



Royal College
of Physicians

Management and care of tracheostomised patients with prolonged disorders of consciousness during the COVID-19 crisis

Supplementary guidance to the
Royal College of Physicians' national
clinical guidelines for prolonged
disorders of consciousness March 2020

Published April 2020

Setting higher standards



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disorders of consciousness March 2020

Supported by:



Prepared by the RCP Guideline Development Group:

Chair: Prof Lynne Turner-Stokes
Co-chairs: Prof Diane Playford, Prof Derick Wade
ENT UK representative: Mr Taran Tatla

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Introduction

This document provides supplemental guidance to the Royal College of Physicians' national clinical guidelines for prolonged disorders of consciousness (PDOC) published in March 2020.¹ It offers guidance for management of tracheostomised patients with PDOC during the COVID-19 crisis.

- > In many respects the principles are similar to those set out in the main guidance except that the unprecedented circumstances brought about by the COVID-19 pandemic mean that many clinicians are currently unable to provide all of the interventions that they would be able to in normal times.
- > This supplementary guidance is designed primarily for the target group of the main guidance, which includes adult patients (aged 16 and over) in PDOC lasting for more than 4 weeks following sudden onset acquired brain injury (ABI) of any cause. However, many of the principles may have wider application for other patients with profound brain injury who require tracheostomisation and who lack the capacity to make decisions regarding their own care and treatment.

Background to tracheostomisation in PDOC

A significant number of patients in PDOC require tracheostomisation. Some of these are short term and can be weaned off, but some are long term.

The tracheostomy may be required for one or more of the following purposes:

- > to reduce the dead space and thus the effort of breathing for those with reduced respiratory effort due to muscle weakness (tetraparesis) or central drive
- > to provide an alternative airway for patients with upper airway obstruction due to obstructive sleep apnoea, paralysed or adducted vocal cords, subglottic stenosis etc
- > to provide access for suction in those unable to cough sufficiently to clear their chest secretions
- > a cuffed tube provides some protection from aspiration of saliva / refluxed stomach contents in patients who are unable to swallow.

Tracheostomy weaning in this context typically involves a staged process that includes:

- > trials of cuff deflation and capping of the tube – typically with progressive downsizing and the introduction of non-fenestrated tubes, to gradually reduce reliance on the neck-breathing stoma
- > upper airway and stomal endoscopy to identify possible sources of obstruction and impediment to decannulation including stenosis, vocal cord paralysis, tracheomalacia or accumulation of tracheal granulation tissue.

Patency of the airway relies on having the right consistency of mucous secretions:

- > If secretions are too wet, they increase the risk of aspiration pneumonia. If they are too dry, mucous plugs can block off the airways causing desaturation.
- > Hyper-salivation due to autonomic dysregulation is a common feature of ABI, but can be reduced through medications such as anticholinergics (eg hyoscine or glycopyrronium) or injection of the salivary glands with botulinum toxin (BoNT-A) which dry up the secretions.
- > Conversely, mucolytics such as carbocysteine, acetyl cysteine or nebulisers can moisten secretions making them easier to suction.

Patients with tracheostomies typically rely on the correct balance of these interventions to modify the consistency of airway secretions. This can be a moving equation requiring regular review, and the consistency changes over time.

Tracheostomy and prognosis

Although some patients in PDOC will subsequently emerge into consciousness, sadly others will remain permanently in vegetative or minimally conscious state. The longer they remain in PDOC the less likely they are to emerge, and those who have been in PDOC for several months will inevitably have severe cognitive and physical disability – the majority requiring life-long care in a specialist nursing home.

Both being in PDOC and requirement for a tracheostomy tube are markers of very severe ABI and are often associated with other comorbidities.

- > In the early stages following ABI, patients who require a tracheostomy are often medically unstable for a variety of reasons, requiring hospitalisation.
- > In the chronic stage, patients may stabilise and can be managed in specialist nursing homes, but the continued requirement for tracheostomisation is a poor prognostic sign both for recovery and survival.
- > A 10-year retrospective cohort analysis of outcomes for tracheostomised patients admitted to one service is summarised in Appendix 1. The findings demonstrate that both being in PDOC and the continued requirement for a tracheostomy are associated with markedly reduced life expectancy – typically of just 2–3 years, in this pre-COVID study.

Treatment escalation planning: core principles

Treatment escalation planning in one form or another is now widely adopted as part of good clinical practice in advance care planning.² For example, the Resuscitation Council (UK)³ has introduced the ReSPECT process which emphasises the need for non-acute healthcare clinicians to help avoid inappropriate treatment by drawing up treatment escalation plans (TEPs) in advance to aid decision-making in an emergency.

The main Royal College of Physicians (RCP) PDOC guidelines highlight the poor outcomes from cardiopulmonary resuscitation (CPR) in patients who already have severe ABI, noting that CPR is rarely indicated in this group as even short periods of CPR are likely to result in worse brain injury. Similarly, escalation to the intensive care unit (ICU) / high-dependency unit (HDU) is unlikely to be effective for patients who already have very severe dependency and respiratory compromise.¹

The guidelines set out as follows the key principles of the decision-making process for patients who lack capacity to make decisions for themselves:¹

- 1 *It is the giving (rather than the withdrawal or not giving) of treatment that needs to be justified.*
- 2 *It is first up to the clinical team to decide which treatments may be clinically appropriate and thus on offer.*
 - *(If a treatment is not on offer, the team is under no obligation to provide it and there is no need to hold a best interests discussion, although the decision and the reasons for it should be explained to the patient's family).*

- 3 *For those treatments that are on offer, a best interests discussion should follow to determine whether the patient would wish to receive that treatment.*

The guidelines also emphasise the need to draw up TEPs from an early stage in the pathway and recommend that those decisions should be transferable across the different settings in the care pathway to avoid the need for repeated discussion. These decisions are not easy and discussion with family / close friends can be very difficult and distressing for all concerned:

- > Many families have high hopes and unrealistic expectations for recovery.
- > It can be hard for them to accept that these acute interventions are unlikely to be effective in severe ABI.

COVID-19, personal protective equipment and risk of transmission

Tracheostomy procedures (insertion, removal, changing or open suctioning) are aerosol generating procedures (AGPs), which pose a very significantly higher risk of transmission – both droplet- and air-borne. The current COVID-19 outbreak has highlighted the risk to healthcare workers who undertake AGPs on a regular basis – including those who care for tracheostomised patients. We know that exposure to high viral loads increases the risk of infection (and possibly the severity) and this is the rationale for having several levels of personal protective equipment (PPE) for different procedures, depending on the likely level or level of exposure.

COVID-19 is mainly transmitted through droplet infection, but air-borne transmission can occur in areas where AGPs are undertaken on a very frequent basis. Guidance from ENT UK⁴ recommends taking all reasonable steps to reduce the number of avoidable AGPs performed and to use the appropriate PPE at all times.

Public Health England has issued guidance for PPE to be worn by staff providing different levels of care.⁵ The guidance recommends that enhanced PPE (with long-sleeved gown, eye protection and filtering face-piece (FFP3) masks) should be worn in high-risk acute care areas, which include areas where AGPs are regularly performed – especially where there are ‘confirmed’ or ‘possible’ COVID-19 cases.

‘Possible COVID-19 cases’ are those in which there are new continuous cough or respiratory symptoms and/or fever. But these criteria may be confounded in PDOC and severe ABI:

- > Patients with tracheostomies are highly susceptible to respiratory infections of any kind and new respiratory symptoms are extremely common.
- > Patients with severe brain injury frequently also have temperature dysregulation.

The only way to determine whether or not these features are due to COVID-19 is through regular (and, if necessary, repeated) testing.

Unfortunately, there is a worldwide shortage of enhanced PPE (especially long-sleeved gowns and FFP3 masks) and the most recent guidance recommends ‘sessional’ (rather than ‘single’) use of these items for those working shifts in high-risk areas, to conserve supplies. This is not due to financial restrictions but to a shortfall in capacity to meet the sudden worldwide demand.

The Royal College of Nursing (RCN) has published advice to nurses to ensure their safety.⁶ The advice highlights the right of nursing staff to refuse to treat a patient if there is inadequate PPE, provided that they have followed the correct RCN guidance.⁷ This includes raising concerns through the appropriate channels and identifying ways to reduce the risk. Importantly, it emphasises that the refusal to treat is not just a matter of protecting the individual staff member's wellbeing but that, by becoming infected, they may spread the virus to other high-risk patients, including both those they are caring for and also potentially vulnerable members of their family.

The RCN recognises that the decision to refuse treatment would be extremely difficult for a nurse to take, and it is therefore essential that all members of the clinical team take active steps to reduce the risk to staff. One such step is appropriate treatment escalation planning to avoid providing high-risk interventions to patients who have little chance of benefitting from them.

These decisions cannot and should not be made on a 'blanket' level, but should take into account the individual circumstances of each patient. However, because many of the higher risk interventions must be delivered urgently when required, advance planning is essential. This should be led by the senior clinician responsible for the patient's care.

Difficult decisions

The current COVID-19 crisis introduces many constraints that limit our ability to deliver previously accepted best practice on the ground. These include:

- > **Staff availability** – due to a combination of infection, self-isolation and understandable fear of becoming infected, nearly all areas of NHS practice are experiencing substantially reduced staffing levels. Re-deployment of staff to prioritised COVID-19 areas has caused further depletion and current nursing and medical staff availability is reduced by 30% or more in some areas.
- > **Shortages of PPE** are well documented. Despite the strenuous efforts being made by the government and manufacturers to ensure adequate supplies, items of enhanced PPE (especially gowns and visors) are internationally in short supply.
- > **Other facilities** – other essential facilities and practical resources on the ground, ranging from basic equipment to specialist ear, nose and throat (ENT) procedures, have been suspended or limited in the rush to support the anticipated requirements for intensive care, leaving services depleted to an extent that we have not experienced in the last 20–30 years.

In the face of these global shortages, difficult decisions may be required when balancing the needs of tracheostomised patients in PDOC with the risks to others. This is by no means unique to this population. Some of the more general ethical issues are set out and discussed in guidance from the British Medical Association.⁸

Where resources fall short of those required to manage patients safely (especially those with proven or suspected COVID-19), difficult decisions may be required to balance the benefits and risks of interventions, taking into account both the patient's prognosis and the risk of infecting staff and the associated consequences for both them and other patients.

This may involve taking a decision not to offer further active treatment/intervention that may potentially mean that the patient does not survive. These are among the most

challenging decisions that any doctor or clinician could be faced with. It is critically important that such decisions should not be left to nurses or junior staff on the ground, but should be made promptly by the senior clinician in charge of the patient's care, with the involvement of at least one other consultant physician – ideally one with experience of PDOC and prognostication of severe ABI.

Before taking such a significant decision, however, the senior clinician should first ensure that they have done everything they reasonably can to resolve the problem. In particular:

- > the various possible options to avoid or minimise risk to an acceptable level – the identified risks should have been considered
- > they should have escalated it within their trust/organisation so that the senior management team is fully aware of the issue and has had the opportunity to address it. Trusts and service managers have a responsibility to ensure the safety of their staff as a critical NHS resource for the care of all patients, and to support the senior clinicians in these difficult decisions when the need arises.

Finally, the senior clinician should document carefully the rationale for their decision including:

- > the prevailing circumstances at the time
- > any steps taken to mitigate the identified risk
- > who else they consulted or discussed the issue with
- > the actions put in place to manage any consequences.

Treatment escalation planning in the context of COVID-19

Both the Resuscitation Council (UK)⁹ and the National Institute for Health and Care Excellence (NICE)^{10, 11} have produced updated guidance in the context of COVID-19.

- > The Resuscitation Council (UK) highlights that CPR is an AGP and the need for staff to don PPE may delay the initiation of full CPR, making it less effective.
- > The NICE guidance notes that, while the Clinical Frailty Scale may not be appropriate in patients under 65 years, it is nevertheless important to consider the patient's underlying condition and their likely ability to benefit from escalation to intensive or high-dependency care settings.

Both of these are important considerations for tracheostomised patients with severe ABI who already have a greatly reduced life expectancy, despite their usually young age.¹²

Decisions on whether or not to offer treatment must now take account not only of the possible benefits/risks to the patient him/herself, but also of the risks to staff of administering them becoming infected and the associated consequences as described above.¹³ In some circumstances, they may fall into the category of 'difficult decisions' where the clinical team is aware that they are not able to offer previously accepted best practice, requiring the additional steps set out above. In all cases, however:

- > Given the constraints on delivery of effective CPR, the poor outcome and the risks to staff, it is once again important to emphasise that CPR is rarely appropriate for patients in PDOC.¹
- > Similarly, escalation to the ICU/HDU is unlikely to be effective for this group of patients.¹

Patients with tracheostomies are more vulnerable to respiratory infection of any kind, and COVID-19 is now prevalent in all acute hospitals with risk of cross infection. For those in specialist nursing home (SNH) settings, GPs should consider carefully what purpose an emergency transfer to hospital would serve for tracheostomised patients in PDOC:

- > If they are COVID-19-negative, they may well contract the disease in hospital and thus be in a worse position.
- > If they are COVID-19-positive, hospitalisation will usually offer little benefit as they are unlikely to be candidates for the ICU or HDU.

TEPs for tracheostomised patients with PDOC in SNHs would typically therefore recommend nursing home-based treatment only – which may for example include antibiotics administered per percutaneous endoscopic gastrostomy (PEG).

But, whatever the setting, where the ceiling of treatment stops short of more active intervention, it is essential that forward planning encompasses arrangements for prompt and effective palliative care, should this be needed.

Care of tracheostomised ABI patients in different settings

Outside of the immediate acute care setting, tracheostomised patients with PDOC are likely to be concentrated in two main settings: hyper-acute / level 1a specialist inpatient rehabilitation services and SNHs.

The following key recommendations are designed to optimise individual patient care, reducing their risk of becoming infected and to minimise the risks to staff who care for this group of patients, and the risks of transmission between patients and staff and onwards to other patients. They apply to both inpatient and SNH settings.

Key recommendations

1 Personal protective equipment

- 1 All staff providing hands-on care of tracheostomised patients and entering high-risk clinical areas must have access to the appropriate enhanced PPE and be properly mask-fitted and trained in its use including donning and doffing.
 - 2 The measures described below will also help to reduce unnecessary use of PPE and thus conserve supplies.
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2 Minimising unnecessary AGPs

- 1 Every effort should be made to minimise the number of avoidable AGPs undertaken through:
 - a adjustment of medication to reduce secretion load and minimise the frequency of suction
 - b removal of tracheostomy tubes wherever possible and safe
 - c avoiding unnecessary tracheostomy-related interventions
 - i changing tracheostomy tubes only when clinically indicated
 - ii no staged weaning programmes such as cuff deflation, capping, downsizing etc
 - iii all cuffed tracheostomies to be managed with cuff permanently inflated.
-

3 Minimising traffic and staff changes through high-risk clinical areas

- 1 The number of staff going in and out of high-risk areas for routine care should be minimised, eg by:
 - a reducing rotation of nursing staff, so that the smallest number of different nurses work in the high-risk area per shift
 - b reducing the different therapy staff involved to one to two members of the team, working in transdisciplinary roles in a single session per day
 - c routine medical reviews conducted by one doctor only seeing all the patients in the area in one session
 - d so far as possible, avoid taking equipment in and out of high-risk areas – and where this is unavoidable, ensure that equipment is properly cleaned.
-

4 Testing and pre-screening for suspected COVID-19

- 1 Tracheostomised patients are vulnerable to COVID-19 and every reasonable effort should be made to avoid mixing COVID-19-positive and -negative patients in the one high-risk area.
 - a If a patient develops a temperature or new respiratory symptoms, a sputum sample should be sent for testing – both from them and from the other tracheostomised patients in the same shared care area (eg multi-bedded bay).
 - b New patients being admitted should be tested before being brought into the area, either by pre-screening in the referring hospital or in an isolated area (eg a single bay, if available) on arrival.
-

5 Gender segregation

- 1 While every effort is made not to mix genders within one clinical area, during the COVID-19 crisis, segregation of positive and negative patients may have to take precedence over gender segregation at this time.
-

6 Treatment escalation planning (TEP)

- 1 Every tracheostomised patient with PDOC should have an individually written TEP which should take account of the following:
 - a Given the constraints on CPR, the poor outcome and the risks to staff and others, CPR is rarely appropriate in this context.
 - b Escalation to an ICU/HDU is unlikely to be effective or appropriate.
 - 2 Where a decision is made that these treatments would not be on offer, the senior clinician in charge of the patients should explain the reasons for this to the family and inform them that this is a clinical decision.
 - a At the same time, they should discuss those treatments that are or may be on offer and ascertain whether the patient might wish to receive those.
 - b Once a TEP is in place and the family has been informed, the plan should carry over between different care settings.
 - c As hospitalisation is likely to result in more risk than benefit to this group of patients who are resident in specialist nursing homes, TEPs would typically recommend nursing home-based treatment only.
 - 3 However, where the ceiling of treatment stops short of more active intervention forward planning must encompass arrangements for prompt and effective palliative care, should this be needed.
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7 Implementation

- 1 A senior manager should review all wards managing tracheostomised patients on a daily basis to ensure that there are sufficient staff and stocks of enhanced PPE to manage the caseload – any shortfall should be reported and escalated promptly on every day that this occurs.
- 2 Tracheostomised patients should be reviewed by the senior clinician in charge of the patient's care (a consultant in hospital or their GP in a nursing home) to ensure that the appropriate measures are in place to:
 - a minimise avoidable AGPs
 - b confirm that each patient has an appropriate and up-to-date TEP.

8 Difficult decisions

- 1 Where resources on the ground fall short of those required to manage patients safely, difficult decisions may be required to balance the benefits of continued AGP interventions to the patient, taking into account both the patient's prognosis and the risk of infecting staff, and the associated consequences for both them and other patients.
 - a These decisions should not be left to nurses or junior staff on the ground but should be made promptly by the senior clinician in charge of the patient's care, ideally with a second clinician with experience of PDOC.
- 2 Before making a decision that further AGPs are not to be offered, the senior clinician should first ensure that they have:
 - a done everything they reasonably can to resolve the problem (such as borrowing PPE/staff from another area), and
 - b escalated the issue within their trust/organisation so that the senior management team is fully aware of the issue and has had the opportunity to address it
 - c considered any possible options to avoid or minimise the identified risks to an acceptable level.
- 3 If a decision is made that further AGPs are not to be offered, the senior clinician should:
 - a explain this to the patient's family, including explaining if and how any concerns for the safety of staff and other patients impacted on the decision
 - b ensure that appropriate alternative management is in place to ensure the patient is kept comfortable, including palliative care if necessary.
- 4 Importantly they should document carefully the rationale for their decision including:
 - a the issue(s) at hand
 - b the prevailing circumstances at the time
 - c the steps they took (or attempted to take) to mitigate the risks
 - d who else they consulted or discussed the solution with
 - e the actions put in place to manage any consequences following the decision, including any arrangements for palliative care symptom management.
- 5 Trusts and service managers must be aware of their responsibilities to ensure the safety of their staff as a critical NHS resource for the care of all patients, and to support the senior clinicians in these difficult decisions when the need arises.

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Appendix 1. 10-year cohort analysis of tracheostomised patients presenting to a tertiary specialist rehabilitation unit between April 2010 and March 2020 (pre-COVID-19)

In this retrospective cohort analysis for data from the UK Rehabilitation Outcomes Collaborative (UKROC) database, we examined the characteristics and outcomes for tracheostomised patients admitted to a single unit during the 10-year period between April 2010 and March 2020.

- > Patients who had a tracheostomy on admission and/or discharge were identified through the 'Tracheostomy' item of the Northwick Park Nursing Dependency Scale (NPDS).
- > Patients in PDOC were identified from the unit's clinical PDOC assessment database.

During the 10-year period, a total of 250 tracheostomised patients were admitted to the regional hyper-acute rehabilitation unit (RHRU). The demographics of this population were as follows:

- > Mean age – 44 years; males 64%, females, 36%
- > Aetiology – traumatic brain injury (BI) 32%, anoxic BI 30%, cerebral vascular accident (CVA) 25%, other 13%
- > Mean length of stay – 105 days.

Of these 250, 145 (58%) were successfully weaned during admission but 105 patients (42%) could not be weaned.

- > 19 (18%) of these died on the unit or very soon after discharge (within 28 days).
- > A further 12% were transferred to an acute hospital due to intercurrent illness.
- > Two-thirds (66%) were discharged to an SNH and just 3% went home.

Longer-term survival

Of those 105 patients still requiring a tracheostomy on discharge, by the time of this extraction (March 2020), 61 (58%) had died and the median survival time to that date was 24.3 months (interquartile range (IQR) 6.9–43), compared with 40.9 (IQR 17.3–70.5) for those who had been weaned.*

Patients in PDOC

Of the 250 patients with a tracheostomy on admission, 172 (69%) were in PDOC of whom 136 (79%) remained in PDOC on discharge and 74 (54%) of these still required a tracheostomy. In this subgroup the death rate was somewhat higher:

- > they accounted for 16 (84%) of the deaths on the unit or within 28 days of discharge
- > by April 2020, the median survival time was just 16.5 months (IQR 6.3–41.7).

In summary

Both being in PDOC and having a tracheostomy are strong predictors of non-survival, independent of age. Being in PDOC is the stronger indicator of the two, but tracheostomy in itself carries a high risk of mortality. These high rates of mortality should be taken into account when making treatment decisions for these individuals.

* NB it should be noted that this is the median survival time to the date of extraction, not the ultimate median survival time until death.

Royal College of Physicians
11 St Andrews Place
Regent's Park
London NW1 4LE

www.rcplondon.ac.uk



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