AWAKE PRONE

Frequently Asked Questions

Data Collection

How do I answer the field on the baseline form 'date / time of first hypoxaemia'?

Please record the first time that pt required 40% oxygen for at least one hour.

Non-Invasive Respiratory Support Form: How do I complete the start / stop date?

For NIV, CPAP and HFNO, please record the date that the patient received each of these for the first and last time.

What is your definition of NIV ?

NIV is one type of non-invasive respiratory support, which we define as a non-invasive mode that delivers both an inspiratory and expiratory pressure. This may be called BIPAP in some hospitals.

What if I do not know the start / stop time of a period of proning?

If you do not know the exact time of either start or stop period of proning, please liaise with the patient or other members of staff to get your best estimate and enter that time. The form does allow blank fields, but it would be our preference to get pts best estimate

Post Day 5 Proning Form: If a patient in the proning arm gets intubated beyond the 5 days after randomisation, and they are proned while intubated, what 'date of the last proning'do we use on the CRF?

We are only interested in *awake* prone positioning, not prone positioning following intubation. Please use the date of last *awake* prone positioning.

Whilst randomising, how do I select the correct 'Care Setting' for the patient?

For the study we have split care setting up into 3 main types which are defined as:

- Critical care = A unit (intensive care unit/high dependency unit/combined unit) that delivers level two or three care.
- Respiratory support unit = A specialised respiratory unit that provides enhanced care and monitoring for patients with respiratory failure, beyond that expected for a routine ward environment. This likely includes the ability to deliver high-flow nasal oxygen, CPAP or non-invasive ventilation.
- Ward / Other = general acute care area, including acute medical units, respiratory wards and surgical wards, or any other care setting

What do I need to complete if a patient dies?

If a patient dies whilst in hospital and the event is not on the Exemption List or the Pre-Specified Complications List, complete the Serious Adverse Event Form immediately; this must be entered within 24 hours of being made aware of the event.

In addition, complete the Notification of Death Form immediately; this will ensure the CTU team do not send questionnaires out to the participant.

Complete the Critical Care Events Form and Ventilation Events Form within the Core part of the database.

When completing the 'Physiology and Non-Invasive Respiratory Support Prior to Intubation Form', do you classify NIV as any non-invasive-oxygen support – inclusive of nasal specs/venturi valve masks? When it also states end date of NIV would you like that to reflect the last date of NIV prior to invasive ventilation (where applicable) or the end date of nasal spec/venturi mask prior to CPAP?

By NIV, we mean non-invasive ventilation that delivers an inspiratory and expiratory pressure. So, this wouldn't include standard oxygen delivery systems, such as nasal cannulae and venturi systems.

When completing the 'Physiology and Non-Invasive Respiratory Support Prior to Intubation Form', when asked for 'end date of NIV', should this reflect the last date of NIV prior to invasive ventilation (where applicable), or the end date of nasal spec/venturi mask prior to CPAP?

For start and end date, we just want to know the date that it was first started and the date that the patient last received it. We know that patients may receive different strategies on the same day (e.g. CPAP and get HFNO for breaks). We are only interested in the period before intubation.

Follow Up

Who co-ordinates follow-up after critical care discharge?

Warwick CTU will co-ordinate all follow-up after critical care discharge. We will contact you for patients' survival status prior to sending out their follow up questionnaires. These questionnaires cannot be sent until survival status is confirmed so it is important you respond promptly to these survival status requests.