration: Guy's and St Thomas' NHS Foundation Trust Service Evaluation Database, Registration number 10769

Background

As everyone is now well-aware, the number of coronavirus disease-2019 (COVID-19) cases, caused by the novel SARS-CoV-2 virus, are rapidly rising globally. Many of the most severe patients may require invasive ventilatory support for respiratory failure or to facilitate general anaesthesia for surgery. Airway management and tracheal intubation are known to be a high-risk aerosol-generating procedure (AGP) and therefore may predispose staff performing it to contracting COVID-19.

The incidence of COVID-19 in healthcare workers is thought to be higher than the general population. This incidence may be even greater in healthcare workers who have been exposed to high viral loads while undertaking AGPs, such as tracheal intubation. There are no large-scale data on the association between airway management and the development of COVID-19.

Methods

The Difficult Airway Society (UK), in association with Guy's and St Thomas' NHS Foundation Trust, London, UK, have therefore developed a COVID-19 airway management project: intubateCOVID. In the UK, this project has been supported by the Association of Anaesthetists, Intensive Care Society, the Royal College of Anaesthetists and the Royal College of Emergency Medicine and is classed as a service evaluation. In the USA, the University of Pennsylvania has now also adopted this project and gained institutional review board exemption and will be disseminating it across the United States. Approvals from Irish, African, Australian and New Zealand sites are in process, making this an international collaborative project.

The objectives of this service evaluation are:

- 1) to ascertain the incidence of airway managers and assistants who develop COVID-19 in the weeks following an airway management episode
- 2) to document associations of risk factors with COVID-19
- 3) to examine the use of personal protective equipment (PPE) during airway management of COVID-19 patients
- 4) to assess the demographic of airway managers
- 5) to allow healthcare professionals to track their airway management activity
- 6) to allow local, national and international reporting of airway management activity and provide information to support policymakers

This will be achieved by users creating an account and self-logging all airway management of COVID-19 patients on an encrypted, anonymous database: www.intubatecovid.org. A weekly reminder will be sent to registered users seeking follow-up for COVID conversion. Users will agree to the disclaimer upon registration (Appendix 2).

Our aims are to work collaboratively with national leads (Table 1) to maximise the data we receive, ensuring generalisability and validity of our results.

Our responsibilities to the international collaborators are:

- 1) to agree to share real-time data and at the stage of data analysis
- 2) to agree on an analysis plan and data interpretation
- 3) to share authorship of the eventual manuscript(s) with the national leads and further co-investigator(s), as appropriate. Authorship will also include all other national leads from other contributing nations, but first, second and final authorship will be allocated to the UK team (KE, DJW, IA).

The responsibilities of the national leads are (Appendix 1):

- 1) to ensure that all national governance and ethical standards, policies, procedures and regulations are adhered to, and required approvals obtained
- 2) to assist in dissemination of the project nationally
- 3) to obtain support from national organisations and bodies for the project

Appendix 1. Requests from national leads.

- 1) Obtain a waiver for ethical approval as this is not defined as research. In the UK and Ireland, this is defined as a service evaluation. In the USA, this is defined as a quality improvement/assurance.
- 2) Determine if any other institutions require a waiver
- 3) Provide a list of all institutions that may be intubating COVID-19 patients
- 4) Provide a logo of institutions demonstrating support
- 5) Seek support from national organisations and bodies
- 6) Disseminate the project widely nationally

Appendix 2. Disclaimer on registration page.

Disclaimer

The intubateCOVID project has been registered as a service evaluation at Guy's and St Thomas' NHS Foundation Trust (London, UK) and has been determined by the University of Pennsylvania Institutional Review Board (Philadelphia, PA, USA) to qualify as a quality assurance/quality improvement initiative that does not meet the definition of human subjects research.

By completing this form, I confirm that I have obtained all necessary institutional approvals required for my participation in this service evaluation/quality improvement/quality assurance initiative.

Additionally, I confirm that:

1. I agree to receive regular reminder e-mails prompting my responses to this project.
2. I understand the purpose of this project.
3. I understand that the risks and benefits of participation and have freely chosen to participate.
4. I understand that there will be no reimbursement for my participation.
5. I understand that my participation is voluntary, and I am free to withdraw any time by contacting the project leads.
6. I understand that the principal purpose of this project is to prevent disease transmission and to improve public health services. I understand that communication of findings from this project may involve presentation or publication of collected data and that all data will be de-identified and reported in aggregate.
7. I understand that my data will be stored in an online encrypted database with access to team only, and in accordance with GDPR principles, and that no personal information will be shared with any third party.

Contact Information:

Global Project Lead and European Coordinating Centre Lead:

Dr. Kariem El-Boghdady at: help@intubatecovid.org

United States Coordinating Centre Lead:

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Appendix 3. Supporting institutions.

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