

Integrated Impact Assessment Report for Service Specifications			
Service Specification Reference Number	1653		
Service Specification Title	Complex Gynaecology: Genito-Urinary Tract Fistulae (Girls and Women aged 16 and above) for routine commission (source A3.1)		
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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 - Activity Impact		
A1 Current Patient Population & Demography / Growth		
A1.1 Prevalence of the disease/condition.	No prevalence data available but the Specification Working Group Clinical Lead notes based on HES data:	
	Vesico-Vaginal Fistula Repair 100/year (range 84-111)	
	Mean age 51 years	
	Urethro-Vaginal Fistula Repair 14/year (range 11-17)	
	Mean age 43 years	
	Source: Service Specification Proposition section 3.2,3.4	
A1.2 Number of patients currently eligible for the service according to the proposed service specification commissioning criteria.	Source: Cromwell D, Hilton P. Retrospective cohort study on patterns of care and outcomes of surgical treatment of lower urinary tract fistula among English National Health Service Hospitals between 2000 - 2009.BJUInt. 2013; 111: 252-262 Please specify In the absence of prevalence data, the diagnosis is 300 per year of which 200 referrals per year are made for surgical intervention of which 160 patients are assessed per year and mean number operated/year = 120 and 40 are not fit for or decline surgery and are discharged back for local/GP management. Those not referred may have conditions such as cancer, which rule out surgery or prefer not to have intervention. It is not clear what happens to non-operated cases (Cromwell D, Hilton P. Retrospective cohort study on patterns of care and outcomes of surgical treatment of lower urinary tract fistula among English National Health	

			009.BJUInt. 2013; 111: 252-262 – ileal conduit (29 women)).
A1.3 Age group for which the service is proposed according to the service specification commissioning criteria.	Girls and Women ag	ged 16 and abo	<u>ove</u>
A1.4 Age distribution of the patient population eligible according to the proposed service specification commissioning criteria	Age 16 and above Click here to enter tex	ĸt.	
A1.5 How is the population currently distributed geographically?	Evenly If unevenly, estimate	regional distrib	oution by %:
	North	enter %	
	Midlands & East	enter %	
	London	enter %	
	South	enter %	
	Source: Service specify Please specify Click here to enter tex		sition section 6
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		
A2.2 Are there likely to be changes in demography of the patient	<u>No</u>		

population and would this impact on activity/outcomes?	Please specify	/	
	Source: Servi	ce specification p	proposition section 3.2
A2.3 Expected net increase or decrease in the number of patients	YR2 +/-	2	
who will be eligible for the service, according to the proposed service specification commissioning criteria, per year in years 2-5	YR3 +/-	3	
and 10?	YR4 +/-	4	
	YR5 +/-	5	
	YR10 +/-	10	
	·	tal Episode Stati d stable over the	stics data suggests fistula repair numbers past 5 years.
Are these numbers in line with ONS growth assumptions for the age specific population? If not please justify the growth assumptions made.	Yes Click here to enter text.		
A3 Activity			
A3.1 What is the purpose of new service specification?	Revision to a	n existing publi	shed service specification
	*PSSAG (Prescribed Specialised Services Advisory Group)		
	care planning a genito-urina care across th	and surgical inte ry tract fistula. T	evide high quality assessment, diagnostics, rvention where appropriate for women with the service will provide continuity of expert and will involve other specialists identified in e.
	outcomes from	n less experience	to variation in patient experience and ed surgeons undertaking less than one er year each (with a far higher failure rate)

A4.1 Patient pathway	Referral to a District General Hospital gynaecology or urology department,
A4 Patient Pathway	
A3.3 What is the estimated annual activity associated with the proposed service specification proposition pathway for the eligible population?	Source: Specification Working Group Lead Clinician Please specify See A3.2 above
A3.2 What is the annual activity associated with the existing pathway for the eligible population?	200 referrals, of which 40 are declined as they are deemed unfit for or decide not to proceed with UVF or VVF surgery, and are referred back for local/GP management.
	and some having a higher urinary diversion rate than would be expected. Urinary diversion is more significant and life changing surgery than fistula repair and may not be required in many fistula patients. It often results in a reduced quality of life consequent to the formation of an external conduit with an adherent urinary collection device or the need to perform catheterisation of a bowel neobladder. There is a correlation in the likelihood of the more invasive abdominal fistula repair surgery being performed in low volume centres and such centres have a median of eight days length of stay. There is also a correlation between the likelihood of the less invasive vaginal repair being undertaken in centres with higher volumes due to the surgeons in these centres being more experienced in these procedures. These centres have a median four day post-operative stay. Click here to enter text.

A4.2. What are the current service access and stopping criteria? Access criteria: Under the current specialised services specification or GP to any willing gynamurologist for treatment in whichever manner is felt appropriate by clinician. Stopping criteria: Successful closure of VVF with minimal symptoms at six month follow-up, successful urinary diversion is for primary fistula closure (then requires life-long follow-up as prindividuals with urinary diversion), patient declining or unfit for some source: Existing NHS England specification and Specification in the successful unitary diversion.	
Group.	ecologist or by that mal f unsuitable er all surgery.
A4.3 What percentage of the total eligible population is expected to: If not known, please specify Click here to enter text.	
a) Be referred to the proposed service a) 100	
b) Be eligible for care according to the proposed criteria for the service b) 80	
c) Take up care according to the proposed criteria for the service c) 80	
d) Continue care according to the proposed criteria for the d) 80	
service? Source: required	

A4.5 Specify the nature and duration of the proposed new service or intervention.	Time limited For time limited services, specify frequency and/or duration. Consultant telephone or face to face follow up at 12 months and unle problems, discharge back to GP if all is well. Source: Service Specification Section 2.2, p6.		p at 12 months and unless	
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: out	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	6		
eligible population by region?	MIDLANDS & EAST	1		

LONDON	4
SOUTH	4
Total	15

There are 15 providers who are contracted to provide the current specialised E10/S/e Complex Gynaecology: Urinary Fistulae service. There are up to 100 providers coding activity for urinary or vesico vaginal fistula. A review published in 2012 of Hospital Episode Statistics (HES) data and outcomes for the period 2000-2009 (Cromwell D; Hilton.P; (2013) Retrospective cohort study on patterns of care and outcomes of surgical treatment for lower urinary-genital tract fistula among English National Health Service hospitals between 2000 and 2009): 490 consultants undertook 905 VVF/UVF procedures; 289 centres only performed one repair or attempted repair in this time period; only three centres performed an average of more than three such procedures per year.

A5.3 Does the proposition require a change of delivery setting or capacity requirements?

<u>yes</u>

The number of contracted and non-contracted providers needs to reduce.

Please specify: NHS England will need to formally designate or procure those procedures through a small number of providers as part of a wider complex gynaecology strategy.

Patients will go to one of the small number of expert centres, which will be a change in the location of expert assessment and treatment. Capacity requirements will depend upon the number of sites determined.

Source: Specification Working Group

A6 Coding				
A6.1 Specify the datasets used to record the new patient pathway	Select all that apply:			
activity.	Aggregate Contract Monitoring *			
*expected to be populated for all commissioned activity	Patient level contract monitoring	\boxtimes		
	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 addition, for audit purposes, activity related to the recorded in the BAUS FNUU registry or the BAUS= British Association of Urological Surgeous FNUU= Functional, Neuro-Urology and Urodyn BSUG = British Society of Urogynaecology RCOG = Royal College of Obstetrics and Gynaecology	he new pathway would also BSUG RCOG database. ons amics		
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:	Not applicable		
How are any drug costs captured?	If already specified in the current NHS England Drug / Devices List, please specify drug name and indication for all that apply: Click here to enter text. If drug(s) NOT already been specified in the current NHS England Drug List please give details of action required and confirm that this has been discussed with the pharmacy lead: Click here to enter text.		
A6.4 Identification Rules for Devices:	Not applicable		
How are device costs captured?	If device(s) covered by an existing category of In Device Category (as per the National Tariff Pays for all that apply: Click here to enter text. If device(s) not excluded from Tariff nor covered Local prices please specify details of action required has been discussed with the HCTED team. Click here to enter text.	ment System Guid	dance) ational or
A6.5 Identification Rules for Activity: How are activity costs captured?	Already captured by an existing specialised code) within the PSS Tool but needs amend		BPS
Tiow are delivity costs captured:	i) This service specification covers the pro- effective care pathway including surgical	ision of a safe and	

genito-urinary tract fistula where the fistula does not heal spontaneously. A fistula repair is the treatment which takes place following (post) the surgery or intervention which caused or precipitated it – the 'precipitating' surgery/intervention. A fistula can occur following surgery (such as a caesarean section or colorectal, urological or gynaecological surgery such as a hysterectomy); or an intervention such as radiotherapy. The repair surgery will include the following procedures as appropriate and the main diagnostic codes for this service are ICD10, N360, N820 and N821 and operative codes are OPCS4, P251 and P252. The 1st Revisional Surgery (second) is (Y71.3), the 2nd Revisional Surgery (Y71.6), the 3rd or More Revisional Surgery is (Y71.7).

- NCBPS04D there is an inconsistency between this and NCBPS023S as OPCS M191 and M192 OPCS codes for adults are currently missing.
- ii) NCBPS023X there is an inconsistency here as it is not picking up patients aged 18 and under (23x) and it needs to
- (iv) there is a high probability that some activity is being erroneously coded to/by CCGs needs resolving as CCGs are not picking up the dominant procedure Y code and need to include it

If the activity is not captured please specify whether the proposed identification rules have been documented and agreed with the Identification Rules team. Choose an item.

A7 Monitoring

A7.1 Contracts

Specify any new or revised data flow or data collection requirements, needed for inclusion in the NHS Standard Contract Information Schedule.

Please identify any excluded drugs or devices relevant to the

None

Please specify

Click here to enter text.

service and their current status with regard to NHS England specialised services commissioning.				
A7.2 Business intelligence	No No			
Is there potential for duplicate reporting?	If yes, please specify mitigation: Click here to enter text.			
A7.3 Contract monitoring	Yes			
Is this part of routine contract monitoring?	If no, please specify contract monitoring requirement: Click here to enter text.			
A7.4 Dashboard reporting	No No			
Specify whether a dashboard exists for the proposed service?	If yes, specify how routine performance monitoring data will be used for dashboard reporting.			
	Click here to enter text.			
	If no, will one be developed?			
	Click here to enter text.			
A7.5 NICE reporting	No No			
Are there any directly applicable NICE or equivalent quality standards which need to be monitored in association with the new	If yes, specify how performance monitoring data will be used for this purpose.			
service specification?	Click here to enter text.			
Section B - Service Impact				
B1 Service Organisation				
B1.1 Describe how the service is currently organised? (i.e. tertiary centres, networked provision etc.)	Any willing urological and gynaecology surgeons in District General and some Tertiary centres provide assessment and surgery for urinary and			
	10			

	vesico vaginal fistulas bu Source: HES data requir		variable results and outcomes.
B1.2 Will the specification change the way the commissioned service is organised?	Yes Please specify:		
	diagnosis to one of the n will have imaging underta available and will attend plan surgical manageme	ational expe aken locally the national nt and then entre and dis all is satisfac	,
B1.3 Will the specification require a new approach to the organisation of care?	treatment Please specify:	to the small	pport appropriate selection of ler number of units that will be
B2 Geography & Access			
B2.1 Where do current referrals come from?	Select all that apply:		
	GP		
	Secondary care	\boxtimes	
	Tertiary care	\boxtimes	
	Other		

	Please specify: Click here to enter text.
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 access?	No impact Please specify: Click here to enter text. Source: Equalities Impact Assessment
B2.4 Is the new service specification likely to improve equality of access and/or outcomes?	Increase Please specify: Click here to enter text. Source: Equalities Impact Assessment
B3 Implementation	
B3.1 Will commissioning or provider action be required before implementation of the proposition can occur?	Provider selection action Please specify: Commissioner and Commissioning Hub to co-ordinate and oversee the reduction in the number of units.
B3.2 Time to implementation: Is a lead-in time required prior to implementation?	Yes - go to B3.3 If yes, specify the likely time to implementation: Enter text

B3.3 Time to implementation:	<u>Yes</u>
If lead-in time is required prior to implementation, will an interim plan	If yes, outline the plan:
for implementation be required?	Provider selection process Regionally led and timeline to be determined
	reionally
B3.4 Is a change in provider physical infrastructure required?	Yes
Bo.4 is a change in provider physical infrastructure required.	Please specify:
	There will be a reduction in the number of centres which are permitted to
	undertake this complex gynaecology surgery.
B3.5 Is a change in provider staffing required?	<u>No</u>
	Please specify:
	The centres which are permitted to undertake this surgery will already
	have the staffing required.
B3.6 Are there new clinical dependency and/or adjacency	<u>No</u>
requirements that would need to be in place?	Please specify:
	Click here to enter text.
B3.7 Are there changes in the support services that need to be in	No No
place?	Please specify:
	Click here to enter text.
B3.8 Is there a change in provider and/or inter-provider governance	No No
required? (e.g. ODN arrangements / prime contractor)	Please specify:
	Click here to enter text.
B3.9 Is there likely to be either an increase or decrease in the	<u>Decrease</u>
number of commissioned providers? If yes, specify the current and	

estimated number of providers required in each region	Please comp	lete the table:		
	Region	Current no. of providers	Future State expected range	Provisional or confirmed
	North	6	1	<u>P</u>
	Midlands & East	1	1	<u>P</u>
	London	4	1	<u>P</u>
	South	4	1	<u>P</u>
	Total	15	Up to 4, with one in each Region	<u>P</u>
	Please specif	fy:		
	another meth	od – with provide	ss – which may be any rs proving whether the a (based on the service	y can evidence that
B3.10 Specify how revised provision will be secured by NHS	Select all the	at apply:		
England as the responsible commissioner.	Publication and notification of new service specification			
	Market intervention required			\boxtimes
	Competitive selection process to secure increase or decrease provider configuration			
	Price-based selection process to maximise cost effectiveness			
	Any qualified provider			\boxtimes
	National Co	mmercial Agreem	es 🗆	
				-

	Procurem	ent	
	Other		
	Please spe	ecify:	
	To be confi	irmed	
B4 Place-based Commissioning			
B4.1 Is this service currently subject to, or planned for, place-based	<u>No</u>		
commissioning arrangements? (e.g. future CCG lead, devolved commissioning arrangements, STPs)	Please spe	•	
	Click here	to enter text.	
Section C	- Finance In	mpact	
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	
		Excluded from tariff - other	
		Not separately charged – part of local or national tariffs	
		Excluded from tariff (excluding ZCM) – pass through	
	Devices	Excluded from tariff (excluding ZCM) – other	
		Via Zero Cost Model	
		1	1

		Paid entirely by National Tariffs	\boxtimes
		Paid entirely by Local Tariffs	
		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 Drug Costs Where not included in national or local tariffs, list each drug or combination, dosage, quantity, list price including VAT if applicable and any other key information e.g. Chemotherapy Regime. NB discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.	Not applica	ble	
C1.3 Device Costs Where not included in national or local tariff, list each element of the excluded device, quantity, list or expected 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 applica	ble	
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 %)	Outpation	ould have: one x new (£142) and one follow up (£54) Gynaecology ent attendance (HRG: 101/502) one x new (£159) and one follow up (£68) Urology Outpa	ıtient

	 attendance (HRG: 101/502) Year 1: one x Telephone consultation follow up £23 (101/502) Year 1: One x day case Diagnostic Flexible Cystoscopy, 19 years and over (TFC LB72A) (£244) OR Year 1: one x Diagnostic Flexible Cystoscopy, 18 years and under (TFC LB72B) (£707) (depending on age of patient) Year 1: one x Contrast Fluoroscopy Procedures with duration of less than 20 minutes (RD30Z/ 31Z) (£118) Year 1: one x Surgery: VA/ AA (MA01Z) (£3,792) OR one x Surgery: UD - Ileal Conduit (LB10C/D + LB67C/D) (£6,655) OR one x Surgery: UD - Neo Bladder (LB10C/D + LB67C/D) (£6,655)
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.	Not applicable – covered by national tariff
C1.6 Other Activity Costs not covered by National or Local Tariff Include descriptions and estimates of all key costs.	Not applicable– covered by national tariff
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	
C2.1 What is the estimated cost per patient to NHS England, in years 1-5, including follow-up where required?	YR1 £4,940.00

	YR2	£4,940.00	
	YR3	£4,940.00	
	YR4	£4,940.00	
Are there any changes expected in year 6-10 which would impact	YR5	£4,940.00	
the model?	If yes, plea	se specify:	
	Click here t	o enter text.	
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 neutr		
relation to the relevant pathway.	Please spe	•	
	Click nere t	o enter text.	
C3.2 If the budget impact on NHS England cannot be identified set out the reasons why this cannot be measured.	Not applica	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?	Not applica	ble	
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 imp	act for CCGs:	
NHS.	Cost neutr		
	Budget imp	act for providers:	

	Cost neutral Please specify:
	Click here to enter text.
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:
	Click here to enter text.
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.	Not applicable
C6 Financial Risks Associated with Implementing this Service sp	pecification
C6.1 What are the material financial risks to implementing this service specification?	None – cost neutral

C6.2 How can these risks be mitigated?	Not applicable	
C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?	Not applicable - cost neutral.	
C6.4 What scenario has been approved and why?	Cost neutral.	
C7 Value for Money		
C7.1 What published evidence is available that the service is cost effective as evidenced in the evidence review?	Published evidence indicates service specification has the potential to be cost-effective Please specify: There is evidence that high volume VVF centres have half the failure of lower volume centres and are far more likely to repair a fistula successfully than perform a urinary diversion such as an ileal conduit (urinary diversion) Cromwell D, Hilton 2013. Five per cent of women VVF will have associated upper tract problems such as ureteric obstror uretero-vaginal fistula and require abdominal repair the majority of rest should be suitable for and have a vaginal repair which is less invand less costly. This does not happen now.	rate t with ruction
C7.2 Has other data been identified through the service	Select all that apply:	
specification development relevant to the assessment of value for money?	Available pricing data suggests the service specification is equivalent cost compared to current/comparator service specification	
	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	
	The data supports a high level of certainty about the impact on value	\boxtimes
	The data does not support a high level of certainty about the impact on value	
	Please specify: Click here to enter text.	
C8.1 Are there non-recurrent revenue costs associated with this	No If yes, please specify and indicate whether these would be incurred passed through to NHS England:	l or
C8.1 Are there non-recurrent revenue costs associated with this	If yes, please specify and indicate whether these would be incurred	l or
C8 Non-Recurrent Costs C8.1 Are there non-recurrent revenue costs associated with this service specification?	If yes, please specify and indicate whether these would be incurred passed through to NHS England: Click here to enter text. If the costs are to be passed through to NHS England please indicate whether this has been taken into account in the budgetary impact.	
C8.1 Are there non-recurrent revenue costs associated with this	If yes, please specify and indicate whether these would be incurred passed through to NHS England: Click here to enter text. If the costs are to be passed through to NHS England please indicate.	