Allocation and withdrawal of organ support and/or treatments during COVID-19 pandemic

Overview

According to our current understanding of the COVID-19 pandemic, with sufficient adherence to hygiene and social distancing measures and sufficient COVID-19 testing, contact tracing and isolation, Devon is unlikely to experience the scenario where there is a shortage of mechanical ventilation. Although the likelihood of such a shortage is low, it is ethically and legally important to prepare for such difficult decision-making.

Where resources of any kind for seriously ill patients become constrained, we should maximise consistency between healthcare providers and across regions using local and regional escalation status and protocols. Mechanical ventilation is the key example used in this document. However, consideration of insufficient resources may occur in other settings. For example, in primary care, in deciding when and whether a deteriorating patient might benefit from hospital assessment and treatment.

Importantly, all patients who would normally be considered for treatment outside of the current COVID-19 crisis remain eligible for treatment. However, if there is scarcity of healthcare resource, treatment decisions would need to be based on more utilitarian principles than in normal times in order to provide the greatest medical benefit for the greatest number of people.

Although it is an unlikely scenario, lawfully withholding or withdrawing treatment could be required if the healthcare system were to be completely overwhelmed, and where local and regional coordination of resources still proves insufficient to meet the needs of seriously ill patients.

This would represent an additional consideration, on top of the more usual clinical focus on doing what is in an individual patient's best interest, because of the need to take account of the interests of the wider population of patients.

Doing so will be stressful. Crucially, there must be real-time support for teams making these challenging decisions with patients and their families, as well as ongoing services for the emotional wellbeing of the staff involved.

Discrimination in treatment decisions based on irrelevant characteristics is unacceptable and may be unlawful. Best use of resources, such as ventilators, is a relevant consideration. 'Best use' in this context means maximising the prospects of a positive outcome based upon an individual assessment of the patients concerned and their capacity to benefit from clinical intervention. This applies equally to patients who do and do not have COVID-19.

Factors to consider include: likelihood of recovery, likely length of time to make that recovery and, of the greatest importance, the capacity of a patient to recover to a quality of life which is acceptable to them.

These considerations are not limited just to the commencement of interventions. In exceptional circumstances, the withdrawal of life-sustaining treatment may be necessary in order to maximise the beneficial treatment outcomes for the population as a whole. These difficult decisions need sensitivity, compassion, clarity, consistency, oversight and support.

For clinical teams making these challenging decisions, timely ethics support will be made available via local clinical ethics groups. Local hospitals will define and communicate how that support can be accessed. Any clinician, patient or patient's recognised representative can query treatment decisions and withdrawal of treatment decisions and seek wider ethical input. Where they wish, if

ethical issues are not reconciled locally, an organisation may seek advice from the Devon Ethical Reference Group.

This document:

- Provides principles for allocation and withdrawal of treatment.
- Provides patient-specific considerations for assessment and review of patients receiving organ support.
- Sets out that decisions based on scarcity must be informed by the treatment resources feasibly available in the wider health and care system, not just within an individual organisation.
- Reinforces that the capacity for a patient to benefit from clinical intervention must be individually assessed.

Principles for system-wide clinical best practice

1. Best practices are gathered here for the sake of promoting consistency, fairness and openness for all seriously ill patients, not just those with COVID-19.

2. It is taken as a given that many or all of the practices included here will already be current, compassionate clinical practice.

3. Essentially, i) do your best; ii) treat people fairly; iii) there will be ethical help available; iv) keep excellent contemporaneous notes; v) notice when you or your colleagues may need help and ask for that help; iv) appropriate emotional support will be made available for healthcare workers and those involved in triage/decision-making processes.

Clarity about age and/or disability in this guidance

1. The Devon system endorses and adopts the following statements from the British Medical Association and the Intensive Care Society:

2. *"Under our guidance, the fact that someone is above a particular age, or that they have a pre-existing medical condition is not, in itself, a factor that should be used to determine access to intensive treatment. Similarly, someone with a disability should not have that disability used by itself as a reason to withhold treatments, unless it is associated with worse outcomes and a lower chance of survival. A decision to exclude from treatment everyone above a particular age, or with a disability, would be both unacceptable and illegal."* (British Medical Association, 2020).[1]

3. *"It is recognised that a factual assessment of likely benefit may take into account age, frailty and comorbidities, but the guidance emphasises that every assessment must be individualised on a balanced, case by case, basis and may inform clinical judgement but not replace it. The effects of a comorbidity on someone's ability to benefit from critical care should be individually assessed. Measures of frailty should be used with care and should not disadvantage those with stable disability."* (Intensive Care Society et al., 2020)[2]

[1] British Medical Association (April 2020). *Statement/briefing about the use of age and/or disability in our guidance*. Retrieved 4 May 2020.

[2] Intensive Care Society (May 2020). *Clinical Guidance: assessing whether COVID-19 patients will benefit from critical care, and an objective approach to capacity challenges*. Guidance endorsed by the Royal College of Physcians (London), Scottish Intensive Care Society, Welsh Intensive Care Society, All-Wales Trauma and Critical Care Network and the National Critical Care Networks of England. Retrieved 6 May 2020.

4. Further, although the BMA and ICS statements and this DERG guidance take as their key context the availability of intensive organ support, the same non-discriminatory ethical and legal principles apply to any treatments for seriously ill patients.

Allocation and withdrawal decisions

5. Crucially, ventilation, staffing and other resources for Devon's seriously ill patients must be considered on a system-wide basis. Organ support or treatment should not be restricted or withheld in one hospital where it can feasibly be accessed in another, including outside of Devon using regional co-ordination mechanisms set up for the pandemic.

6. For this reason, hospitals must make known to the staff involved the processes and triggers for accessing resources outside of their own institution.

7. Where resources are sufficient, usual clinical decision-making practices remain in place.

8. Where resources are insufficient for the number of patients, inappropriate continuation of support for a patient who is unlikely to survive their stay may have the effect of denying necessary support to other patients.

9. The duration of ventilation for an individual patient must not be too brief. It should remain in line with what is reasonably known at the time about the natural history of the patient's condition. This remains the same whether their condition is COVID-19 or another pathology.

10. Where resources are insufficient to meet demand, it is best practice to seek multiple, senior clinical views in deciding on the allocation or withdrawal of treatment and for this to include clinicians not involved in the direct care of those patients. Local organisations should put in place a system enabling timely access to ethical opinion.

11. Where possible, it is desirable to create a separate triage team. This is intended to enhance objectivity, avoid conflicts of commitment and minimise the moral distress of the clinicians providing treatment. This does not preclude clinicians involved in the patient's care being part of those triage discussions: it is important for all involved that a clear understanding of the patient's condition, prognosis and wishes are reliably conveyed.

12. The ethical and legal principles around decisions to withdraw organ support are the same as the same as those relating to the withholding of support.

13. Thresholds for admission to ICU or withdrawal of support may have to change over the course of the pandemic if the shortfall between supply of resources and demand varies. Under extreme pressure, requiring triage, the focus will become that of delivering the greatest medical benefit to the greatest number of people.

14. There must be no categorical exclusion criteria (such as age). Capacity to benefit remains the key consideration in the scenario where the availability of a treatment or of organ support is insufficient for the number of patients.

15. Where restriction of ICU access takes place, it could be the case that a patient predicted to benefit from only a short stay on ICU should be taken ahead of a patient predicted to require organ support for many days or weeks.

16. Such decisions, may be finely balanced clinically and ethically. There may be more than one interpretation of the facts. In the event of such a decision having to be made, the principles of

good decision-making must be upheld, with no decision falling to a single individual, all decisions being rational and evidence based, and their rationale being transparent and recorded.

17. Records regarding treatment choices and the allocation, review and discontinuation of critical care must be kept and form part of the patient's clinical record. This will include the decision made, parameters considered in the decision (including any influence of the lack of resources) and communication with the patient and family. Hospital ethics groups and committees must record their decisions also.

Patient specific considerations

18. Hospital survival is not the only outcome measure to be considered – longer-term survival and change in quality of life may be more meaningful and more important to the patient and family.

19. A decision not to provide organ support, eg invasive ventilation, does not mean that other less invasive support (eg CPAP) should not be used for the patient. Such a ceiling of support, if appropriate, should be included in the patient's escalation plan.

20. Ventilation and other organ support can be prolonged and distressing and should not be undertaken without due consideration of the likely benefit or harm to the patient. It should not be undertaken if it is only likely to delay death for a short period, rather than enable recovery.

21. While there must be no blanket exclusions of patients based upon their characteristics, on a case-by-case basis, it is relevant to consider whether the patient's comorbidities affect their capacity to benefit from treatment or organ support. Comorbidities may impact both the chances of surviving the acute illness in the short term and the likelihood of recovery to a quality of life which is acceptable to the patient.

22. No single scoring system of acute physiological disturbance or chronic health conditions/frailty is recommended as a stand-alone tool for decision-making in individual patients as none are validated for an individual's prediction of outcome, but they can be useful to inform clinical judgements.

23. It may be appropriate to make reasonable adjustments to the way that assessments are undertaken for patients with disabilities. For example, that could include permitting a learning disabled patient or a patient with a serious mental health condition to be accompanied by a carer even if additional persons are generally not permitted as part of social isolating or infection control rules.

Support to patients and families

24. The particular circumstances of COVID-19 may mean that if mechanical ventilation does not lead to recovery for a patient there may be less time to ready a family for the withdrawal of that support.

25. When first discussing the use of mechanical ventilation with patients and families, it is necessary as good practice to talk through the patient's treatment plan, including that ventilator use will not be open-ended and may need to be brought to an end.

26. Patient views must be sought and taken into account. The expected effects and burden of ICU support will form part of that discussion. If the patient lacks capacity, the patient's family should be consulted about what they believe the patient would want to happen. Organisations' ordinary legal duties in respect of patients who lack capacity apply.

27. There is an expectation that all patients admitted to hospital will have an escalation plan discussed and documented as near as possible to the time of admission.

28. The continuation of ventilation should be informed by regular review of each ICU patient.

29. Patients and their families should be made aware where resource limitations may cause treatment standards to deviate from the normal standard of practice.

30. If ventilation is discontinued, expert comprehensive palliative care is imperative.

31. Providing comfort at the end of life when patients may be in isolation is of course difficult. Wherever possible, and where Personal Protective Equipment (PPE) stocks allow, family members of patients near death should be granted compassionate use of PPE so that they can be with the dying patient if they wish.

32. Where this is not possible, families should be permitted and helped to use video conferencing technologies in ways that do not compromise the duties of confidentiality and dignity in respect of other co-located patients. While the patient's condition may not allow interaction, the family may be helped by being virtually at the patient's bedside. This choice should be discussed in advance as part of treatment planning.

Disagreements with treatment

33. A patient or their close family may disagree with a treatment decision.

34. A clinician may disagree with a treatment decision.

35. In this circumstance, a discussion allowing all clinical staff involved in the care of the patient (at least two senior clinicians) should be convened by or on behalf of the Medical Director of the relevant organisation. The aim will be to reach a mutually acceptable solution. Ultimately, the Medical Director will hold responsibility for the decision reached. The clinicians will likely be a combination of consultants from the relevant specialties, all professional groups, nursing and ICU. It is assumed that the Medical Director or their representative would not be involved in the patient's direct care.

36. If disagreement persists, the hospital's own ethics infrastructure shall provide for an escalation to the local organisation's ethics committee for advice. The Devon Ethical Reference Group (DERG) is available should an organisational ethics committee wish to invite a further perspective. The DERG's contact details are Devonstp.ethics@nhs.net or 01392 675124.

37. In the case of unresolved disagreement with patient or family, the Medical Director should follow the Trust's process for accessing advice from the Trust's lawyers. Any member of clinical staff should have the right to challenge formally the decision of the Trust. There should be a route to do so through the Trust's policies and procedures.

38. While the withholding or withdrawal of treatment can be lawful, as described in this guidance, individual clinicians should have the right to legal advice separate to the Trust through their own medical indemnity organisation.

Key Sources:

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Royal Devon & Exeter Foundation Trust (21 April 2020). *Guidelines for the escalation and provision of support for critically ill patients during the COVID-19 pandemic.* Unpublished draft.

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White, D.B. (27 March 2020). *A framework for rationing ventilators and critical care beds during the COVID-19 pandemic*. JAMA. doi:10.1001/jama.2020.5046

World Health Organization (2016). *Guidance for managing ethical issues in infectious disease outbreaks*. Retrieved 31 March 2020.

Appendix 1:

Treatment allocation and withdrawal at times of scarce availability