

Integrated Impact Assessment Report for Clinical Commissioning Policies

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| Policy Reference Number | D16X01 | | |
| Policy Title | Extra corporeal membrane oxygenation (ECMO) service for adults with cardiac failure | | |
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| Section K - Activity Impact | | | |
| Theme | Questions | Comments (Include source of information and details of assumptions made and any issues with the data) | |
| K1 Current Patient Population & Demography / Growth | K 1.1 What is the prevalence of the disease/condition? | <p>K1. 1 This policy proposes a non-routine commissioning position for extra corporeal membrane oxygenation (ECMO) service for adults with cardiac failure.</p> <p>There are around 900,000 people with heart failure in the UK;ⁱ and on a proportional basis there may be around 755,000 people with heart failure in England.ⁱⁱ</p> | |

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K1.2 What is the number of patients currently eligible for the treatment under the proposed policy?

K1.2 The group **eligible for treatment** with ECMO can be divided into 3 main categories:

- 1) **Following heart surgery (bridge to recovery or bridge to decision).** In 2010/11 there were around 30,200 cardiac proceduresⁱⁱⁱ and around 0.24% of these patients may require a ventricular assist device such as ECMO.^{iv} There may therefore be c. 70 patients eligible for ECMO.
- 2) **Acute heart failure (bridge to recovery, transplantation or implantation of a long term mechanical assist device).** This category describes patients with rapid decline of heart function, often in cases of infection or toxicity, who present in the emergency department. There were c. 44,000 hospital admissions for acute heart failure in 2013/14^v and a very small subset of these may be eligible for treatment.^{vi}
- 3) **Augmented CPR (bridge to decision, recovery, transplantation, implantation of a long term mechanical assist device).**
 - a. In England there are c.30,400 cardiac arrests outside of hospital a year where the emergency services attempt to resuscitate a patient; and a very small subset of these may be eligible for ECMO.^{vii, viii}
 - b. There would also be a number of in-hospital cardiac arrests where CPR has been unsuccessful.^{ix}

Given the difficulty in identifying the exact subsets for the three groups above, the number of patients with cardiac failure eligible for ECMO is uncertain, but is expected to be a small subset of the patients identified above.^x

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K1.3 What age group is the treatment indicated for?

K1.3 The treatment is indicated for adults (aged 18 years or over).

K1.4 Describe the age distribution of the patient population taking up treatment?

K1.4 The prevalence of heart failure is higher in men than in women and increases with age.^{xi} In England, a very small proportion of those on the Heart Failure Registry are aged under 45 (prevalence of 0.05%), while a much higher proportion (prevalence of 8% in men and 6% in women) are aged over 75.^{xii}

The age distribution of those receiving ECMO under the policy is likely to differ by each of the indications in K1.2, and may be lower than the general population with heart failure.

K1.5 What is the current activity associated with currently routinely commissioned care for this group?

K1.5 Venoarterial^{xiii} ECMO is estimated to be used in around 15-20 providers in England for patients with cardiac failure. Among five of these providers, 133 patients were recorded as receiving ECMO for cardiac failure in 2014.^{xiv} Of the other 10-15 providers undertaking this, there is estimated to be between 1 and 9 patients receiving ECMO at each. Based on this estimation, there could be around **143-268^{xv} patients a year receiving ECMO for cardiac failure.**^{xvi}

Of these patients it is estimated that they relate to the three indications listed in K1.2 as follows:

- 1) Following heart surgery: **64 to 121** (45%);
- 2) Acute heart failure: **64 to 121** (45%); and
- 3) Augmented CPR: **14 to 27** (10%).

After receiving ECMO, the subsequent activity differs for each of the indications listed above. The pathways are summarised as:

- 1) Patients following heart surgery, who cannot be separated from a

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bypass machine, would receive ECMO for **c. 5-7 days**. If these patients survive and are discharged from ECMO, they may require intensive care management for up to 2-3 weeks. They would then likely stay in a general ward for a number of weeks.^{xvii} Depending on the patient, some may require life-time support, whereas others may make a full recovery.

- 2) Patients with acute heart failure are treated with ECMO to stabilise (although there is variation in practice, this is typically for **3-5 days**) and to allow them to be transferred to a specialist cardiac centre. Once at a centre, patients may spend a long period of time in intensive care while waiting to receive a transplant. They may instead receive the implantation of a long term mechanical assist device.^{xviii} Following a procedure, patients may receive long term pharmacological therapies such as diuretics and inotropic agents, as well as other long term drugs.^{xix}
- 3) Patients who do not recover within 30 minutes from CPR may receive ECMO (for **3-5 days**) to both keep the organs perfused and to allow for assessment of neurological recovery^{xx}. The patients who recover would likely follow the same pathway as for those with acute heart failure; as described in point 2) above.

As ECMO is used in most, if not all, instances as a final line intervention, there is not much by the way of comparative treatment for the patient groups. Without ECMO, patients in the first two groups may be treated with multiple inotropes and mechanical devices; however, ECMO does not substitute for these treatments, but is rather received in addition.^{xxi} For the final group of patients, there is no alternative treatment, and without ECMO the outcome for these patients is likely to be fatal.^{xxii}

K1.6 What is the projected growth of the disease/condition prevalence (prior to applying the new policy) in 2, 5, and 10

K1.6 The prevalence of heart failure substantially increased between 1955/56 and 1970/71, however, more recent trends in heart failure prevalence are not available.^{xxiii} Therefore, no future change to

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| | <p>years?</p> <p>K1.7 What is the associated projected growth in activity (prior to applying the new policy) in 2,5 and 10 years</p> <p>K1.8 How is the population currently distributed geographically?</p> | <p>prevalence of heart failure is anticipated, and the prevalent population identified in K1.1 may grow in line with population growth and is estimated to be in the region of:^{xxiv}</p> <ul style="list-style-type: none"> • ~ 770k in 2016/17 (year 1) • ~ 775k in 2017/18 (year 2) • ~ 790k in 2018/19 (year 5) <p>K1.7 Under a do-nothing scenario, the activity for ECMO is anticipated to grow in line with the population growth and is estimated to be in the region of:^{xxv}</p> <ul style="list-style-type: none"> • 145 to 270 in 2016/17 (year 1) • 145 to 275 in 2017/18 (year 2) • 150 to 280 in 2020/21 (year 5) <p>K1.8 Based on the number of patients on the Heart Failure register in each region, the prevalence of heart failure is higher in the north of England than in the south. The prevalence of heart failure is highest in the north east (0.9%) and lowest in London (0.5%).^{xxvi}</p> |
| <p>K2 Future Patient Population & Demography</p> | <p>K2.1 Does the new policy: move to a non-routine commissioning position / substitute a currently routinely commissioned treatment / expand or restrict an existing treatment threshold / add an additional line / stage of treatment / other?</p> | <p>K2.1 This policy proposes a non-routinely commissioned position.</p> |

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K2.2 Please describe any factors likely to affect growth in the patient population for this intervention (e.g. increased disease prevalence, increased survival)

K 2.3 Are there likely to be changes in geography/demography of the patient population and would this impact on activity/outcomes? If yes, provide details

K2.4 What is the resulting expected net increase or decrease in the number of patients who will access the treatment per year in year 2, 5 and 10?

K2.2 Heart failure is caused by a variety of diseases and conditions that are classed under cardiovascular disease. There are a number of environmental factors that are associated with this disease, which may affect the prevalence. These include, but are not limited to:^{xxvii}

- Nutritional and lifestyle choices;
- Exposure to tobacco smoke;
- Pollution;
- Exposure to chemicals; and
- Maternal exposure to drugs, toxins, and infections.

K2.3 There is evidence that there is an inverse relationship between cardiovascular disease and many of the indicators of social economic status.^{xxviii}

K2.4 The proposed policy establishes a 'not routinely commissioned' proposal for the relevant population (the specific cohort set out in K1.2). The number of patients who fall outside of the cohort covered by the proposed policy, or for whom exceptionality might be demonstrated is likely to be very small.

It is therefore expected that there would be no further ECMO activity for patients with cardiac failure, and therefore a **net decrease** in the number patients accessing the treatment each year of:

- 145 to 270 in 2016/17 (year 1)
- 145 to 275 in 2017/18 (year 2)
- 150 to 280 in 2020/21 (year 5)

This decrease is equal to the 'do-nothing' activity identified in K1.7.

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| <p>K3 Activity</p> | <p>K3.1 What is the current annual activity for the target population covered under the new policy? Please provide details in accompanying excel sheet</p> <p>K3.2 What will be the new activity should the new / revised policy be implemented in the target population? Please provide details in accompanying excel sheet</p> <p>K3.3 What will be the comparative activity for the 'Next Best Alternative' or 'Do Nothing' comparator if policy is not adopted? Please details in accompanying excel sheet</p> | <p>K3.1 Current annual activity is estimated in K1.5.</p> <p>K3.2 Future ECMO activity for the target population is expected to be zero in future years given a non-routinely commissioned position.</p> <p>K3.3 It is expected that the first two groups of patients (c. 128-242) in K1.5 who would have received ECMO in the 'do-nothing' would receive cardiopulmonary resuscitation (CPR) under the policy. Those patients in the third group who have already received regular CPR (c. 14-27) would receive nothing in place of ECMO.</p> <p>The activity for these patients further along the pathway could be different when compared to the 'do-nothing'. This is dependent on the extent to which ECMO improves the survival rates for the patient groups. There is some evidence to suggest that ECMO is more effective than comparator treatments. One study which looked at comparative outcomes for patients before and after ECMO found a risk reduction in 30-day survival of 33%.^{xxx} Although this evidence is not sufficient to quantify the financial impact, for each of the patient groups there may be less activity than in the do-nothing:</p> <ol style="list-style-type: none"> 1) It is estimated that 36% of adult cardiac surgery patients survive with ECMO.^{xxx} Following ECMO these patients may receive intensive care management for up to 2-3 weeks.^{xxxi} With a lower survival rate without ECMO, this activity may be lower. 2) It is estimated that up to 73% of patients with acute-on-chronic |
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| | | <p>heart failure survive to discharge with ECMO.^{xxxii} Under the assumption that the survival rate is lower without ECMO, the activity, described in K1.5, may be lower than in the 'do-nothing'.</p> <p>3) It is estimated that 43% of patients with profound cardiogenic shock that is refractory to conventional therapy promptly supported with ECMO survive to discharge.^{xxxiii} On the assumption that without ECMO, fewer of these patients may survive to discharge, the activity in K1.5 may fall with the policy in place.</p> |
| <p>K4 Existing Patient Pathway</p> | <p>K4.1 If there is a relevant currently routinely commissioned treatment, what is the current patient pathway? Describe or include a figure to outline associated activity</p> <p>K4.2. What are the current treatment access criteria?</p> <p>K4.3 What are the current treatment stopping points?</p> | <p>K4.1 There is no routinely commissioned treatment for patients with acute heart failure.^{xxxiv}</p> <p>K4.2 N/A</p> <p>K4.3 N/A</p> |
| <p>K5 Comparator (next best alternative treatment) Patient Pathway</p> | <p>K5.1 If there is a 'next best' alternative routinely commissioned treatment what is the current patient pathway? Describe or include a figure to outline associated activity.</p> | <p>K5.1 As described in K1.5, Inotropes and other mechanical devices may be used before or after ECMO in some indications but these are not direct comparators.</p> |

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| | <p>K5.2 Where there are different stopping points on the pathway please indicate how many patients out of the number starting the pathway would be expected to finish at each point (e.g. expected number dropping out due to side effects of drug, or number who don't continue to treatment after having test to determine likely success). If possible please indicate likely outcome for patient at each stopping point.</p> | <p>K5.2 N/A</p> |
| <p>K6 New Patient Pathway</p> | <p>K6.1 Describe or include a figure to outline associated activity with the patient pathway for the proposed new policy</p> <p>K6.2 Where there are different stopping points on the pathway please indicate how many patients out of the number starting the pathway would be expected to finish at each point (e.g. expected number dropping out due to side effects of drug, or number who don't continue to treatment after having test to determine likely success). If possible please indicate likely outcome for patient at each stopping point.</p> | <p>K6.1 N/A – no new pathway proposed</p> <p>K6.2 N/A</p> |
| <p>K7 Treatment Setting</p> | <p>K7.1 How is this treatment delivered to the patient?</p> <ul style="list-style-type: none"> ○ Acute Trust: Inpatient/Daycase/ | <p>K7.1 Patients receive ECMO either in an Intensive Care Unit (ICU) at a designated respiratory ECMO centre, a tertiary cardiothoracic centre or in a mobile setting with a team dispatched to stabilise and initiate ECMO in another centre (with subsequent transfer by</p> |

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| | <p>Outpatient</p> <ul style="list-style-type: none"> ○ Mental Health Provider: Inpatient /Outpatient ○ Community setting ○ Homecare delivery <p>K7.2 Is there likely to be a change in delivery setting or capacity requirements, if so what? <i>e.g. service capacity</i></p> | <p>ambulance, helicopter or a fixed wing aircraft)^{xxxv}.</p> <p>K7.2 No change anticipated</p> |
| K8 Coding | <p>K8.1 In which datasets (e.g. SUS/central data collections etc.) will activity related to the new patient pathway be recorded?</p> <p>K8.2 How will this activity related to the new patient pathway be identified?(e.g. ICD10 codes/procedure codes)</p> | <p>K8.1 The activity for ECMO may be recorded in SUS, as well as in the ELSO international registry.</p> <p>K8.2 Activity related to ECMO for the indications associated with cardio vascular disease may be identified in SUS using the OPCS code - X58.1 Extracorporeal membrane oxygenation – and the relevant ICD-10 codes for cardio vascular disease.^{xxxvi}</p> |
| K9 Monitoring | <p>K9.1 Do any new or revised requirements need to be included in the NHS Standard Contract Information Schedule?</p> <p>K9.2 If this treatment is a drug, what pharmacy monitoring is required?</p> | <p>K9.1 N/A</p> <p>K9.2 N/A</p> |

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| | <p>K9.3 What analytical information /monitoring/ reporting is required?</p> <p>K9.4 What contract monitoring is required by supplier managers? What changes need to be in place?</p> <p>K9.5 Is there inked information required to complete quality dashboards and if so is it being incorporated into routine performance monitoring?</p> <p>K9.6 Are there any directly applicable NICE quality standards that need to be monitored in association with the new policy?</p> <p>K9.7 Do you anticipate using Blueteq or other equivalent system to guide access to treatment? If so, please outline. <i>See also linked question in M1 below</i></p> | <p>K9.3 N/A</p> <p>K9.4 N/A</p> <p>K9.5 N/A</p> <p>K9.6 N/A</p> <p>K9.7 N/A</p> |
| Section L - Service Impact | | |
| Theme | Questions | Comments (Include source of information and details of assumptions made and any issues with the data) |
| L1 Service Organisation | L1.1 How is this service currently | L1.1 ECMO for adults with respiratory failure is delivered by 5 |

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| | <p>organised? (i.e. tertiary centres, networked provision)</p> <p>L1.2 How will the proposed policy change the way the commissioned service is organised?</p> | <p>contracted specialist centres. These centres occasionally also deliver ECMO for acute heart failure in some patients. Specialist cardiothoracic centres may also acquire the ECMO technology.</p> <p>L1.2 No change</p> |
| <p>L2 Geography & Access</p> | <p>L2.1 Where do current referrals come from?</p> <p>L2.2 Will the new policy change / restrict / expand the sources of referral?</p> <p>L2.3 Is the new policy likely to improve equity of access</p> <p>L2.4 Is the new policy likely to improve equality of access / outcomes?</p> | <p>L2.1 Current referrals come from: heart surgery (when patients cannot be separated from bypass machine); emergency departments or ICUs (when patients present with rapidly declining heart function or cardiac arrest).</p> <p>L2.2 The policy may restrict the use of ECMO for acute heart failure.</p> <p>L2.3 Yes, through consistent commissioning position across the country.</p> <p>L2.4 No</p> |
| <p>L3 Implementation</p> | <p>L3.1 Is there a lead in time required prior to implementation and if so when could implementation be achieved if the policy is agreed?</p> | <p>L3.1 N/A</p> |

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| L3.2 Is there a change in provider physical infrastructure required? | L3.2 No |
| L3.3 Is there a change in provider staffing required? | L3.3 No |
| L3.4 Are there new clinical dependency / adjacency requirements that would need to be in place? | L3.4 No |
| L3.5 Are there changes in the support services that need to be in place? | L3.5 No |
| L3.6 Is there a change in provider / inter-provider governance required? (e.g. ODN arrangements / prime contractor) | L3.6 No |
| L3.7 Is there likely to be either an increase or decrease in the number of commissioned providers? | L3.7 No |
| L3.8 How will the revised provision be secured by NHS England as the responsible commissioner? (e.g. | L3.8 N/A |

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| | publication and notification of new policy, competitive selection process to secure revised provider configuration) | |
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| L4 Collaborative Commissioning | L4.1 Is this service currently subject to or planned for collaborative commissioning arrangements? (e.g. future CCG lead, devolved commissioning arrangements)? | L4.1 No |
| Section M - Finance Impact | | |
| Theme | Questions | Comments (Include source of information and details of assumptions made and any issues with the data) |
| M1 Tariff | M1.1 Is this treatment paid under a national prices*, and if so which? | <p>M1.1 There is no national price for ECMO for cardiac failure.</p> <p>There is significant uncertainty around how ECMO for cardiac failure is currently being reimbursed, and this is expected to be different across providers. As ECMO is used as an addition to some procedures and is often used in an emergency setting, with little forward planning for its use, some hospitals are not able to assess the cost directly^{xxxvii}. Some providers are expected to therefore have this cost covered by the tariff they receive for a transplant, while others may just absorb this cost or use the intensive care day-stay HRG code for respiratory ECMO to assess the cost.^{xxxviii}</p> <p>The five occupied bed day (OBD) tariffs for adult respiratory ECMO range from c. £4,600 to £6,500.^{xxxix} This cost includes any equipment costs.^{xl}</p> <p>In some cases, there may also be a retrieval cost as patients require transfer to a cardiac centre. The cost of this is dependent on the mode of transport, which is most commonly road retrieval.^{xli} There is a significant variation in these costs across providers. These are</p> |

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| | <p>M1.2 Is this treatment excluded from national prices</p> <p>M1.3 Is this covered under a local price arrangements (if so state range), and if so are you confident that the costs are not also attributable to other clinical services?</p> <p>M1.4 If a new price has been proposed how has this been derived / tested? How will we ensure that associated activity is not additionally / double charged through existing routes</p> <p>M1.5 is VAT payable (Y/N) and if so has it been included in the costings?</p> <p>M1.6 Do you envisage a prior approval / funding authorisation being required to support implementation of the new policy?</p> | <p>expected to range between c. £480 and £7,500.^{xliii}</p> <p>M1.2 Yes.</p> <p>M1.3 N/A</p> <p>M1.4 N/A</p> <p>M1.5 N/A</p> <p>M1.6 N/A</p> |
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| M2 Average Cost per Patient | M2.1 What is the revenue cost per patient in year 1? | <p>M2.1 The cost of the EMCO service will vary from patient to patient and is dependent on a number of different variables, which include: the retrieval method and time of retrieval and the length of ECMO use. The cost per patient on EMCO is comprised of two main components:</p> <ol style="list-style-type: none">1. The retrieval cost refers to the cost associated with assessing, stabilising, initiating ECMO and transporting a patient to a specialist centre, as identified in M1.1. This cost may differ across the three patient groups and some patients could have had cardiac bypass surgery at a centre that has an ECMO service. The retrieval cost may vary between £480 and £7,500, as identified in M1.1.2. The service cost includes the in-hospital costs associated with ECMO. These costs may be absorbed into the overheads of hospitals in some cases and include:^{xliii}<ol style="list-style-type: none">a) ECMO initiation. This involves percutaneous cannulation with ultrasound guidance and is performed in the ICU by medical staff and surgeons. After EMCO support has been established, pre and post oxygenator pressure monitoring begins.b) Systemic anticoagulation. Patients receive heparin to prevent bleeding.c) Weaning off ECMO support. An echocardiography is performed to assess cardiac function. After cardiac function is improved, the patient may be decannulated.d) Cannula removal and circuit disposal. <p>The total service cost for patients with cardiac indications is likely to be higher than the service cost for respiratory ECMO. This is because of the higher costs associated with the weaning of ECMO and cannula removal.^{xliiv} The cost per day of intensive care may therefore be towards the upper bound of the cost range for respiratory ECMO,</p> |
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| | | <p>which range between c. £4,600 and £6,500.</p> <p>Assuming a cost per occupied bed day whilst on ECMO of c. £6,500, the service cost per patient for each group is estimated to be:</p> <ol style="list-style-type: none">i. £32k to £45k for patients who have had cardiac bypass surgery.^{xlv}ii. £19k to £32k for patients who have acute heart failure.^{xlvi}iii. £19k to £32k for patients following augmented CPR.^{xlvii} <p>The cost per patient after ECMO is dependent on the survival rate to discharge for each patient group, outlined in K3.3, and are generally associated with the interventions that are performed once stabilised:</p> <ol style="list-style-type: none">i. Patients stabilised after cardiac bypass surgery may be managed in an ICU for up to 2-3 weeks. Assuming a cost per day in an adult critical care unit of c. £965,^{xlviii} the immediate post ECMO cost for these patients may range from c. £14k to £20k.ii. Patients stabilised or transferred to a specialist centre after heart failure may receive a variety of interventions that aim to manage their cardiovascular disease. This could include a long length of time spent in intensive care whilst waiting for treatment. Due to the variation in treatment and, therefore, cost for each patient, it is not possible to quantify the financial costs for patients in this group who survive ECMO.iii. Subsequent costs for patients stabilised who had not recovered from regular CPR are likely to be similar to those for patients with acute heart failure, as described above. <p>To the extent that ECMO improves survival rates, the cost per patient may be lower without ECMO.</p> |
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| | <p>M2.2 What is the revenue cost per patient in future years (including follow up)?</p> | <p>M2.2 There are no specific follow up costs associated with ECMO, however, the patients that successfully recover following ECMO, who receive the treatments outlined in K1.5, may receive follow-ups in relation to the intervention that was performed.</p> |
| <p>M3 Overall Cost Impact of this Policy to NHS England</p> | <p>M3.1 Indicate whether this is cost saving, neutral, or cost pressure to NHS England</p> | <p>M3.1 The overall cost impact of not routinely commissioning ECMO would comprise the following:</p> <ol style="list-style-type: none"> 1. Direct cost savings from not undertaking ECMO on the target population; and 2. Indirect cost impacts for subsequent treatments/outcomes, further along the pathway <p>There is limited information on the current reimbursement mechanism, i.e.</p> <ul style="list-style-type: none"> • Are the ECMO costs being absorbed by the trusts themselves or covered by cardiac surgery tariffs; or • Are they being paid for by NHSE under the respiratory ECMO tariff (OBD tariff) <p>In the absence of this information, it is difficult to quantify the budgetary impact of this not routinely commissioned position on NHS England.</p> <p><u>Direct cost savings</u></p> <p>There would be direct cost savings from not undertaking ECMO for the current population with acute cardiac failure. Assuming all ECMO activity for acute cardiac failure currently is being reimbursed through the ECMO respiratory tariff (as in M1.1), the impact could be broadly between c. £3.7m and £10.4m in year 1, excluding any retrieval costs, however, not only is there significant uncertainty around this impact, but reliable activity, costing and pricing data is yet to reach a consistent and accurate level, with numerous broad assumptions</p> |

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| | <p>M3.2 Where this has not been identified, set out the reasons why this cannot be measured</p> | <p>made at this stage of the exercise.</p> <p><u>Indirect cost impacts</u></p> <p>In addition to the direct impacts, there could be a range of potential outcomes/treatments further along the pathway for patients who would have ECMO including:</p> <ul style="list-style-type: none"> • Long recovery periods in intensive care and general wards • Transplant or implantation of a long term mechanical assist device • Continuing pharmacological treatments • Mortality <p>There is limited evidence to estimate the difference in outcomes in the absence of these patients receiving ECMO. Further, these costs would be borne by different organisations (e.g. locally by CCGs, NHSE, or Trusts). As such, the indirect cost impacts are not possible to quantify.</p> <p><u>Summary</u></p> <p>Overall, given the significant uncertainty across various dimensions (activity, reimbursement, outcomes) – it is not possible to provide a reasonable estimate of the budgetary impact.</p> <p>M3.2 Please refer to M3.1.</p> |
| <p>M4 Overall cost impact of this policy to the NHS as a whole</p> | <p>M4.1 Indicate whether this is cost saving, neutral, or cost saving for other parts of the NHS (e.g. providers, CCGs)</p> | <p>M4.1 Please refer to M3.1.</p> |

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| | <p>M4.2 Indicate whether this is cost saving, neutral, or cost pressure to the NHS as a whole</p> <p>M4.3 Where this has not been identified, set out the reasons why this cannot be measured</p> <p>M4.4 Are there likely to be any costs or savings for non NHS commissioners / public sector funders?</p> | <p>M4.2 Please refer to M3.1.</p> <p>M4.3 Please refer to M3.1.</p> <p>M4.4 Please refer to M3.1.</p> |
| <p>M5 Funding</p> | <p>M5.1 Where a cost pressure is indicated, state known source of funds for investment, where identified <i>e.g. decommissioning less clinically or cost-effective services</i></p> | <p>M5.1 Please refer to M3.1.</p> |
| <p>M6 Financial Risks Associated with Implementing this Policy</p> | <p>M6.1 What are the material financial risks to implementing this policy?</p> <p>M6.2 Can these be mitigated, if so how?</p> <p>M6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and</p> | <p>M6.1 Please refer to M3.1.</p> <p>M6.2 N/A</p> <p>M6.3 N/A</p> |

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| | most likely total cost scenarios? | |
| M7 Value for Money | <p>M7.1 What evidence is available that the treatment is cost effective? <i>e.g. NICE appraisal, clinical trials or peer reviewed literature</i></p> <p>M7.2 What issues or risks are associated with this assessment? <i>e.g. quality or availability of evidence</i></p> | <p>M7.1 No studies assessing the cost-effectiveness of ECMO for adult acute heart failure have been identified.</p> <p>M7.2 N/A</p> |
| M8 Cost Profile | <p>M8.1 Are there non-recurrent capital or revenue costs associated with this policy? <i>e.g. Transitional costs, periodical costs</i></p> <p>M8.2 If so, confirm the source of funds to meet these costs</p> | <p>M8.1 No</p> <p>M8.2 N/A</p> |

ⁱ The Health Foundation (2010). Bridging the quality gap: Heart failure. March 2010. Accessed online via: http://www.health.org.uk/sites/default/files/BridgingTheQualityGapHeartFailure_0.pdf

ⁱⁱ This adjusted the UK estimate for the proportion of the population of England in the UK. The population of England is around 84% of the total for the UK, based on ONS (2014) population mid-year estimates.

ⁱⁱⁱ National Institute for Cardiovascular Outcomes Research (2011).

^{iv} A telephone survey of cardiac surgical units in the UK and Ireland in 2007/08 found that ventricular assist devices for postcardiotomy cardiogenic shock were required in 0.24% of patients undergoing coronary artery bypass grafting and/or valve surgery. Borisenko, O., Wylie, G., Payne, J., Bjessmo, S., Smith, J., Firmin, R. and Yonan, N.

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(2014). The cost impact of short-term ventricular assist devices and extracorporeal life support systems therapies on the National Health Service in the UK. *Interact CardioVasc Thorac Surg*, 19(1), pp.41-48.

^v National Heart Failure Audit (2013). Accessed online via; <https://www.ucl.ac.uk/nicor/audits/heartfailure/documents/annualreports/hfannual12-13.pdf>

^{vi} Based on discussions with the policy working group.

^{vii} NHS England Ambulance Quality Indicators (2014/15), <https://www.england.nhs.uk/statistics/statistical-work-areas/ambulance-quality-indicators/>

^{viii} The survival rate was 8.6%.

^{ix} Data from the Hospital and Episode Statistics (2014/15) show that there were 25,565 episodes with an ICD-10 code I46.0 (Cardiac arrest with successful resuscitation) in any position, and 13,685 for ICD-10 code I46.9 (Cardiac arrest, unspecified) in any position.

^x Although the exact number of patients eligible cannot be ascertained, the number of patients eligible is likely to be closer to the current activity estimate (in K1.5).

^{xi} Prevalence of heart failure, by gender and age, England, Scotland, Wales, Northern Ireland and United Kingdom 2014. Chapter Two – Morbidity – British Heart Foundation.

^{xii} Prevalence of heart failure, by gender and age, England, Scotland, Wales, Northern Ireland and United Kingdom 2014. Chapter Two – Morbidity – British Heart Foundation.

^{xiii} There are two common forms of ECMO: venoarterial and venovenous ECMO. Venoarterial is used to provide patients with respiratory and circulatory support. Whereas venovenous is used for respiratory support for lung failure.

^{xiv} Based on discussions with the policy working group.

^{xv} The lower bound is calculated by taking the 133 patients from the five centres, and adding the product of the lower bound of patient (1) and remaining provider (10) estimates. The upper bound is calculated by taking the 133 patients from the five centres, and adding the product of the upper bound of patient (9) and remaining provider (15) estimates.

^{xvi} ECMO activity for cardiac can be the voluntarily input to the Extracorporeal Life Support Organization registry. Given this is only voluntary, there is significant uncertainty around current activity.

^{xvii} Based on discussions with the policy working group.

^{xviii} Based on discussions with the policy working group.

^{xx} Based on discussions with the policy working group.

^{xxi} Based on discussions with the policy working group.

^{xxii} Based on discussions with the policy working group.

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^{xxiii} British Heart Foundation (2011). Trends in coronary heart disease, 1961-2011.

^{xxiv} Demographic growth rates are sourced from ONS (2012), Population projections. The demographic growth rate for the over 18s is applied.

^{xxv} Demographic growth rates are sourced from ONS (2012), Population projections. The demographic growth rate for the over 18s is applied. Figures are rounded to the nearest 5.

^{xxvi} Prevalence of selected cardiovascular conditions by Government Office Region and country, United Kingdom 2012/13. England - Information Centre QOF achievement data 2012/13. British Heart Foundation (2014). Cardiovascular disease statistics 2014. Accessed online via https://www.bhf.org.uk/~media/files/publications/research/bhf_cvd-statistics-2014_web_2.pdf

^{xxvii} O'Toole, T., Conklin, D. and Bhatnagar, A. (2008). Environmental Risk Factors for Heart Disease. *Reviews on Environmental Health*, 23(3).

^{xxviii} Kaplan, G. and Keil, J. (1993). Socioeconomic factors and cardiovascular disease: a review of the literature. *Circulation*, 88(4), pp.1973-1998.

^{xxix} NHS SPH (2014). Evidence Summary Report: Extracorporeal membrane oxygenation (ECMO) in adult acute heart failure. Inside which contains the citation: Tweet, M., Schears, G., Cassar, A., Sheldon, S., McGlinch, B. and Sandhu, G. (2013). Emergency Cardiac Support With Extracorporeal Membrane Oxygenation for Cardiac Arrest. *Mayo Clinic Proceedings*, 88(7), pp.761-765. .

^{xxx} NHS SPH (2014). Evidence Summary Report: Extracorporeal membrane oxygenation (ECMO) in adult acute heart failure. Inside which contains the citation: Elsharkawy HA. Li L. Essa WAS. Sessler DI. Bashour CA. Outcome in patients who require venoarterial extracorporeal membrane oxygenation support after cardiac surgery. *Journal of Cardiothoracic and Vascular Anesthesia* 2010, 24(6): 946-951.

^{xxxi} Based on discussions with the policy working group.

^{xxxii} NHS SPH (2014). Evidence Summary Report: Extracorporeal membrane oxygenation (ECMO) in adult acute heart failure. Inside which contains the citation: Loforte, A., Marinelli, G., Musumeci, F., Folesani, G., Pilato, E., Martin Suarez, S., Montalto, A., Lilla Della Monica, P., Grigioni, F., Frascaroli, G., Menichetti, A., Di Bartolomeo, R. and Arpesella, G. (2014). Extracorporeal Membrane Oxygenation Support in Refractory Cardiogenic Shock: Treatment Strategies and Analysis of Risk Factors. *Artificial Organs*, 38(7), pp.E129-E141

^{xxxiii} NHS SPH (2014). Evidence Summary Report: Extracorporeal membrane oxygenation (ECMO) in adult acute heart failure. Inside which contains the citation: Chung, S., Sheu, J., Lin, Y., Sun, C., Chang, L., Chen, Y., Tsai, T., Chen, C., Yang, C., Hang, C., Leu, S., Wu, C., Lee, F. and Yip, H. (2012). Outcome of Patients With Profound Cardiogenic Shock After Cardiopulmonary Resuscitation and Prompt Extracorporeal Membrane Oxygenation Support. *Circulation Journal*, 76(6), pp.1385-1392.

^{xxxiv} Based on discussions with the policy working group.

^{xxxv} [Leicestershospitals.nhs.uk](http://www.leicestershospitals.nhs.uk), (2016). Transport to Hospital. [online] Available at: <http://www.leicestershospitals.nhs.uk/aboutus/departments-services/heart-services/ecmo/transport-to-hospital/> [Accessed 11 Jan. 2016].

^{xxxvi} These ICD10 codes may range from I00X to I99X. These codes generally relate to conditions associated with the heart.

^{xxxvii} Based on discussions with the policy working group.

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xxxviii Based on discussions with the policy working group.

xxxix Based on discussions with the policy working group. It is expected that these would be greater for cardiac failure as there would likely be additional costs such as operating room time and for VA removal.

xl Based on discussions with the policy working group.

xli Based on discussions with the policy working group.

xlii Based on data supplied to the policy working group.

xliii Alfred Health Guideline (2012). Extracorporeal Membrane Oxygenation (ECMO). Accessed online via: <http://www.alfredicu.org.au/assets/Documents/ICU-Guidelines/ECMO/ECMOGuideline.pdf>

xliv Based on discussions with the policy working group.

xlv This assumes that patients receive ECMO for 5-7 days. Based on discussions with the policy working group.

xlvi This assumes the patient receives ECMO FOR 3-5 days. Based on discussions with the policy working group.

xlvii This assumes the patient receives ECMO FOR 3-5 days. Based on discussions with the policy working group.

xlviii After applying an MFF of 10% and accounting for inflation of 2.5% and efficiency of 4% to the Adult Critical Care, 1 Organ Supported HRG tariff of £890. National Schedule of Reference Costs Year : 2013-14 - All NHS trusts and NHS foundation trusts - HRG Data