

Integrated Impact Assessment Report for Clinical Commissioning Policies

Policy Reference Number	B16X01		
Policy Title	Robotic assisted trans-oral surgery fo	or throat and voice box car	ncers
Accountable Commissioner	Kim Fell	Clinical Lead	Vinidh Paleri
Finance Lead	Justine Stalker Booth	Analytical Lead	Ceri Townley
	Section K - Act	ivity Impact	
Theme	Questions	Comments (Include sou made and any issues wi	urce of information and details of assumptions ith the data)
K1 Current Patient Population & Demography / Growth	K 1.1 What is the prevalence of the disease/condition?	K1.1 The policy propose assisted surgery (TORS These two cancers are o of the most common car	ed to not routinely commission trans oral robotic) for cancers of the oropharynx and supraglottis. classed as head and neck cancers, which are one neers in England.
		Head and neck cancer h around 50,000 in 2010. ⁱ cancers is around 18:10	has an estimated prevalence of 90:100,000 or The crude incidence rate of head and neck 10,000. ⁱⁱ
		In England, the incidenc cancer are 3.5:100,000 within laryngeal cancer, around 7 per million. ^{iv} In	e rates of laryngeal cancer and oropharyngeal and 4.4:100,000 respectively. ⁱⁱⁱ Supraglottis falls and has an estimated incidence in England of England in 2014/15, it is estimated that around

K.1.2 What is the number of patients currently eligible for the treatment under the proposed policy?	2,900 people per year are diagnosed with cancer of the oropharynx (~ 2,500) or supraglottis (~ 400). ^v K1.2 TORS is most likely to be suitable for patients with oropharyngeal cancer indications of T1N0 to T2N1, ^{vi} as well as being suitable for some patients with cancer of the supraglottis. TORS enables the surgeon to resect squamous and non-squamous cancers without disrupting the external muscles of the throat, and can give better access to tumours in otherwise hard to reach areas in this region. ^{vii} There are estimated to be 430 to 720 patients eligible for TORS. ^{viii} This is around 20% of the population diagnosed with cancer of the oropharynx or supraglottis.
K1.3 What age group is the treatment indicated for?	K1.3 The policy relates to adults (18 years and over).
K1.4 Describe the age distribution of the patient population taking up treatment?	K1.4 This condition mainly affects adult males, and is most frequently diagnosed in those aged 55 years to 64 years. ^{ix}
K1.5 What is the current activity associated with currently routinely commissioned care for this group?	 K1.5 For the population that is eligible for TORS, the current activity is estimated to be in the region of:^x Chemoradiotherapy: 151 to 251 patients Open surgery: 43 to 72 patients Transoral laser microsurgery (TLM): 87 to 144 patients TORS: 43 to 72 Radiotherapy: 178 to 297
K1.6 What is the projected growth of the disease/condition prevalence (prior to applying the new policy) in	 K1.6 In future, the number of patients diagnosed with oropharyngeal and supraglottal cancer is estimated to be in the region of :^{xi} ~3,300 in 2016/17

a - 1/a a	
2, 5, and 10 years?	• ~3,600 in 2017/18
	• ~4 500 in 2020/21
K1.7 What is the associated	K1.7 Activity is estimated to grow in line with the overall population
projected growth in activity (prior to	requiring treatment as there are no expected pathway changes. Based on
applying the new policy) in 2.5 and	this growth rate, the future activity for the eligible population set out in K1.2
	is estimated to be in the range of xi
10 years?	is estimated to be in the range of.
	Chemoradiotherany; XIII
	Chemoradiotherapy.
	 ~175 - 291 in 2016/17
	• ~188 - 313 in 2017/18
	225 201 in 2020/21
	• ~255 - 591 11 2020/21
	Open surgery:
	• ~ 52 - 87 in 2016/17
	• $\sim 58 - 96$ in 2017/18
	• ~ 75 - 126 IN 2020/21
	TLM:
	 ~ 105 - 176 in 2016/17
	• ~ 115 - 192 in 2017/18
	- 161 - 252 in 2020/21
	• ~ 151 - 252 11 2020/21
	TORS:
	 ~ 43 - 72 in future years
	·
	Radiotherapy:
	$\frac{1}{2}$
	• ~207 - 345 in 2016/16
	 ~223 - 371 in 2017/18
	• ~278 - 463 in 2020/21
K1.9 How is the negulation summarthy	K1.8 The population is distributed across England, but most registrations
KI.8 How is the population currently	The population is distributed across England, but most registrations
	are in the North West and South East of the country. ^{xiv} These cancers are

	distributed geographically?	largely linked to lifestyle factors such as alcohol consumption and smoking and are therefore associated with deprivation. ^{xv}
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?	K2.1 TORS is already being carried out at a number of centres in England, but NHS England does not have a commissioning policy for the surgery. Under this policy, TORS would not be routinely commissioned.
	K2.2 Please describe any factors likely to affect growth in the patient population for this intervention (e.g. increased disease prevalence, increased survival)	K2.2 Human papillomavirus (HPV) incidence and lifestyle factors such as smoking and alcohol affect the growth in the population. ^{xvi} As the population ages, this may also affect the growth of these cancers. ^{xvii}
	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	K2.3 No evidence of any changes was identified.
	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?	K2.4 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.
		As compared to the do nothing case, there would be a net decrease in the number accessing TORS every year, with around 45 to around 70 fewer patients accessing the service as compared to the 'do nothing' scenario each year.

		These patients are assumed to take up comparator surgical procedures (open surgery and TLM) in their relative proportion to current activity. ^{xviii}
K3 Activity	K3.1 What is the current annual activity for the target population covered under the new policy? Please provide details in accompanying excel sheet	K3.1 For the target population, the levels of current (2014/15) activity have been estimated in K1.5. xix
	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	 K3.2 Should the policy be implemented, i.e. TORS is not routinely commissioned, TORS would no longer be undertaken except as described in K2.4. As a result, activity of comparators is expected to rise by the number of patients no longer undergoing TORS in the future. Therefore, activity under the policy is estimated in the region of:^{xx} Chemoradiotherapy: ~175 - 291 in 2016/17 ~188 - 313 in 2017/18 ~235 - 391 in 2020/21 Open surgery: ~67 - 111 in 2016/17 ~72 - 120 in 2017/18 ~90 - 150 in 2020/21
		TLM: • ~ 134 - 223 in 2016/17 • ~ 144 - 240 in 2017/18 • ~ 180 - 300 in 2020/21 TORS: • ~ Very few if any

		Radiotherapy: • ~207 - 345 in 2016/16 • ~223 - 371 in 2017/18 • ~278 - 463 in 2020/21
	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	K3.3 The 'do nothing' case would be the same as the position set out in K1.7. ^{xxi}
K4 Existing Patient Pathway	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.	K4.1 Patients with oropharyngeal cancers can be treated by surgery (using open or minimally invasive approaches for tumour resection and reconstruction), radiotherapy, chemotherapy, or a combination of these methods. Surgical resection may include neck dissection to remove lymph nodes. When the malignancy is considered to be unresectable, palliative chemotherapy and radiotherapy can be used.
	K4.2. What are the current treatment access criteria?	K4.2 Not applicable.
	K4.3 What are the current treatment stopping points?	K4.3 Not applicable.
K5 Comparator (next best alternative treatment) Patient Pathway	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.	K5.1 Transoral Laser Microsurgery (TLM) is the current comparator. It is a minimally invasive procedure to remove oropharynx and supraglottis cancers through the mouth. The pathway would be the same for TORS and TLM.
	K5.2 Where there are different stopping points on the pathway please indicate how many patients	K5.2 Not applicable.

	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.	
K6 New Patient Pathway	K6.1 Describe or include a figure to outline associated activity with the patient pathway for the proposed new policy	K6.1 – K6.2 No change.
	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.	
K7 Treatment Setting	K7.1How is this treatment delivered to the patient? • Acute Trust: Inpatient/Daycase/Outpatie	K7.1 The procedure is carried out in an inpatient setting.
	 nt Mental Health Provider: Inpatient /Outpatient Community setting 	

	 Homecare delivery K7.2 Is there likely to be a change in delivery setting or capacity requirements, if so what? e.g. service capacity 	K7.2 Not applicable as the position is to not routinely commission.
K8 Coding	K8.1 In which datasets (e.g. SUS/central data collections etc.) will activity related to the new patient pathway be recorded?	K8.1 Patients undergoing trans oral surgery would be recorded in the Secondary Uses Services (SUS) dataset.
	K8.2 How will this activity related to the new patient pathway be identified?(e.g. ICD10 codes/procedure codes)	K8.2 This could be identified using a combination of ICD-10 and relevant OPCS codes. ^{xxii}
K9 Monitoring	K9.1 Do any new or revised requirements need to be included in the NHS Standard Contract Information Schedule?	K9.1 – K9.7 Not applicable.
	K9.2 If this treatment is a drug, what pharmacy monitoring is required?	
	K9.3 What analytical information /monitoring/ reporting is required?	
	K9.4 What contract monitoring is required by supplier managers? What changes need to be in place?	
	K9.5 Is there inked information required to complete quality dashboards and if so is it being incorporated into routine	

	 performance monitoring? K9.6 Are there any directly applicable NICE quality standards that need to be monitored in association with the new policy? 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 below	
	Section L - Serv	rice 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)	L1.1 Robotic surgery is currently carried out in specialist centres with the robotic equipment.
	L1.2 How will the proposed policy change the way the commissioned service is organised?	L1.2 No change.
L2 Geography & Access	L2.1 Where do current referrals come from?	L2.1 [Referrals currently come from tertiary centres] – Need to confirm with PWG
	L2.2 Will the new policy change / restrict / expand the sources of referral?	L2.2 No
	L2.3 Is the new policy likely to improve equity of access?	L2.3 Yes. Moving to a consistent commissioning position will improve equity of access.
	L2.4 Is the new policy likely to	L2.4 No

	improve equality of access / outcomes?	
L3 Implementation	L3.1 Is there a lead in time required prior to implementation and if so	L3.1 No
	when could implementation be achieved if the policy is agreed?	L3.2 No
	L3.2 Is there a change in provider physical infrastructure required?	L3.3 No
	L3.3 Is there a change in provider staffing required?	
	124 Are there now elipical	L3.4 No
	dependency / adjacency requirements that would need to be	
in place?	in place?	L3.5 No
	L3.5 Are there changes in the support services that need to be in place?	L3.6 No
	L3.6 Is there a change in provider / inter-provider governance required? (e.g. ODN arrangements / prime contractor)	L3.7 No
	L3.7 Is there likely to be either an increase or decrease in the number of commissioned providers?	L3.8 Not applicable.
	L3.8 How will the revised provision be secured by NHS England as the responsible commissioner? (e.g.	

L4 Collaborative Commissioning	publication and notification of new policy, competitive selection process to secure revised provider configuration)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 - Fina	nce 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?	M1.1 The underlying procedure for oropharyngeal and supraglottis cancer (mouth or throat procedures) is within tariff. ^{xxiii}
	M1.2 Is this treatment excluded from national prices?	M1.2 Partly. National prices apply for the main procedure, but robotic consumables are excluded from national tariff.
	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?	M1.3 Consumables for robotic assisted surgery are excluded form tariff. These are paid for by NHS trusts, with a current estimate from northern England at around £490 per procedure (in addition to the tariff). ^{xxiv}
	M1.4 If a new price has been	M1.4 Not applicable.

	proposed how has this been derived / tested? How will we ensure that associated activity is not additionally / double charged through existing routes.	
	M1.5 is VAT payable (Y/N) and if so has it been included in the costings?	M1.5 Not applicable.
	M1.6 Do you envisage a prior approval / funding authorisation being required to support implementation of the new policy?	M1.6 Not applicable.
M2 Average Cost per Patient	M2.1 What is the revenue cost per patient in year 1?	M2.1 Under the policy to not routinely commission, patients would undergo comparator treatments, as set out in K3.2. The cost for treating patients with the comparator treatments such as TLM or open surgery is estimated at c. £2,400 for the procedure.xxv
		estimated to be in the region of £490 for robotic consumables. ^{xxvi} This would be in addition to the baseline cost for the underlying mouth/throat procedure of an estimated c. £2,400, for a total of c. £2,900. ^{xxvii}
	M2.2 What is the revenue cost per patient in future years (including follow up)?	M2.2 Not applicable.
M3 Overall Cost Impact of this Policy to NHS England	M3.1 Indicate whether this is cost saving, neutral, or cost pressure to	M3.1 Cost saving. There could be a reduction in the cost to NHS England in relation to robotic consumables. The savings could be around £29k

	NHS England?	(range £21k - £35k) in 2016/17 assuming that around 60 individuals (43 to 72 individuals) would be receiving the procedure and the £490 cost applied to all procedures. ^{xxviii}
	M3.2 Where this has not been identified, set out the reasons why this cannot be measured?	M3.2 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)	M4.1. Cost neutral. As TORS would not be undertaken under the policy, no direct costs to other parts of the NHS apply. However, as set out in M2.2 there could be cost pressure to the extent that TORS helps reduce other costs for providers (e.g. in terms of reduced speech and language therapy rehabilitation needs). ^{xxix}
	M4.2 Indicate whether this is cost saving, neutral, or cost pressure to the NHS as a whole?	M4.Cost saving as described in M3.1.
	M4.3 Where this has not been identified, set out the reasons why this cannot be measured	M4.3 Not applicable.
	M4.4 Are there likely to be any costs or savings for non NHS commissioners / public sector funders?	M4.4 No cost savings for other funders were identified.
M5 Funding	M5.1 Where a cost pressure is indicated, state known source of funds for investment, where identified e.g. decommissioning less	M5.1 Not applicable.

	clinically or cost-effective services	
M6 Financial	M6.1 What are the material financial risks to implementing this policy?	M6.1 Not applicable.
	M6.2 Can these be mitigated, if so how?	M6.2 Not applicable.
	M6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?	M6.3 Not applicable.
M7 Value for Money	M7.1 What evidence is available that the treatment is cost effective? e.g. NICE appraisal, clinical trials or peer reviewed literature	M7 With respect to cost effectiveness, there was no evidence identified that would allow an assessment of the return on investment in improved outcomes. There was no direct evidence to address whether or not robotic surgery is likely to be cost effective in the event that it is only concentrated in a few special centres. Reporting on learning curves associated with the technique suggests that around 20 cases is sufficient for a proficient thoracic surgeon to realise benefits in perioperative outcomes and nodal upstaging over other procedures. There was no direct evidence relating to other aspects of surgeon or centre volume effects.
	M7.2 What issues or risks are	M7.2 The evidence on cost effectiveness was inconclusive, and so no specific risks have been identified with it.

	associated with this assessment? e.g. quality or availability of evidence	
M8 Cost Profile	M8.1 Are there non-recurrent capital or revenue costs associated with this policy? <i>e.g. Transitional costs, periodical costs</i>	M8.1 Not applicable.
	M8.2 If so, confirm the source of funds to meet these costs.	M8.2 Not applicable.

ⁱⁱⁱ Based on the National Head and Neck Cancer Audit 2013, DAHNO Ninth Annual Report. 2014 and as noted it the policy proposition. The National Head and Neck Cancer Audit is commissioned and by the Healthcare Quality Improvement Partnership (HQIP) as part of the National Clinical Audit and Patient Outcomes Programme (NCAPOP), and developed in partnership with the British Association of Head and Neck. <u>www.hscic.gov.uk/catalogue/PUB14257/clin-audi-supp-prog-head-neck-dahn-12-13.pdf</u>.

^{iv} Based on data from the National Head and Neck Cancer Audit 2013.

^v This figure is based on the National Head and Neck Cancer Audit 2013. Numbers are rebased to 2014/15 based on the growth rate set out in K1.6. The total number of malignant tumours of the larynx is estimated in the region of 1,700, which is the number listed in the policy proposition.

vⁱ T1N0 and T2N0 refer to cancer stages. "T" describes the size of the primary tumour, and "N" describes the extent of the cancer's spread to the lymph nodes.

vii Please refer to the policy proposition.

viii This range is based on 15% to 25% of the incident population noted in K1.1 being eligible for surgery, based on discussions with the policy working group. Based on DAHNO data, around 21% of the reported oropharyngeal cases were T1N0 to T2N1.

^{ix} Based on data from the Office for National Statistics (ONS) (2012), Cancer Registry.

* Figures are estimated for 2014/15 relate to treatment for the eligible population and are based on discussions with the clinicians from the policy working group. Includes follow up chemoradiotherapy (12%) and radiotherapy (28%) for the subset of the population that undergoes surgery as a first line treatment. These figures assume an estimated two TORS centres operating ~30 patients each per year in a 'mid' case (around 10% of the target population), and twice as much laser surgery. Much more invasive open surgery is estimated at similar levels to TORS, and the remaining patients not undergoing surgery are estimated to receive either chemoradiation or radiation alone as first line treatment. The activity figures presented are higher than the 430-720 eligible patients mentioned in K1.2 because some patients require follow-up chemoradiotherapy or radiotherapy (see above).

ⁱ National Cancer Intelligence Network (NCIN) 20 year prevalence figures. Source: NCIN and Macmillan (2015). "Cancer Prevalence UK Summary Table", [Online]. Accessed at: <u>http://www.ncin.org.uk/item?rid=2955</u> [Accessed 12/11/2105]

ⁱⁱ Based on the policy proposition.

xⁱ The incidence statistics by tumour type published in the ONS (2012) Cancer Registry are used to estimate the growth rate. The annual growth in incidence from 2007 to 2012 for these tumours is around 9.3% p.a. for oropharyngeal, and 1.2% for laryngeal cancers (which includes the supraglottis – supraglottis is assumed to comprise 21% of all laryngeal cancer cases (based on newly diagnosed cancer statistics in 2013/14 from DAHNO)). The weighted CAGR is c.7.7%. This rate is applied to the estimated 2014/15 incidence rates set out in K1.2

^{xii} Population growth rates are set out in K1.6

xiii The numbers for chemoradiotherapy and radiotherapy include follow up treatments after surgery. It is assumed that after TLM, open surgery or TORS, 28% of patients require radiotherapy, 12% require chemoradiotherapy and 60% require no further treatment. Based on discussions with the policy working group.

xiv Based on the ONS (2012), Cancer Registry.

^{xv} A study conducted on English data by the NCIN [NCIN (2004)."Cancer Incidence by Deprivation England, 1995 – 2004"] found that incidence rates for head and neck cancer are around 130% higher for men living in deprived areas compared with least deprived, and more than 74% higher for women.

xvi NCIN. Potentially HPV-related head and neck cancers. [Online] Available from

http://www.ncin.org.uk/publications/data_briefings/potentially_hpv_related_head_and_neck_cancers [Accessed 06/11/2015] and Macmillan (2012). Risk factors and causes of head and neck cancer. [Online] Available from http://www.macmillan.org.uk/Cancerinformation/Cancertypes/Headneck/Aboutheadneckcancers/Causes.aspx [Accessed 06/11/2015] and Macmillan (2012). Risk factors and causes of head and neck cancer. [Online] Available from http://www.macmillan.org.uk/Cancerinformation/Cancertypes/Headneck/Aboutheadneckcancers/Causes.aspx [Accessed 06/11/2015].

xvii The effect of these factors on growth is considered to be accounted for within the population growth rate applied, which is based on incidence growth historically (See K1.6).

xviii TLM would take up 2/3 and open surgery would cover 1/3 of the patients no longer receiving RAS.

xix These figures have been estimated based on discussions with clinicians, and are set out in relation to K1.7. For those undergoing surgery as a first line treatment, historic case studies have seen 60% receive no additional treatment, 12% receive chemoradiotherapy, and 28% receive radio, but only as a follow up to surgery, based on discussions with clinicians.

^{xx} This assumes that the activity that is undertaken as TORS currently would be instead treated using TLM or open surgery. 2/3 of these patients would receive TLM and 1/3 would receive open surgery (based on current relative frequency of these two procedures). The overall activity (across treatments) is grown in line with historic incidence rates as set out in K1.6.

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

xxii Some typical OPCS codes could be F34 or E24. Related ICD-10 codes are: C01, C09, C10, C32

^{xxiii} Based on the analysis of a SUS data extract for the years 2011/12 to September 2015, the main OPCS codes for oropharynx and larynx were mapped to HRG codes using the HRG grouper tool. The relevant HRG codes mapped were CZ01-CZ05.

xxiv Based on a case study of one hospital currently undertaking TORS in the northern England.

^{xxv} Estimate based on average spell costs from a SUS data extract between 2011/12 to September 2015 for those with oropharynx or larynx cancer in the first ICD-10 position. This estimate takes into account the distribution of costs for procedures undertaken in this period. However, tariff costs could be significantly higher or lower depending on case complexity of individual cases. This number is based on the five most frequently undertaken procedures (based on the number of spells over the data time period) and excludes biopsies. The main OPCS codes identified were: F349 - Unspecified excision of tonsil, F341 - Bilateral dissection tonsillectomy, F348 - Other specified excision of tonsil, F231 - Excision of lesion of tongue, F222 - Partial glossectomy. The average cost listed is approximate only as some spells with associated zero costs may have been included within the spells reported (although the estimate has been adjusted accordingly).

^{xxvi} It has been noted by clinicians that the consumables cost of TORS is lower than for other types of robotic surgery.

- xxvii See footnote xxv for an explanation of the estimate.
- xxviii Trans oral surgery would fall under the specialised service Specialist cancer services (adults) [Source: Manual for Prescribed Specialised Services 2013/14].

xxix Possible cost pressures have not been quantified as there was not sufficient evidence of reductions within the literature reviewed in terms of effectiveness.