Integrated Impact Assessment Report for Service Specifications

Reference Number	A10/S(HSS)/a/b and E05/S(HSS)/a		
Title	Heart and Lung Transplantation services (Adult Heart, Adult Lung and Paediatric Cardiothoracic Transplantation)		
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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?	Eligibility for an elective transplant is set out in criteria agreed by consensus at the Cardiothoracic Advisory Group of NHS Blood and Transplant and is published on the NHS BT website. The decision to recommend heart transplantation depends on a balance of the benefits, risks and alternatives. However, the scarcity of suitable donor hearts makes it necessary

		to also consider the population of potential heart transplant candidates; selection is based both on the patient's clinical need and on their capacity to benefit.
	K1.2 What is the number of patients eligible for this treatment under currently routinely commissioned care arrangements?	In 2014/15 318 NHS England patients received a transplant. The overall UK number of adult patients actively waiting for a heart transplant increased each year from 72 in 2007 to 231 in 2015 across all UK centres. The overall UK number of adult patients actively waiting for a lung transplant decreased from 297 in 2006 to 211 in 2011 and has since been on the increase, reaching 321 in 2015. The overall number of paediatric patients actively waiting for a heart transplant increased substantially from 16 in 2013 to 31 in 2015.
	K1.3 What age group is the treatment indicated for? K1.4 Describe the age distribution of the patient population taking up treatment?	All ages The median age of an adult heart transplant recipient in 14/15 was 53 (42, 59)(IQR). The median age of an adult lung transplant recipient in 14/15 was 46 (35, 54) The median age of a paediatric transplant recipient in 14/15 was 5 (1,10)

	K1.5What is the current activity associated with currently routinely commissioned care for this group?	In 2014/15 318 NHS England patients received a heart or lung (or heart+lung) transplant. NHS BT have a strategy to increase organ donation each year to 2020, with the consequent increase in heart and lung transplant numbers as follows, year 1 accounts for 2 years of missed targets 2015/16 73 2016/17 33 2017/18 20 2018/19 25 2019/20 17
	K1.6 What is the projected growth of the disease/condition prevalence (prior to applying the new policy) in 2, 5, and 10 years	
	K1.7 What is the associated projected growth in activity (prior to applying the new policy) in 2,5 and 10 years	The changes to the service specification would not change the eligibility for the service so numbers would not change as a result of a change to the specification.
	K1.8 How is the population currently distributed geographically?	**Cardiothoracic organ transplant rates per million population (pmp) in the UK, 1 April 2014 - 31 March 2015 Strategic Health Total (pmp)** **Authority** Total ppm North East 15 (5.7) North West 44 (6.2) Yorkshire and The Humber 25 (4.7) **North of England 84 (5.6)** East Midlands 30 (6.5) West Midlands 44 (7.8)

		East of England 45 (7.6) **Midlands and East 119 (7.3)** **London 24 (2.9)** South East Coast 23 (5.1) South Central 24 (5.6) South West 41 (7.6) **South of England 88 (6.2)** **England 155 315 (5.8)**
K2 Future Patient Population & Demography	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? K2.3 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	The service specification described the service as currently provided whilst splitting out adult lung transplantation and heart transplantation into separate specifications plus updates with regard to NHS England policy on ongoing immunosuppression. There is now a separate specification for paediatric transplantation. There are factors to increased heart failure however the limiting factor for transplantation is the availability of organs. Change in numbers will depend on availability of organs. Projected figures: 2014/15 – 318 transplants 2015/16 391 2016/17 424 2017/18 444 2018/19 469 2019/20 486

<table>
<tr><td></td><td>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?</td><td>These planning figures are taken from Taking Organ Donation to 2020. The number of heart transplants increased steadily between 2009 and 2013, after which a substantial increase occurred. Overall the number of transplants decreased in14/15 by 15% over the last financial year.</td></tr>
<tr><td>K3 Activity</td><td>K3.1 What is the current annual activity for the target population covered under the new policy? Please provide details in accompanying excel sheet

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

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</td><td>Transplant activity as follows, this will not change as a result of the specification changes being adopted or not.

Number of adult heart transplants in the UK, by centre, 1 April 2014 to 31 March 2015
<table><tr><td></td><td>Urgent</td><td>Non–urgent</td></tr><tr><td>Newcastle</td><td>13</td><td>2</td></tr><tr><td>Papworth</td><td>23</td><td>11</td></tr><tr><td>Harefield</td><td>23</td><td>2</td></tr><tr><td>Birmingham</td><td>28</td><td>3</td></tr><tr><td>Manchester</td><td>23</td><td>2</td></tr><tr><td>Glasgow</td><td>8</td><td>5</td></tr><tr><td>TOTAL</td><td>118</td><td>25</td></tr></table>
Number of adult lung transplants in the UK, by centre, 1 April 2014 to 31 March 2015
<table><tr><td></td><td>Transplants</td></tr><tr><td>Newcastle</td><td>42</td></tr><tr><td>Papworth</td><td>39</td></tr></table></td></tr>
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		Harefield 49 Birmingham 24 Manchester 24 TOTAL 178 **Paediatric transplants , by centre, 1 April 2014 to 31 March 2015** **Transplants** Newcastle 22 GOSH 22 The overall national median waiting time for an adult heart transplant is 195 days and ranges from 57 days at Birmingham to 1043 days at Harefield The national median waiting time for an adult lung transplant is 265 days and ranges from 200 days at Papworth to 353 days at Birmingham. Within six months of listing, 27% of non-urgent paediatric heart patients were transplanted while 18% died waiting. Three years after listing, 36% received a transplant. Within six months of listing, 7% of paediatric lung patients were transplanted while 14% died waiting. Three years after listing, 57% received a transplant.
K4 Existing Patient Pathway	K4.1 If there is a relevant currently routinely	Transplantation is the current pathway In

	commissioned treatment, what is the current patient pathway? Describe or include a figure to outline associated activity.	2014/15 318 NHS England patients received a transplant.
	K5. What are the current treatment access criteria?	Heart Transplantation: Selection Criteria and Recipient Registration and Lung Candidate Selection Criteria are agreed and available on the NHS BT website. The aim of this document is to provide guidelines for the selection of adult and paediatric patients on to the UK national transplant list and, where necessary, criteria for their de-selection. These criteria apply to all recipients of organs from deceased donors.
	K6. What are the current treatment stopping points?	Patients on the waiting list should continue to be reviewed regularly by the transplant centre to assess urgency and confirm on-going suitability for transplantation; if this is not practical, the referrer should provide regular clinical updates to the transplant centre. Within six months of listing, 30% of non-urgent adult heart patients were transplanted while 9% died waiting. Three years after listing, 48% received a transplant.
K5 Comparator (next best alternative treatment) Patient	K5.1 If there is a 'next best' alternative routinely commissioned treatment what is the current patient	Medical management of patients.

Pathway	pathway? Describe or include a figure to outline associated activity. 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.	The financial planning is based on the numbers of increased transplants based on the expected used donor organs. The number of adult patients waiting for a lung transplant fell each year from 304 in 2006 to 229 in 2009 but has subsequently increased to 338 in 2015. The number of patients waiting for a heart transplant has increased substantially from 93 in 2009 to 267 in 2015. The overall number of paediatric patients actively waiting for a heart transplant increased substantially from 16 in 2013 to 31 in 2015. The number of paediatric patients actively waiting for a lung transplant has increased from 4 in 2006 to 15 in 2015.
K6 New Patient Pathway	K6.1 Describe or include a figure to outline associated activity with the patient pathway for the proposed new policy 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	The pathway isn't new and is long established. Within six months of listing, 30% of non-urgent heart patients were transplanted while 9% died waiting. Three years after listing, 48% received a transplant. Within six months of listing, 39% of lung patients were transplanted while 8% died

	test to determine likely success). If possible please indicate likely outcome for patient at each stopping point.	waiting. Three years after listing, 69% received a transplant. The national rate of survival 30 days after first heart transplantation of adults is 88.3%. The national rate of survival 90 days after first lung transplantation of adults from deceased donors is 90.4%. The national rate of survival 30 days after first heart transplantation of paediatrics is 96.9, ranging from 96.7% to 97% The national rate of survival 90 days after first lung transplantation of paediatrics from deceased donors is 94.4%.
K7 Treatment Setting	K7.1How is this treatment delivered to the patient? K7.2 Is there likely to be a change in delivery setting or capacity requirements, if so what? *e.g. service capacity*	Acute Trust: Inpatient Ongoing monitoring in tertiary centre and provision of immunosuppression at home. No change in delivery model anticipated.
K8 Coding	K8.1 In which datasets (e.g. SUS/central data collections etc.) will activity related to the new patient pathway be recorded? K8.2 How will this activity related to the new patient pathway be identified?(e.g. ICD10 codes/procedure codes)	Data is recorded in the UK Transplant Registry. Also activity returns directly to the HSS team. Z94.1 & Z94.2
K9 Monitoring	K9.1 Do any new or revised requirements need to be included in the NHS Standard Contract Information Schedule? If so, these must be	Would need to be included.

	communicated to CTownley@nhs.net, ideally by end of October to inform following year's contract	
	K9.2 If this treatment is a drug, what pharmacy monitoring is required?	Not applicable
	K9.3 What analytical information /monitoring/ reporting is required?	A process for activity monitoring in line with all HSS would be put in place
	K9.4 What contract monitoring is required by supplier managers? What changes need to be in place?	Activity reports would be submitted to supplier managers as for all HSS
	K9.5 Is there inked information required to complete quality dashboards and if so is it being incorporated into routine performance monitoring?	This service would not be included in a quality dashboard and outcome data would be reported separately
	K9.6 Are there any directly applicable NICE quality standards that need to be monitored in association with the new policy?	No
	K9.7 Do you anticipate using Blueteq or other equivalent system to guide access to treatment? If so, please outline. *See also linked question in M1*	No
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 organised (i.e. tertiary centres, networked provision)	Tertiary centres

	L1.2 How will the proposed policy change the way the commissioned service is organised?	No change for pre-transplant and transplant. In February 2014 NHS England published Specialised Services Circular (SSC) no. 1405 - Repatriation of patients receiving immunosuppressive drugs post-transplant to specialist centres. This SSC explained how the prescribing of immunosuppressant drugs to patients following solid organ transplantation would be returned to specialist centres. In addition, there would be opportunities to move to prescribing generic forms of some immunosuppressant drugs instead of the branded versions. This service specification update brings the specification into line with NHS England agreed policy on the prescribing of immunosuppression.
L2 Geography & Access	L2.1 Where do current referrals come from?	Data by commissioning hub shown above for transplanted patients.
	L2.2 Will the new policy change / restrict / expand the sources of referral?	No
	L2.3 Is the new policy likely to improve equity of access?	No
	L2.4 Is the new policy likely to improve equality of	The changes to the ongoing

	access / outcomes?	immunosuppression have been agreed to improve the ongoing management of patients as well as reduce costs by moving to generic prescribing.
L3 Implementation	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?	There are issues to be addressed with the move to transplant centre prescribing of ongoing immunosuppression. Hub pharmacists are addressing this change and have been for some time since the change in NHS England policy.
	L3.2 Is there a change in provider physical infrastructure required?	The growth in activity anticipated by NHS BT's 2020 strategy will impact on the infrastructure in the cardiothoracic transplant centres. There are enough centres to cope with this additional activity if resourced to do so.
	L3.3 Is there a change in provider staffing required?	Additional staffing will be required to meet the additional demand for the service. The growth in activity is uncertain; we would expect the timelines for TODT 2020 to be stretched beyond 2020. Additional work on cardiothoracic transplant tariffs is needed to enable centres to staff adequately to meet the additional number of transplants they will need to do.
	L3.4 Are there new clinical dependency / adjacency requirements that would need to be in place?	No additional. There are interdependencies with the VAD as a bridge to transplant service and also ECMO services. We would not expect ECMO as a bridge to bridge to transplant

		to be delivered outside of transplant centres unless by agreement with one of the paediatric transplant centres and we would not expect these circumstances to arise more than once or twice a year. There would need to be a commissioning position agreed on a case by case basis as now.
	L3.5 Are there changes in the support services that need to be in place?	No
	L3.6 Is there a change in provider / inter-provider governance required? (e.g. ODN arrangements / prime contractor)	No
	L3.7 Is there likely to be either an increase or decrease in the number of commissioned providers?	No
	L3.8 How will the revised provision be secured by NHS England as the responsible commissioner (e.g. publication and notification of new policy, competitive selection process to secure revised provider configuration)	No revised provision.
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)?	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?	No, treatment paid under HSS block arrangements outside of national tariff scope.
	M1.2 Is this treatment excluded from national prices?	Yes
	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?	The HSS blocks include children's transplant services with some providers. The cost estimates are indicative based on pro-rata assumptions and cost splits where they have been made available.
	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	Not applicable, ring-fenced HSS service costs considered only.
	M1.5 is VAT payable (Y/N) and if so has it been included in the costings?	No
	M1.6 Do you envisage a prior approval / funding authorisation being required to support implementation of the new policy?	No.
M2 Average Cost per Patient	M2.1 What is the revenue cost per patient in year 1?	Current costs have been increased pro-rata to activity to assumed variable element of contract costs. Across future years costs per patient assumed to remain

		around £106k
	M2.2 What is the revenue cost per patient in future years (including follow up)?	As above
M3 Overall Cost Impact of this Policy to NHS England	M3.1 Indicate whether this is cost saving, neutral, or cost pressure to NHS England?	The changes to the service specification are cost neutral. The growth in activity expected is a cost pressure. Activity growth will result in cost increases. Profile increases Yr 1 +£7.7m, Yr 2 +£11.2m, Yr 3 +£13.3m, Yr 4 +£15.9m, Yr 5 onwards +£17.7m. The additional cost presure could be reduced through delivering efficiency savings and negotiating lower contract prices.
	M3.2 Where this has not been identified, set out the reasons why this cannot be measured?	Not applicable
M4 Overall cost impact of this policy to the NHS as a whole	M4.1 Indicate whether this is cost saving, neutral, or cost saving for other parts of the NHS (e.g. providers, CCGs)	As above. The changes to immunosuppression are cost saving and are a national QIPP scheme.
	M4.2 Indicate whether this is cost saving, neutral, or cost pressure to the NHS as a whole?	As above
	M4.3 Where this has not been identified, set out the reasons why this cannot be measured?	Not applicable
	M4.4 Are there likely to be any costs or savings for non NHS commissioners / public sector funders?	No

M5 Funding	M5.1 Where a cost pressure is indicated, state known source of funds for investment, where identified	e.g. decommissioning less clinically or cost-effective services
M6 Financial Risks Associated with Implementing this Policy	M6.1 What are the material financial risks to implementing this policy? M6.2 Can these be mitigated, if so how? M6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios	Assumed funded from specialised commissioning allocation envelope. Implementing this service specification will not impact the costs described as activity volumes unlikely to be affected. Cost reductions could be achieved through service efficiency savings. Indicative cost estimates based on projected activity volumes. There would be variation over time if the projected volumes are different from NHSBT's planning figures.
M7 Value for Money	M7.1 What evidence is available that the treatment is cost effective? M7.2 What issues or risks are associated with this assessment?	NHS BT has produced a paper on the cost effectiveness of solid organ transplantation. National service funded at c£33.6m excluding ongoing immunosuppression.
M8 Cost Profile	M8.1 Are there non-recurrent capital or revenue costs associated with this policy? M8.2 If so, confirm the source of funds to meet	No

	these costs.	