

# Outline of research proposal for the RFH Research and Innovation Group

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### **Study title**

Evaluation of the impact of using anaesthetic machines for ventilation on COVID-19 patients and professionals. An observational and qualitative study.

### **Project collaborators**

Agnieszka Walecka, ICU Consultant, Royal Free London NHS Foundation Trust –  
[agnieszka.walecka@nhs.net](mailto:agnieszka.walecka@nhs.net)

Annalisa Casarin, Senior Research Adviser, NIHR Research Design Service East of England, University of Hertfordshire - [annalisa.casarin@nihr.ac.uk](mailto:annalisa.casarin@nihr.ac.uk)

### **Introduction and background**

COVID-19 pandemic dramatically increased the demand for the ventilator beds, generating, at the same time, Intensive Therapy Unit (ITU) ventilators shortages [1]. Anaesthetic machines have been commonly used as a solution to supplement ventilator capacity. Modern anaesthetic machines are capable of providing mechanical ventilation to patients with respiratory failure, however they are not ITU grade ventilators. For example, the use of anaesthetic machine as a long-term ventilator is considered as off-label use. Safe and effective use of anaesthetic machines as ventilators requires understanding the differences between anaesthetic machines and ITU ventilators and their limitations in mimicking ventilation strategies. Identifying the risks of using this equipment for long term is a priority in order to advise professionals on potential threat to patients' health and care.

The need to increase ITU capacity due to the pandemic forced, not only the use of anaesthetic machines as ITU ventilators, but also the necessity of managing them while in use by non-anaesthetically trained ITU staff and deployment of non-ITU trained staff to look after ITU patients. Potentially all those factors may have an impact on quality of care [2].

In order to meet the increased demand for ITU beds, many hospitals in the UK, and in particular the Royal Free Hospital in London, UK (RFH), adapted general care wards in order to make more intensive care beds available. The ward 2NA at RFH has been equipped with anaesthetic machines with a view to transfer there surge ventilated COVID -19 patients who are relatively stable. Patients have been looked after by either Anaesthetic or Intensive Care Consultants as well as ITU and non-ITU nurses and doctors and we hypothesize that this setting may have had an impact on patients' outcome.

Evidence around the use of anaesthetic machine for long-term ventilation and weaning of critically ill patients is scarce and this study aims to explore the clinical outcome of patients

in 2NA and capture the experience of staff using unfamiliar equipment and managing non typical cases in order to identify areas for improvement of care [3].

## **Methods**

### Aim

This observational study is set to evaluate the impact of using anaesthetic machines for ventilation of COVID-19 positive ITU patients admitted to the RFH 2NA ITU location. The clinical outcomes of patients and the experience of staff are explored.

### Design

This project consists of two steps: a quantitative, observational, cohort study to detect the effect of exposure to anaesthetic machine ventilation on the clinical outcome of COVID-19 patients; a qualitative component entailing interviewing professionals that manage patients in an unfamiliar environment (nurses and doctors).

The quantitative phase is also divided in two parts, a retrospective data collection of patients admitted to RFH ITU (and possibly the Barnet Hospital ITU) and connected to anaesthetic machines between the 1<sup>st</sup> April and 30<sup>th</sup> June 2020, and a prospective data collection of cases that occur between the 1<sup>st</sup> June and the 30<sup>th</sup> September 2020 in order to cover a new period of possible COVID-19 surge.

### Proposed study duration

From the 15<sup>th</sup> May to the 30<sup>th</sup> November 2020:

- 2 weeks to set up the study
- Data collection: 1<sup>st</sup> of June – 30<sup>th</sup> of October 2020
- One month for analysis and preparing reports for dissemination.

### Objectives

- Preparing the study protocol and related forms to be submitted to the RFH Ethic Committee and the Health research Authority (HRA).
- Screening for eligibility and enrolling patients admitted to 2NA from 1<sup>st</sup> April 2020, to the 30<sup>th</sup> September 2020.
- Collecting quantitative data related to the outcomes of interest (see below) and the core outcome set for ventilation trials retrospectively and prospectively [4].

- Interviewing consenting professionals that rotated in 2NA in the study period (3 to 5 nurses, 3 to 5 physiotherapists, 3 to 5 doctors trained in Intensive Care, and 3 to 5 doctors trained in Anaesthesia).
- Statistical and thematic analysis of data.
- Preparing report for the RFH Research and Development (R&D) Department, dissemination of study results to participants and appropriate stakeholders, preparing manuscript for publication into an Intensive Care/Anaesthetic journal.

### Eligibility Criteria

All anaesthetic machine ventilated COVID-19 patients admitted to RFH ward 2NA – we are exploring the possibility of broadening recruitment to the Barnet Hospital ITU.

Anaesthesia and ITU professionals who rotate in ward 2NA that consent to be interviewed.

### Primary Outcomes

- Proportion of ventilation weaning failure – defined either as lack of progress or need for ventilation on ITU grade ventilator
- Experience of ITU professionals in managing patients using anaesthetic machines
- Experience of Anaesthesia professionals in managing ITU patients

### Clinical Outcome measures (including but not limited to)

Failure to ventilate on anaesthetic machine: event of transferring a patient back on to ICU grade ventilator.

Duration of Weaning: a measurement of the time from reducing ventilator support until no support is required.

Duration of Ventilation: the start of ventilation until the first period of mechanical ventilation is complete.

Successful Extubation: an event recorded when the patient is free from an endo-tracheal tube at a specified time point.

Tracheostomy: event of requiring a tracheostomy.

Use of Non-Invasive Ventilation: following removal of the ET tube the patient requires further ventilatory support with non-invasive ventilation.

RASS: Richmond Agitation-Sedation Scale.

Length of ICU Stay: number of days spent in the Intensive Care Unit.

Length of Hospital Stay: number of days spent in hospital.

Mortality: the event of death.

The topic guide for interviews will focus on the experience of professionals in managing patients ventilated on the anaesthetic machine, any issue with ventilatory support and how was resolved, if managing unusual cases had an impact on professionals' performance and wellbeing.

### **Data Analysis**

Descriptive statistic to be used for the quantitative component; thematic analysis for the interviews.

### **Ethics**

Consent procedures – The R&D department at RFH has been contacted and this project needs to pass HRA approval in order to interview professionals. The deanonymized data collection of patients' data does not require ethical approval.

### **Impact**

Future trajectory of the study: dissemination of results and development of a guidance about the practice and risks of ventilating patients with anaesthetic machines and how to overcome ventilation issues. This will be especially of interest to Low- and Middle-Income countries where scarce resources may hinder the possibility of buying new ITU equipment not only in case of COVID\_19 but also in any future pandemic.

### **Provisional Budget**

**tot 4500£**

AW: 0.05FTE x 6 months (supervision of the study) – 1600£

AC: 0.10FTE x 6 months (monitoring and qualitative component) – 2000£

Research assistant for data collection: 0.15FTE x 5months – 1800£ - **this could be waved involving an ITU trainee**

Transcription of maximum 20 interviews x 45minutes – 900£

## References

1. Virus patients more likely to die may have ventilators taken away - <https://www.theguardian.com/society/2020/apr/01/ventilators-may-be-taken-from-stable-coronavirus-patients-for-healthier-ones-bma-says>
2. Covid-19 ventilator appeal 'pointless' without staff and other kit - <https://www.nursingtimes.net/news/coronavirus/covid-19-ventilator-appeal-pointless-without-staff-and-other-kit-16-03-2020/>
3. M A van Bokhoven, G Kok, T van der Weijden. Designing a quality improvement intervention: a systematic approach. Qual Saf Health Care 2003; 12:215–220
4. A Core Outcome Set for Critical Care Ventilation Trials <http://www.comet-initiative.org/studies/details/292>