

Integ	rated Impa	ct Assessment Report	for Service	e Specifications		
Service Specification Reference Number	1641 1643	1641 1643				
	Small bowel	Small bowel transplantation service (Adults)				
Service Specification Title		transplantation service (Pa	,			
	Proposal <u>IOI</u>	routine commission (sou	ICE AS. I)			
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#### About this Impact Assessment: instructions for completion and explanatory notes

- Each section is divided into themes.
- Each theme sets out a number of questions.
- All questions are answered by selecting a drop down option or including free text.
- Free text boxes are provided to enable succinct relevant commentary to be added which explains the rationale for response or assumption. Please limit responses to 3 sentences of explanatory text.
- Data in this document is either drawn from one of the relevant service specification documents or a source for the information is provided.
- Where assumptions are included where data is not available, this is specified.

Section A	A - Activity Impact
A1 Current Patient Population & Demography / Growth	
A1.1 Prevalence of the disease/condition.	Primary indications for adult intestinal transplant include depletion of central venous access sites, multiple episodes of catheter related sepsis, electrolyte disturbance, dehydration, and progressive cholestatic liver failure. Approximately 20 adults and 10 children are on the waiting list for a small bowel transplant at any one time. In children transplant is considered for patients with life threatening complications of bowel (intestinal) failure which may be caused by Short bowel syndrome, motility disorders and mucosal disorders. <i>Source: Service Specification Proposition section 3.2</i>
A1.2 Number of patients currently eligible for the service according to the proposed service specification commissioning criteria.	The following describes the one- and five-year adult and paediatric patient survival rates following first elective small bowel transplantation between 1         April 2007 and 31 March 2017, by transplant centre.         Adult patients         Centre Number of 1-year survival (95% CI)         transplants       Unadjusted         Cambridge       62       81.5       (69.0-89.3)         Oxford       35       79.2       (61.2-89.6)         TOTAL       97       80.7       (71.0-87.4)         Centre Number of 5-year survival (95% CI)         Transplants       Unadjusted         Cambridge       62       55.6       (37.8-70.2)         Oxford       35       59.8       (35.7-77.3)         TOTAL       97       57.4       (43.5-69.1)         Paediatric patients       Centre       Number of transplants       1-year survival (95% CI)

	Birmingham King's College <b>TOTAL</b>	43 15 <b>58</b>	83.7 93.3 <b>86.1</b>	(68.9-91.9) (61.3-99.0) <b>(74.2-92.8)</b>
	78 follow up pa extract has ider been used as the In 17/18 there w for such a smal variability.	tients, 46 ad ntified 68 pat he basis of tl were 14 adul Il volume ser	54.4 71.1 <b>58.8</b> n be estima ults, 22 chi ients, 46 ac ne impact a t transplant vice the yea	vival (95% CI) (37.4-68.6) (39.8-88.1) (44.2-70.8) ated that at 5 years there would be Idren. The NHS England data dults, 22 children so this figure has assessment and financial model. ts done and 8 paediatric. As is usual ar on year activity shows some estine Transplantation 2016/2017
A1.3 Age group for which the service is proposed according to the service specification commissioning criteria.	All ages Please specify Service specific	cations		
A1.4 Age distribution of the patient population eligible according to the proposed service specification commissioning criteria	recipient registr recipients were The demograph registrations in male and the m	rations in the male and th hic character the 10 year nedian age fo	10 year pe e median a istics of the period show or recipients	e paediatric intestine transplant eriod show that 60% of these age for recipients was 4 years old. e adult intestine transplant recipient w that 50% of these recipients were s was 45 years old. estine Transplantation 2016/2017

	Click here to enter tex	xt.			
A1.5 How is the population currently distributed geographically?	Evenly If unevenly, estimate regional distribution by %:				
	North	enter %			
	Midlands & East	enter %			
	London	enter %			
	South	enter %			
	Please specify	cification proposition section 6 ort on Intestine Transplantation 2016/2017			

# A2 Future Patient Population & Demography

A2.1 Projected changes in the disease/condition epidemiology, such as incidence or prevalence (prior to applying the new service specification) in 2, 5, and 10 years?	Constant If other, Click here to Source: Service spec	enter text. Sification proposition section 3.1
A2.2 Are there likely to be changes in demography of the patient population and would this impact on activity/outcomes?	No Please specify Click here to enter tex Source: Service spec	xt. Sification proposition section 6/other
A2.3 Expected net increase or decrease in the number of patients	YR2 +/- 0	
who will be eligible for the service, according to the proposed	YR3 +/- 0	

YR4 +/-	0			
YR5 +/-	0	-		
YR10 +/-	0			
Source: Service specification proposition section 3.1				
Not applicable				
Revision to an o	existing publishee	service specification		
Please specify				
including an upd immunosuppress	late with regard to I sion, transition of p	~ 1		
year follow up for specification cha	or patients as part o anges that responsi	f the transplant service. The redrafted bility to be clear the transplant centres		
planned transitio	on pathway. These	ments to ensure patients follow a transition pathways have been been been by hub funding for the Cambridge		
	YR5 +/- YR10 +/- Source: Service There are factor limiting factor for Not applicable Not applicable Mot applicable Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable	YR5 +/-       0         YR10 +/-       0         Source: Service specification proportion         There are factors to increased integritmiting factor for transplantation is the limiting factor facto		

A3.2 What is the annual activity associated with the existing pathway for the eligible population?	c22 transplants per year (this is 1718 data, though there is year on year variability this is this level of activity is typical). 46 adult patients as at the point the data was submitted need lifelong follow up for small bowel transplant and 22 children. Source: NHS BT Annual Report on Intestine Transplantation 2016/2017
A3.3 What is the estimated annual activity associated with the proposed service specification proposition pathway for the eligible population?	The financial model sets out a change to the long term funding of patients post 1 year follow up and is calculated based on 46 adults and 22 children. Follow up for new patients will also be included in the pathway. <i>Source:</i> NHS BT Annual Report on Intestine Transplantation 2016/2017 section 11.2 and 11.1 Data extract covering ICD10 codes G681/G688/G689 cross referenced against a list of transplant patients.
A4 Patient Pathway	
A4.1 Patient pathway	The key components of the service are:
Describe the current patient pathway and service.	pre-transplant assessment;
	listing;
	transplant;
	management of complications;
	<ul> <li>post-surgical follow up</li> <li>1 year follow up</li> </ul>
	Source: A02/S(HSS)/b Small bowel transplantation service (Adult)
	E03/S(HSS)/c Small bowel transplantation service - paediatrics
A4.2. What are the current service access and stopping criteria?	The access criteria are not changing; the egress criteria are currently to offer shared care after 1 year with financial responsibility transfer to the CCG after 3 months (including immunosuppressive drugs). The financial

	model has not considered the financial consequences of changes to immunosuppression, this is subject to separate work being done within NHS England. <i>Source:</i> A02/S(HSS)/b Small bowel transplantation service (Adult) E03/S(HSS)/c Small bowel transplantation service - paediatrics
<ul> <li>A4.3 What percentage of the total eligible population are:</li> <li>a) Referred</li> <li>b) Meet any existing criteria for care</li> <li>c) Considered to meet any existing exclusion criteria</li> </ul>	If not known, please specify Click here to enter text. a) 100 b) 100 c) 100 Source: required
<ul> <li>A4.4 What percentage of the total eligible population is expected to:</li> <li>a) Be referred to the proposed service</li> <li>b) Be eligible for care according to the proposed criteria for the service</li> <li>c) Take up care according to the proposed criteria for the service</li> <li>d) Continue care according to the proposed criteria for the service?</li> </ul>	If not known, please specify Click here to enter text. a) 100 b) 100 c) 100 d) 86.1% 1 year survival 58.8% 5 year survival in children 80.7% 1 year survival 57.4% 5 year survival in adults Source: required
A4.5 Specify the nature and duration of the proposed new service or intervention.	Life long For time limited services, specify frequency and/or duration. Click here to enter text. Source: required
A5 Service Setting	
A5.1 How is this service delivered to the patient?	Select all that apply:

	Emergency/Urgent care atte	endance		
	Acute Trust: inpatient		$\boxtimes$	
	Acute Trust: day patient		$\boxtimes$	
	Acute Trust: outpatient		$\boxtimes$	
	Mental Health provider: inpa	atient		
	Mental Health provider: outp	patient		
	Community setting			
	Homecare			
	Other			
	Please specify: Click here to enter text.			
A5.2 What is the current number of contracted providers for the	NORTH	0		
eligible population by region?	MIDLANDS & EAST	2		
	LONDON	1		
	SOUTH	1		
A5.3 Does the proposition require a change of delivery setting or capacity requirements?	<u>No</u> Please specify: Click here to enter text. <i>Source: required</i>			
A6 Coding				

A6.1 Specify the datasets used to record the new patient pathway activity.	Select all that apply:				
	Aggregate Contract Monitoring *				
*expected to be populated for all commissioned activity	Patient level contract monitoring				
	Patient level drugs dataset				
	Patient level devices dataset				
	Devices supply chain reconciliation dataset				
	Secondary Usage Service (SUS+)				
	Mental Health Services DataSet (MHSDS)				
	National Return**				
	Clinical Database**				
	Other**				
	**If National Return, Clinical database or other HSS provider information monthly submission	selected, please specify:			
A6.2 Specify how the activity related to the new patient pathway will	Select all that apply:				
be identified.	OPCS v4.8				
	ICD10				
	Service function code				
	Main Speciality code				
	HRG				
	SNOMED				
	Clinical coding / terming methodology used by clinical profession				

A6.3 Identification Rules for Drugs: How are any drug costs captured?	Not applicableIf already specified in the current NHS England Drug / Devices List, pleasespecify drug name and indication for all that apply:If drug(s) NOT already been specified in the current NHS England DrugList please give details of action required and confirm that this has beendiscussed with the pharmacy lead:
A6.4 Identification Rules for Devices: How are device costs captured?	Not applicableIf device(s) covered by an existing category of HCTED please specify the Device Category (as per the National Tariff Payment System Guidance) for all that apply:If device(s) not excluded from Tariff nor covered within existing National or Local prices please specify details of action required and confirm that this has been discussed with the HCTED team.
A6.5 Identification Rules for Activity: How are activity costs captured?	Already correctly captured by an existing specialised service line (NCBPS code within the PSS Tool If activity costs are already captured please specify the specialised service code and description (e.g. NCBPS01C Chemotherapy). NCBPS12d If activity costs are already captured please specify whether this service needs a separate code. <u>No</u> If the activity is captured but the service line needs amendment please specify whether the proposed amendments have been documented and agreed with the Identification Rules team. If the activity is not captured please specify whether the proposed

	identification rules have been documented and agreed with the Identification Rules team.
A7 Monitoring	
A7.1 Contracts	None
Specify any new or revised data flow or data collection	Please specify
requirements, needed for inclusion in the NHS Standard Contract Information Schedule.	Data flows according to HSS already in place
Please identify any excluded drugs or devices relevant to the service and their current status with regard to NHS England specialised services commissioning.	
A7.2 Business intelligence	Yes
Is there potential for duplicate reporting?	If yes, please specify mitigation:
	Application of the HSS code to activity
A7.3 Contract monitoring	No
Is this part of routine contract monitoring?	If no, please specify contract monitoring requirement:
	Would be reported under usual HSS contract monitoring as activity labelled as HSS.
A7.4 Dashboard reporting	No
Specify whether a dashboard exists for the proposed service?	If yes, specify how routine performance monitoring data will be used for dashboard reporting.
	If no, will one be developed?
	No – activity and mortality are monitored through an agreed contract with

	NHS BT. Discussions have started concerning the collection of other outcome data including QoL for transplantation
A7.5 <b>NICE reporting</b> Are there any directly applicable NICE or equivalent quality standards which need to be monitored in association with the new service specification?	No If yes, specify how performance monitoring data will be used for this purpose.
Section B	B - Service Impact
B1 Service Organisation	
B1.1 Describe how the service is currently organised? (i.e. tertiary centres, networked provision etc.)	There are 2 adult centres and 2 paediatric transplant centres. Currently there is an inconsistent approach to how patients are being followed up. The specification changes are intended to clarify ongoing responsibility for the transplant centres to have long term responsibility for management of patients. <i>Source: required</i>
B1.2 Will the specification change the way the commissioned service is organised?	Yes Please specify: The transplant centres will be responsible for the long term care of patients post transplant <i>Source: required</i>
B1.3 Will the specification require a new approach to the organisation of care?	Implement a new model of carePlease specify:The intention of the changes to the specification are to ensure the transition of patients within the national service is well managed and age appropriate and to formalise the model of care for patient follow up. All

	transplant recipients require regular follow up post-operative care. Follow up must be patient focused and units should consider local shared care arrangements with blood tests and telephone follow up in addition to clinic visits.
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### B2 Geography & Access

B2.1 Where do current referrals come from?	Select all that apply:		
	GP		
	Secondary care		
	Tertiary care	$\boxtimes$	
	Other		
	Please specify:	<u>.                                    </u>	
	Click here to enter text.		
P2.2 W/bat impact will the new convice aposition have on the	No impost		
B2.2 What impact will the new service specification have on the sources of referral?	No impact Please specify:		
	Click here to enter text.		
B2.3 Is the new service specification likely to improve equity of	<u>No impact</u>		
access?	Please specify:		
	Click here to enter text.		
	Source: Equalities Impact Ass	sessmen	t
B2.4 Is the new service specification likely to improve equality of	Increase		
access and/or outcomes?	Please specify:		

	The intention is to formalise the approach to the centre's responsibility for managing patient's long term and bring this into line with other transplant services, thereby improving long term outcomes for patients and appropriate drug therapies. Ensuring appropriate transiton plans are in place will improve patient care, in the past it has been difficult at times to transition patients from paediatric to adult services. <i>Source: Equalities Impact Assessment</i>
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## **B3** Implementation

B3.1 Will commissioning or provider action be required before	No action required
implementation of the proposition can occur?	Please specify:
	Click here to enter text.
B3.2 Time to implementation:	<u>No - go to B3.4</u>
Is a lead-in time required prior to implementation?	If yes, specify the likely time to implementation: Enter text
B3.3 Time to implementation:	<u>No - go to B3.4</u>
If lead-in time is required prior to implementation, will an interim plan	If yes, outline the plan:
for implementation be required?	Click here to enter text.
B3.4 Is a change in provider physical infrastructure required?	No
	Please specify:
	Click here to enter text.
D2.5 lo o chongo in provider staffing required?	
B3.5 Is a change in provider staffing required?	No
	Please specify:
	Click here to enter text.

B3.6 Are there new clinical dependency and/or adjacency requirements that would need to be in place?	No Please specif Click here to	•		
B3.7 Are there changes in the support services that need to be in place?	No Please specif Click here to			
B3.8 Is there a change in provider and/or inter-provider governance required? (e.g. ODN arrangements / prime contractor)	management identify and n Shared care i	ntinue to be interp of follow up of pa	provider relationships atients Routine follov ging problems relation with the referrer	v-up is intended to
B3.9 Is there likely to be either an increase or decrease in the number of commissioned providers? If yes, specify the current and	No change Please complete the table:			
estimated number of providers required in each region	Region	Current no. of providers	Future State expected range	Provisional or confirmed
	North	0	0	<u>C</u>
	Midlands & East	2	2	<u>C</u>
	London	1	1	<u>C</u>
	South	1	1	<u>C</u>
	Total	4	4	<u>C</u>
	Please specif	y:		

	Published service specifications A02/S(HSS)/b Small bo transplantation service (Adult) E03/S(HSS)/c Small bow service - paediatrics	
B3.10 Specify how revised provision will be secured by NHS	Select all that apply:	
England as the responsible commissioner.	Publication and notification of new service specification	
	Market intervention required	
	Competitive selection process to secure increase or decrease provider configuration	
	Price-based selection process to maximise cost effectiveness	
	Any qualified provider	
	National Commercial Agreements e.g. drugs, devices	
	Procurement	
	Other	
	Please specify: Click here to enter text.	
B4 Place-based Commissioning		
B4.1 Is this service currently subject to, or planned for, place-base commissioning arrangements? (e.g. future CCG lead, devolved commissioning arrangements, STPs)	ed No Please specify: Click here to enter text.	

### C1 Tariff/Pricing

C1.1 How is the service contracted and/or charged?	Select all	that apply:	
Only specify for the relevant section of the patient pathway		Not separately charged – part of local or national tariffs	
	Drugs	Excluded from tariff – pass through	$\boxtimes$
		Excluded from tariff - other	
		Not separately charged – part of local or national tariffs	
	Devience	Excluded from tariff (excluding ZCM) – pass through	
	Devices	Excluded from tariff (excluding ZCM) – other	
		Via Zero Cost Model	
		Paid entirely by National Tariffs	
		Paid entirely by Local Tariffs	$\boxtimes$
		Partially paid by National Tariffs	
	Activity	Partially paid by Local Tariffs	
		Part/fully paid under a Block arrangement	
		Part/fully paid under Pass-Through arrangements	
		Part/fully paid under Other arrangements	
C1.2 <b>Drug Costs</b> Where not included in national or local tariffs, list each drug or combination, dosage, quantity, <b>list</b> price including VAT if applicable and any other key information e.g. Chemotherapy Regime.	work strear responsibil	opression – the funding of these drugs is subject to an one m by NHS England that started in 2014, repatriation of one ity from CCGs to NHS England. Some progress has been ansplant services in some parts of the country.	going

NB discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.	
C1.3 <b>Device Costs</b> Where not included in national or local tariff, list each element of the excluded device, quantity, <b>list or expected</b> price including VAT if applicable and any other key information. NB: Discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.	Not applicable
C1.4 Activity Costs covered by National Tariff List all the HRG codes, HRG descriptions, national tariffs (excluding MFF), volume and other key costs (e.g. specialist top up %)	Not applicable
C1.5 Activity Costs covered by Local Tariff List all the HRGs (if applicable), HRG or local description, estimated average tariff, volume and any other key costs. Also indicate whether the Local Tariff(s) is/are newly proposed or established and if newly proposed how is has been derived, validated and tested.	The data extract is based on treatment received by the transplant cases.In the data extract there are 55 day case HRG's , 15 elective and 76 non elective and within out patients there are 28 TFC's
C1.6 Other Activity Costs not covered by National or Local Tariff Include descriptions and estimates of all key costs.	Not applicable
C1.7 Are there any prior approval mechanisms required either during implementation or permanently?	No Please specify: Click here to enter text.
C2 Average Cost per Patient	

C2.4 What is the estimated east new patient to NUIC England in			
C2.1 What is the estimated cost per patient to NHS England, in years 1-5, including follow-up where required?	YR1	£6.6k	-
	YR2	£6.6k	
	YR3	£6.6k	
	YR4	£6.6k	
	YR5	£6.6k	
Are there any changes expected in year 6-10 which would impact the model?	lf yes, pleas Additional fo	e specify: bllow up patients	
C3 Overall Cost Impact of this Service specification to NHS Eng	land		
C3.1 Specify the budget impact of the proposal on NHS England in relation to the relevant pathway.	Cost press Please spec		
	The costs of	f small bowel transplant	s treatments not covered by NHSE reating an average of 64 patients.
C3.2 If the budget impact on NHS England cannot be identified set out the reasons why this cannot be measured.	Not applicat	ble	
C3.3 If the activity is subject to a change of commissioning responsibility, from CCG to NHS England, has a methodology for the transfer of funds been identified, and calculated?	identify the r		een analysed over the last 5 years to lata has been analysed so that we transplant
C4 Overall cost impact of this service specification to the NHS a	as a whole		
C4.1 Specify the budget impact of the proposal on other parts of the	Budget impa	act for CCGs:	
	20		

NHS.	Cost savingBudget impact for providers:Cost neutralPlease specify:No impact on each of the four providers in total there may be switchesbetween providers
C4.2 Taking into account responses to C3.1 and C4.1, specify the budget impact to the NHS as a whole.	Cost neutral Please specify: The service specification does not change the level of activity or prices charged
C4.3 Where the budget impact is unknown set out the reasons why this cannot be measured	Not applicable
C4.4 Are there likely to be any costs or savings for non-NHS commissioners and/or public sector funders?	No Please specify: Click here to enter text.
C5 Funding	
C5.1 Where a cost pressure is indicated, state known source of funds for investment, where identified, e.g. decommissioning less clinically or cost-effective services.	CPAG Prioritisation Funding. It is suggested that the costs within CCG's could be transferred to NHSE if this is not possible then prioritisation is sought
C6 Financial Risks Associated with Implementing this Service sp	pecification

C6.1 What are the material financial risks to implementing this service specification?	The risk is the additional costs to NHSE are based on actual activity over time whether post transplant costs increase per patient. This is not expected to happen.
C6.2 How can these risks be mitigated?	Patient numbers are small and any growth will be limited so risk is minimal. Contract mechanisms could be put in place to deal with outlier episodes of care.
C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?	Patient level data has been reviewed so real life episode scenarios have been modelled.
C6.4 What scenario has been approved and why?	
C7 Value for Money	
C7.1 What published evidence is available that the service is cost	There is no published evidence of cost-effectiveness
	There is no published evidence of cost-effectivenessPlease specify:NHS England has committed to supporting solid organ transplantation and growth in transplantation as a service strategy. In fact the number of small bowel transplants that are done each year is very small and stable, there is however cumulative growth in numbers of survivors and therefore numbers of patients to be followed up.
C7.1 What published evidence is available that the service is cost	Please specify: NHS England has committed to supporting solid organ transplantation and growth in transplantation as a service strategy. In fact the number of small bowel transplants that are done each year is very small and stable, there is however cumulative growth in numbers of survivors and therefore

	Available pricing data suggests the service is lower cost compared to current/comparator treatment	
	Available clinical practice data suggests the new service specification has the potential to improve value for money	
	Other data has been identified	
	No data has been identified	$\boxtimes$
	The data supports a high level of certainty about the impact on value	
	The data does not support a high level of certainty about the impact on value	

#### C8 Non-Recurrent Costs

C8.1 Are there non-recurrent revenue costs associated with this service specification?	No         If yes, please specify and indicate whether these would be incurred or passed through to NHS England:         If the costs are to be passed through to NHS England please indicate whether this has been taken into account in the budgetary impact.
C8.2 Are there any non-recurrent provider capital costs associated with the service specification?	No If yes, please specify and indicate with there is a separate source of funding identified (commissioners cannot reimburse capital costs). Click here to enter text.