A. Service Specifications

<table>
<thead>
<tr>
<th>Service Specification No.</th>
<th>A14/S/02</th>
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<tbody>
<tr>
<td>Service</td>
<td>Respiratory: Weaning from prolonged mechanical ventilation (Adult)</td>
</tr>
<tr>
<td>Commissioner Lead</td>
<td>Kathy Blacker</td>
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<tr>
<td>Period</td>
<td>12 months</td>
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<td>Date of Review</td>
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1. Population Needs

1.1 National/local context and evidence base

Context

Prevalence of Weaning Failure in UK critical care

- The majority of patients treated within critical care achieve liberation from invasive mechanical ventilation (IMV) without difficulty; weaning (the process of withdrawing invasive ventilatory support) is usually achieved within a matter of days.¹
- However, 5-10% of critical care patients fail to wean from IMV within 3 weeks.²
- Such patients experience higher mortality and occupy a disproportionate number of critical care beds, leading to increased health care costs.
- Patients who require prolonged IMV account for up to 40% total critical care expenditure.³,⁴
- Real-life UK data confirms the importance of weaning failure; the North East & Cumbria Critical Care Network surveyed the incidence of weaning problems. Over a period of one year, a weekly telephone survey identified that 12% of all ICU patients required more than 28 days of respiratory support.

Patient demographics

- Advances in critical care have led to an increasing proportion of patients who survive critical illness. Such advances also widen the boundaries in which successful outcomes may be achieved; hence, increasingly frail patients may access and benefit from critical care.
- Although critical care outcomes have improved, there are an increasing number of patients with ‘chronic critical illness,’ in which life-sustaining organ support...
continues to be required following resolution of the acute process.\textsuperscript{5}

- Invasive ventilation, typically via tracheostomy, is a key aspect of chronic critical illness.
- Weaning problems are more likely in patients with chronic conditions that affect breathing, such as Chronic Obstructive Pulmonary Disease (COPD) and neuromuscular disorders.\textsuperscript{6}
- Weaning failure may also occur in any patient who survives a prolonged period of severe multi-organ failure. Critical care-related neuropathy and muscle weakness are common in such circumstances and may contribute to a significant loss of respiratory muscle function.\textsuperscript{7}

**Role of the Specialised Weaning Unit**

For patients who continue to require prolonged IMV after resolution of the acute pathology, management options within UK NHS care include continuation of care within the existing critical care or to organise transfer to a specialised weaning unit.

- A European Respiratory Society Consensus statement \textsuperscript{8} summarises the role of the specialised weaning unit, in comparison to continued critical care. It states;
  - ‘Acute care units probably lack the necessary focus, personnel and organisational structure to care for patients with prolonged weaning failure.
  - In contrast, specialised weaning units offer specialised teams (e.g. nurses, physiologists, respiratory therapists, nutritionists, etc.) and an appropriate “bridge to home” environment for such patients and their families (e.g. privacy, daytime activity, longer visiting hours and undisturbed sleep).
  - They also relieve pressure on scarce ICU beds.’\textsuperscript{8}

- Patients who continue to require additional organ support (e.g. renal replacement therapy) cannot be managed safely out of the critical care environment.
- An NHS Modernisation Agency point prevalence survey of critical care facilities in England (2002) recommended the creation of specialist weaning units to manage critical care patients who require prolonged IMV.\textsuperscript{9}
- At the time of the point prevalence survey, few patients meeting criteria for transfer to a specialist weaning service were actually transferred.
- Current data are limited, although it appears likely that only a minority of patients who have required prolonged IMV are transferred to a specialised weaning service.
- Published UK data support the role of the specialised weaning unit as a model of care. Data from the Papworth RSSC (Cambridge)\textsuperscript{10-12} and Lane Fox (London) units\textsuperscript{13,14} show low hospital mortality rates (9-15%) and that a high proportion of patients achieve discharge home (75%, Papworth RSSC). These data compare favourably to a meta-analysis of 124 international studies, which demonstrated 46% hospital mortality and 22% discharge home.\textsuperscript{15}
- Expertise in the use of non-invasive ventilation (NIV) is an important factor in the successful management of patients who experience weaning failure. As described above, chronic neuromuscular and respiratory problems (such as COPD) are common in patients who require prolonged IMV. For such patients, long-term
nocturnal NIV may represent the maximum level of weaning that is possible.

- Papworth and Lane Fox data show that 25-45% of patients transferred for weaning continue to require nocturnal NIV after decannulation. For some patients, long-term NIV is associated with a survival benefit.
- Use of NIV has been shown to be important in the weaning process itself. Its use requires specific expertise.
- Existing UK specialised weaning units also serve as regional complex home ventilation services (i.e. same staff and unit infrastructure to deliver both services). The skills and service infrastructure required for each aspect of the overall service are essentially the same. However, such skills are not necessarily available in a non-specialised critical care setting.
- Transfer to a specialised weaning centre may increase the travel times for the visiting families of the patients concerned. Average weaning unit length of stay is 19-27 days.

National Drivers

- **Bed Occupancy**: Patients with single-organ respiratory failure experience prolonged critical care stays. As such, they account for a significant proportion of bed occupancy. This may result in increasing bed pressures for acute admissions and cancelled major elective surgery.

- **Bed Provision**: There are fewer UK critical care beds than for any other developed nation (5 times fewer than Germany). Reducing occupancy via transfer to weaning services should increase access to critical care.

- **New Standards of Care**: New Core Standards for Critical Care services have been published by the Intensive Care Society in partnership with the Faculty of Intensive Care Medicine state the following (standard 2.15):
  - “Level 3 units should have access to a Regional Home Ventilation and weaning unit.”
  - “Arrangements should be in place to collaboratively manage patients with weaning difficulties and failure, including the transfer of some patients with complex weaning problems to the Regional centre.”

- **Complexity of long-term care**: Patients may be discharged from hospital with inappropriately complex ventilatory care packages, such as continued IMV via tracheostomy when decannulation to NIV was feasible. This results in unnecessarily cumbersome and expensive home care services. Reducing the proportion of patients who require long-term ventilation via tracheostomy would be expected to reduce overall healthcare costs.

Cost effectiveness

- Based on existing literature that included cost-analysis, it has been calculated that the cost of stay in critical care is almost double the cost in a weaning centre.
Overall cost is of course dependent upon length of stay and there are no data to inform the comparison between transfer to a specialised weaning unit and continued management within critical care. The reduced weaning unit costs arise from the lower staffing ratio.

References

1. Kramer and Zimmerman BMC Medical Informatics and Decision Making 2010, 10:27
2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

<table>
<thead>
<tr>
<th>Domain</th>
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<td>Domain 1</td>
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The following data be collected annually to monitor clinical outcomes:

**Weaning: Domain 2,3,4**

- Critical care length of stay (total, plus waiting time from weaning unit acceptance).
- Weaning outcomes (needs to be adjusted for case mix) - Hospital mortality percentage, percentage of patients ultimately discharged to their own home (from weaning unit and ultimate discharge location).
- Weaning rates - fully weaned, NIV overnight, tracheostomy ventilation and death.
- Weaning unit length of stay during index weaning episode.

3. Scope
3.1 Aims and objectives of service

**Aim**

- To commission an adult Respiratory Specialist Weaning Service to meet the needs of patients who fail to wean from invasive ventilation in whom transfer to a Specialised Weaning Unit is clinically appropriate.

- To improve the life expectancy and quality of life for this selected patient group.

- To improve critical care throughput, improving access to level 3 care to other patients who require this.

**Objectives**

The Specialist Weaning Service will deliver these aims by:

- Ensuring equitable access to appropriate highly specialist, integrated multi-disciplinary care.

- Providing clinical support to critical care units within their network to ensure appropriate access to those who require transfer to, or advice from, the specialist weaning unit.

- Addressing any outstanding aspects of the patient’s care that may affect safe discharge to the community, such as gastrostomy feeding tube insertion, appropriate secretion clearance (e.g. cough assist device) and tracheostomy tube management (in those patients who continue to require invasive ventilation).

- Maximising the possibility of patients being able to live in their own homes on the most appropriate and least invasive mode of ventilatory support with the maximum amount of time possible each day spent breathing spontaneously. This will be achieved by transitioning the patient to the collocated Complex Home Ventilation Service (i.e. Specialist Weaning Services will also provide home ventilation care to patients who require this following exit from the weaning service).

- Ensuring cost effective use of expensive resources, ideally also demonstrating an improvement in network critical care capacity.

3.2 Service description/care pathway

The service is commissioned to provide Specialist Weaning support to patients within critical care who remain in single organ (respiratory) failure (prolonged IMV) once the acute pathology has resolved.

Where appropriate, patients will be tracheostomised.
Specialist Weaning services will provide advice to critical care units within their region in the care of difficult-to-wean patients. This may include outreach assessment according to agreed local network pathways.

Currently, there is considerable variability in the provision of weaning services. It is expected that weaning centres will work closely with their commissioners and area critical care network to develop weaning services. Each Critical Care Operational Delivery Network should ensure patient pathways are identified from each local critical care unit into a weaning centre.

Sharing protocols, plus benchmarking data between centres, should be a key objective as services emerge and evolve.

The care pathway encompasses;

**Patient identification**

Optimal clinical and cost-effectiveness of the Specialised Weaning Service relies upon appropriate patient selection. Duration of IMV and individual patient factors can be combined to identify those patients most likely to benefit and the timeframes for transfer;

1. **Duration of IMV**
   - Discussion with the weaning service should be considered for patients who require IMV alone (no other organ support) for 2 weeks or more and transfer should be considered after 3 weeks. To ensure relative clinical stability, patients should not have required other organ support in the week prior to transfer.

2. **Patient Factors**
   - Whilst IMV duration is a simple measure, it fails to identify patients who would benefit from transfer at an earlier stage.
   - Prompt early referral for consideration of long term ventilatory support should be considered for patients with comorbidities that are anticipated to result in weaning difficulties.
   - These include patients with neuromuscular disorders (such as motor neurone disease) and patients with known respiratory comorbidity (e.g. patients with COPD who fail to extubate rapidly to NIV).
   - A need for continued IMV after resolution of the acute pathology in such patients typically signifies a more chronic problem with ventilation. Spontaneous breathing trials should not be fruitlessly repeated when success is unlikely. Early transfer to the weaning service may reduce the total duration of IMV and enable continued long-term care via the linked home ventilation service.
Core Specialist Weaning Unit Infrastructure

- Bed(s) utilised for weaning should be staffed at a ratio of one nurse to 2 patients (NHS Modernisation Agency recommendation for staffing of a high dependency unit -- compared with 1 to 1 for critical care).

- Care should be led by a consultant with specific expertise in respiratory physiology, weaning and complex ventilation. Consultant work patterns must deliver continuity of care 24/7, and be able to attend within 30 minutes.

- Combined Nursing and Physiotherapy expertise must include Tracheostomy and invasive ventilation management, the use of NIV, management of weaning trials, specialist secretion clearance techniques and rehabilitation. This expertise must be available 24/7, and Specialist Physiotherapy should be able to attend within 40 minutes.

- UK modelling has shown that the provision of specialist weaning unit beds, with respect to critical care beds, ranges from 1:12 to 1:32. There are currently fewer weaning service beds than this and geographical access is patchy. Given the variation in modelling, it is envisaged that provision should evolve from 1:32 according to need.

Weaning Unit Patient Management

The overarching principle of patient management is to achieve weaning to the minimum effective level of respiratory support. Multi-disciplinary decisions will be made as to whether the patient can be weaned from invasive ventilatory support to NIV or even weaned fully from ventilation.

Standard patient management strategies include;

- Ensure adequate ventilation, aiming to normalise gas exchange as much as possible (normalise carbon dioxide).

- Review underlying diagnoses, with multi-disciplinary input reviewing the reasons around weaning failure to date.

- Normalisation of environment and function (for example, sleep-wake cycles).

- Daytime weaning attempts, with ventilation fully supported overnight, at least initially.

- Weaning to the correct level of ventilatory support that is anticipated to provide the maximal opportunity for discharge back to prior residence (ideally own home) and long-term survival.

- General physical rehabilitation to proceed alongside the weaning process.
• Regular multi-disciplinary meetings throughout the patient’s hospital stay to include all aspects of care, including input (where necessary) from Medical, Nursing, Physiotherapy, Dietetics, Speech and Language Therapy.

Exit Criteria

• A major aim of the weaning service is to enable discharge to the patient’s own home. After successful weaning, further general rehabilitation may be required. According to factors such as geographical convenience, such rehabilitation may take place within the weaning unit or via transfer back to a local service.

• Some patients will continue to require ventilatory support and will transfer initially to the Complex Home Ventilation Service. Again, long-term care will depend upon factors such as complexity of patient care and local provision of services.

• For example, a patient who continues to require IMV via tracheostomy at home will continue to require Complex Home Ventilation Service. Care may therefore continue via the same centre, or could transfer to a more convenient / local Complex Home Ventilation Service (all Specialised Weaning Services will provide home ventilation. However, not all Complex Home Ventilation Services will provide weaning).

• Existing UK weaning unit data show 9-15% unit mortality. This reflects the fact that some patients will fail to improve despite transfer and it may become clear that prognosis is poor. In such circumstances, the multi-disciplinary team, including Palliative Care, should meet to discuss treatment options and incorporate the patient. It is expected that providers will follow best practice.

3.3 Population covered

The service outlined in this specification is for patients ordinarily resident in England*; or otherwise the commissioning responsibility of the NHS in England (as defined in ‘Who Pays?: Establishing the responsible commissioner’ and other Department of Health guidance relating to patients entitled to NHS care or exempt from charges).

* Note: for the purposes of commissioning health services, this EXCLUDES patients who, whilst resident in England, are registered with a GP practice in Wales, but INCLUDES patients resident in Wales who are registered with a GP practice in England.

3.4 Any acceptance and exclusion criteria

Acceptance criteria:

1. Early discussion with the specialised weaning service for patients with comorbid conditions (neuromuscular, respiratory, chest-wall). For such patients, successful extubation to NIV should not exclude transfer to the weaning / complex home ventilation centre.
2. All patients who have required IMV for at least 2 weeks, including active attempts to wean from IMV for at least 7 days. Such patients are likely to be tracheostomised.

**Exclusion criteria:**

- Individuals with high cervical spine injuries. The provision of ventilator support for these individuals is addressed by the Spinal Injuries CRG service specification.

- This specification does not cover paediatric care.

- Patients with ongoing clinical instability or requirement for other organ support (for example, inotropic support and haemofiltration, uncontrolled sepsis and FiO₂ requirements at 0.5 or above (successful weaning is unlikely if FiO₂ requirements exceed 0.4).

- Patients for whom long term ventilation is not in their best interests on the grounds of futility (for example, very poor limited prognosis due to associated or underlying disease severity). This should usually only be after the case has been discussed with the Specialist Weaning Unit.

3.5 Interdependencies with other services/providers

**Co-located services**

- Complex Home Ventilation Service (all specialised weaning services will also provide home ventilation)
- Critical care
- Imaging
- Respiratory and Cardiology clinicians
- Physiotherapy
- Dietetics
- Occupational Therapy
- Social Work
- Speech and language therapy

**Interdependent services**

- Neurology/neurosciences

**Related services**

- Critical care units in the local Critical Care Networks.
- Neurorehabilitation (medical, physiotherapy and occupational therapy)
• Gastroenterology (gastrostomy feeding tube insertion for example)
• Cardiology
• Palliative Care

4. Applicable Service Standards

4.1 Applicable standards set out in Guidance and/or issued by a competent body (e.g. Royal Colleges)


4.2 Core Service Standards

• Care should be led by a consultant with specific expertise in respiratory physiology, weaning and complex ventilation. Consultant work patterns must deliver continuity of care.
• A consultant with expertise in respiratory physiology, weaning and complex ventilation must be immediately available in working hours and be able to attend within 30 minutes on an on-call basis.
• Consultant-led ward rounds supported by the senior nursing team must occur every day and include daily input from the specialist nursing and physiotherapy teams.
• An identified Lead Nurse with overall responsibility for the nursing elements of the service.
• A Nursing training programme that enables the generation and maintenance of
competencies in the management of patients who are invasively ventilated via tracheostomy and in the provision of assisted ventilation via NIV. It is expected that there will be a designated Nurse lead with responsibility for this role.

- An identified designated Lead Physiotherapist with overall responsibility for the respiratory physiotherapy and rehabilitation elements of the service.
- A physiotherapist with expertise in the management of this patient group (expertise in secretion clearance techniques) must be immediately available in working hours and be able to attend within 40 minutes on an on-call basis.
- All patients should have on-site access to a Speech and Language Therapist, Occupational Therapist(s), and Dietetic support, when clinically indicated.
- An on-site critical care unit is necessary to provide higher level care in the event of patient deterioration.
- There must be 24/7 on-call cover of sufficient expertise and seniority to manage common airway emergencies.
- It must be possible to undertake bronchoscopy on an urgent basis (not more than 30 minutes) within the weaning unit.

4.3 Databases

- Consideration would need to be given to database formation and maintenance.
- Ideally, there should be a national registry. As a starting point providers will be expected to provide a patient list on an annual basis.

5. Applicable quality requirements and CQUIN goals

1. 5.1 Applicable quality requirements (See Schedule 4 Parts A-D)
1. 5.2 Applicable CQUIN goals (See Schedule 4 Part E)

To be agreed with the commissioner.

6. Location of Provider Premises

The Provider’s Premises are located at:

These services are not nationally designated services.
7. **Individual Service User Placement**

*Not applicable.*

**Appendix Two**

Quality standards specific to the service using the following template:

<table>
<thead>
<tr>
<th>Quality Requirement</th>
<th>Threshold</th>
<th>Method of Measurement</th>
<th>Consequence of breach</th>
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<tr>
<td><strong>Domain 1: Preventing people dying prematurely</strong></td>
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