Integrated Impact Assessment Report for Clinical Commissioning Policies

Policy Reference Number	B10X03		
Policy Title	Robotic assisted lung resection for primary lung cancer		
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Section K - Activity Impact			
Theme	**Questions**		**Comments** (Include source of information and details of assumptions made and any issues with the data)
K1 Current Patient Population & Demography / Growth	K 1.1 What is the prevalence of the disease/condition?		K1.1 This policy proposes **to not routinely commission** robotic assisted thoracoscopic surgery (RATS) for lung resections in patients diagnosed with lung cancer. In 2006, the 20 year prevalence of lung, bronchus and tracheal cancer in England was estimated at around 73:100,000.[i] This relates to a prevalence of c.39,000 people with the condition in 2014/15.[ii] In 2014/15, an estimated 37,200 individuals in England

		were diagnosed with lung cancer.[iii]
	K.1.2 What is the number of patients currently eligible for the treatment under the proposed policy?	K.1.2. Patients eligible for RATS would predominantly be those with early stage lung cancer, and potentially more advanced cancer (N2)[iv] who are undergoing lung resection surgeries. Currently, lung resection procedures being commissioned include open and video assisted thoracoscopic (VATS) procedures. The exact number of these procedures that could be eligible for RATS is uncertain. It is expected that this could range from around 90% of those undergoing VATS only to around 90% of all lung resections. [v] Based on this, **the number of patients eligible** for the treatment in England in 2014/15 is estimated at between 1,900 and 4,700, or between 5% and 13% of the incident population.[vi]
	K1.3 What age group is the treatment indicated for?	K1.3 This treatment is indicated for adults (over 18 years).
	K1.4 Describe the age distribution of the patient population taking up treatment?	K1.4 Lung cancer is most frequently diagnosed in older adults. It is most commonly diagnosed in those aged 70-74 years.[vii]
	K1.5 What is the current activity associated with currently routinely commissioned care for this group?	K1.5 As described in K1.2, currently, open surgery and VATS are commissioned for lung resection. The total number of resections in England using VATS is estimated at around 2,100 in 2014/15[viii] as compared

		to an estimated 3,200 non-VATS surgeries in the same year.[ix] Currently, around 250 to 400 of these surgeries are estimated to be carried out with robotic assistance.[x]
	K1.6 What is the projected growth of the disease/condition prevalence (prior to applying the new policy) in 2, 5, and 10 years?	K1.6 Lung resection surgery is noted as more common in early stage cancers, and is not an ongoing treatment.[xi] Incidence figures are therefore more relevant in understanding possible demand. Based on historic trends in lung cancer incidence, the growth in the population is estimated at ~1.7% p.a.[xii] Future incidence is estimated to be in the region of:[xiii] • ~ 38,400 in 2016/17 • ~ 39,100 in 2017/18 • ~ 41,100 in 2020/21
	K1.7 What is the associated projected growth in activity (prior to applying the new policy) in 2, 5 and 10 years?	K1.7 The number of surgical interventions for lung cancer is estimated to have grown at circa 3.4% p.a. in recent years.[xiv] If these historic trends in inpatient activity for lung cancer indications continue, the future activity for the eligible population as described in K1.5 is estimated to be in the region of: [xv] • ~2,000 to 5,000 resections in 2016/17 • ~2,100 to 5,200 resections in 2017/18 • ~2,300 to 5,700 resections in 2020/21 Of these, in the do nothing scenario, the number of RATS is expected to remain broadly constant at 250 – 400 procedures.[xvi] This is based on there being four centres of robotic surgery that are offering or will shortly be offering the procedure.[xvii] As robots can be

		shared across specialties, routine commissioning of other robotic procedures may mean that providers continue to offer RATS in the 'do nothing' scenario.[xviii]
	K1.8 How is the population currently distributed geographically?	K1.8 The prevalence of lung cancer was relatively higher in the North of England, which had an age standardised prevalence of 32.3 per 100,000 as compared to the all England rate of 28.8 in 2006.[xix]
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 The policy proposes that RATS will not be routinely commissioned. RATS is currently being carried out locally in a number of areas, but is not routinely commissioned by NHS England.
	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 Lung cancer prevalence is linked to lifestyle factors, in particular smoking. Changes in smoking rates in particular could affect the prevalence of this disease.[xx]
	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 Earlier diagnosis could increase the use of surgery in the treatment of lung cancer,[xxi] but it has not been possible to estimate how changes to screening or diagnosis might impact different areas differently.
	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.

		RATS would no longer be available to patients. There would be a net decrease in the number accessing RATS which is estimated at around 250 to 400 fewer patients each year compared to the do nothing case. These patients would likely be treated using alternative surgical procedures.
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 K3.2 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 provide details in accompanying excel sheet	K3.1 The current levels of activity for the target population are set out in K1.5; patients would undergo open or thoracoscopic resections, with an estimated 250 to 400 patients per year undergoing RATS. K3.2 As described in K2.4 should the policy be implemented, there would be a decrease in the number of patients accessing RATS and an increase in comparator procedures. The new activity figures are estimated at: • ~2,000 to 5000 non RATS resections in 2016/17 • ~2,100 to 5,200 non RATS resections in 2017/18 • ~2,300 to 5,700 non RATS resections in 2020/21 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. K3.3 The activity under the 'do nothing' case is set out in K1.7; patients would undergo open or thoracoscopic resections, with an estimated 250 to 400 patients per year undergoing RATS. The number of total resections would increase with RATS remaining broadly constant.
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.	K4.1-4.3 The clinical pathway for lung cancer varies considerably depending on a range of factors, including the type of cancer and stage at diagnosis. A NICE pathway for the diagnosis and treatment of lung cancer

	K4.2. What are the current treatment access criteria? K4.3 What are the current treatment stopping points?	exists. The general pathway is as follows: If the condition is diagnosed early and the cancerous cells are confined to a localised and resectable area, surgery to remove the affected area of lung is usually recommended. If surgery is unsuitable due to the general health of the patient or if the tumour is attached to important structures, radiotherapy to destroy the cancerous cells may be recommended instead. If the cancer has spread too far for surgery or radiotherapy to be effective, chemotherapy is usually used.
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. K5.2 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.	K5.1 VATS K5.2 Not applicable.
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 test to determine likely success). If possible please indicate likely outcome for patient at each stopping point.	K6.1 The pathway would not change from that set out in K4.1. K6.2 Not applicable.

K7 Treatment Setting	K7.1How is this treatment delivered to the patient? o Acute Trust: Inpatient/Daycase/Outpatient o Mental Health Provider: Inpatient /Outpatient o Community setting o Homecare delivery K7.2 Is there likely to be a change in delivery setting or capacity requirements, if so what? e.g. service capacity	K7.1 RATS is carried out as an inpatient procedure. K7.2 Not applicable.
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)	K8.1 The underlying procedure would be recorded in SUS. K8.2 Robotic procedures would not be specifically identified within the data, but the underlying procedure could be identified.[xxii]
K9 Monitoring	K9.1 Do any new or revised requirements need to be included in the NHS Standard Contract Information Schedule? 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?	K9.1 Not applicable. K9.2 Not applicable. K9.3 Not applicable. K9.4 Not applicable.

	K9.5 Is there inked information required to complete quality dashboards and if so is it being incorporated into routine performance monitoring?	K9.5 Not applicable.
	K9.6 Are there any directly applicable NICE quality standards that need to be monitored in association with the new policy?	K9.6 Not applicable.
	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*	K9.7 Not applicable.
Section L - Service Impact		
Theme	**Questions**	**Comments** (Include source of information and details of assumptions made and any issues with the data)
L1 Service Organisation	L1.1 How is this service currently organised? (i.e. tertiary centres, networked provision)	L1.1 Robotic surgery is currently carried out in four specialist centres with robotic equipment.
	L1.2 How will the proposed policy change the way the commissioned service is organised?	L1.2 Not applicable.
L2 Geography & Access	L2.1 Where do current referrals come from?	L2.1 Existing pathway.
	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 No. Whilst a consistent commissioning position will be in place, as noted earlier, the use of RATS is likely to continue in certain centres.
	L2.4 Is the new policy likely to improve equality of access / outcomes?	L2.4 No.
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?	L3.1 No.

	L3.2 Is there a change in provider physical infrastructure required?	L3.2 No.
	L3.3 Is there a change in provider staffing required?	L3.3 No.
	L3.4 Are there new clinical dependency / adjacency requirements that would need to be in place?	L3.4 No.
	L3.5 Are there changes in the support services that need to be in place?	L3.5 No.
	L3.6 Is there a change in provider / inter-provider governance required? (e.g. ODN arrangements / prime contractor)	L3.6 No.
	L3.7 Is there likely to be either an increase or decrease in the number of commissioned providers?	L3.7 No.
	L3.8 How will the revised provision be secured by NHS England as the responsible commissioner? (e.g. publication and notification of new policy, competitive selection process to secure revised provider configuration)	L3.8 Not applicable.
L4 Collaborative Commissioning	L4.1 Is this service currently subject to or planned for collaborative commissioning arrangements? (e.g. future CCG lead, devolved commissioning arrangements)?	L4.1 None known.
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*,	M1.1 The underlying procedure for RATS (thoracic surgery) would be within tariff. HRG codes that relate to

	and if so which?	thoracic surgery for lung cancer include DZ02A - DZ02C (Pneumocotomy and Lobectomy).[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 c. £1,500 per procedure (in addition to tariff for VATS).[xxiv]
	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.	M1.4 Not applicable.
	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 not to commission RATS, the cost for treating patients with the comparator treatments VATS or open resection is estimated at around £7,000 (which is the same as the underlying procedure for RATS).[xxv] The revenue cost per patient in relation to RATS would be nil as the decision is to not routinely commission.

		For reference, the additional unit cost of the RATS surgery currently is estimated to be in the region of £1,500[xxvi] for robotic consumables, in addition to the base tariff noted above.
	M2.2 What is the revenue cost per patient in future years (including follow up)?	M2.2 RATS is a one-off cost per patient. Patients otherwise follow the lung cancer pathway for their specific cancer, so there would be no change to revenue consequences in future years.
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?	M3.1 Cost saving. As the policy is to not routinely commission RATS, NHS England will no longer pay the cost of robotic consumables that are additional to the tariff cost associated with comparator treatments. This could lead to savings in the region of £375k, although this figure could vary (please refer to M6 for details).[xxvii]
	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.[xxviii]
	M4.2 Indicate whether this is cost saving, neutral, or cost pressure to the NHS as a whole?	M4.2 Cost saving.
	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 None identified.
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	M5.1 Not applicable.
M6 Financial	M6.1 What are the material financial risks to implementing this policy?	M6.1 The level of potential savings is uncertain as the extent to which consumables are paid may vary across England, and the number of patients undergoing RATS that are included within the current baseline is uncertain.
	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 The cost estimate is based on 250 patients receiving VATS currently (low estimate), and at a price of £1,500 for consumables as set out in M2.1. Using the high estimate of procedures, the savings could be £600k, or it could be lower than £375 if fewer patients would have consumables paid at £1,500.
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*	M7.1 With regards 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 robotic surgery is only likely to be cost effective if it is concentrated in a few special centres.

	M7.2 What issues or risks are associated with this assessment? *e.g. quality or availability of evidence*	M7.2 No risks have been identified as evidence of cost effectiveness was not identified.
M8 Cost Profile	M8.1 Are there non-recurrent capital or revenue costs associated with this policy? *e.g. Transitional costs, periodical costs* M8.2 If so, confirm the source of funds to meet these costs	M8.1 Not applicable. M8.2 Not applicable.

[i] This figure is based on the 20 year prevalence of ICD-10 C034 Cancer of the Lung and Bronchus. Based on: National Cancer Intelligence Network (2010). One, Five and Ten Year Cancer Prevalence by Cancer Network, UK, 2006. available at: www.ncin.org.uk/view?rid=76 [Accessed: 03 November 2015], which has been divided by the ONS (Office for National Statistics) population estimate for year end 2005/06 for the population of England to arrive at an estimated prevalence rate.

[ii] This is based on the prevalence rate stated in footnote iii multiplied by the ONS overall population projection for England in 2014/15.

[iii] Based on ONS cancer registry data. The estimate is based on the incidence of lung cancer in 2012, rebased to 2014/15 using the historic growth rate of lung cancer incidence from 2008 to 2012 (ONS Cancer Registry data). This number covers only the population in England and is hence smaller than the 41,000 new diagnoses mentioned in the policy proposition (which refers to the UK).

[iv] As noted in the policy proposition.

[v] Based on discussions with the policy working group.

[vi] The total estimated resection procedures for lung cancer are around 5,200 in 2014/15 (see source/methodology detailed in question K1.5 or footnote viii). Up to 90% of those needing resections could be eligible for RATS. Based on discussions with the policy working group, and based on an estimated one resection per patient.

[vii] Based on data from the ONS Cancer Registry in relation to number of patients diagnosed. Age specific rates peak at 80 to 84. Source: Cancer Research UK. Lung Cancer Incidence Statistics.[Online]. Available at: http://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/lung-cancer/incidence#heading-One [Accessed: 03 December 2015].

[viii] The number of VATS in the UK and Ireland in 13/14 was reported as 2,021 in the Society for Cardiothoracic Surgery in Great Britain and Ireland. *Thoracic Surgery Registry Brief Report, Audit Years 2011-12 to 2013-14*, available at: http://www.scts.org/_userfiles/pages/file/Audit%20and%20Outcomes/3_year_data_summary_2015%5B1%5D.pdf [Accessed: 03 November 2015]. The 2014/15 figures are estimated using the annual growth rate in open and video assisted surgery from 2011/12- 2013/14.This figure is adjusted by a multiplier of 77%, which is the percentage of the general population of the UK and Ireland that resides in England (population estimates obtained from ONS population statistics and Central Statistics Office (CSO): http://www.cso.ie/multiquicktables/quickTables.aspx?id=cna13 [Accessed: 03 November 2015].

[ix] Based on the Thoracic Surgery Registry Brief Report figures for 2013/14, growth rates for non-VATS procedures and the proportion of England's population in the UK and Ireland, as outlined in relation to the estimation methodology for the number of VATS procedures in England in 2014/15.

[x] Range based on correspondence with the policy working group..

[xi] 46% of Stage I patients and 19% of Stage II and III may need lung resection surgery. Based on "National Lung Cancer Audit", HQIP, HSCIC & RCP, 2014 available at: http://www.hscic.gov.uk/lung [Accessed: 03 November 2015].

[xii] This rate is based on the compounded annual growth rate of incidence (based on ONS Cancer Registry statistics) from 2008 to 2012.

[xiii] These figures are estimated based on the number of new lung cancer diagnoses from the ONS cancer registry data as described in K1.1 and the yearly growth factor of 1.7%.

[xiv] Estimates are based on data reported in the Thoracic Surgery Registry Brief Report. The growth is the compounded annual growth rate for the number of resections for lung cancer in the years 2011/12 to 2013/14.

[xv] Estimates are based on data reported in the Thoracic Surgery Registry Brief Report as in question K1.5, with the annual growth factor of 3.4% applied.

[xvi] In the absence of a policy, the activity would be limited by the number of robotic centres and trained surgeons. As such it is assumed that the current activity would be rolled forward under the do nothing.

[xvii] Based on discussion with clinicians. Middlesbrough, Newcastle offer RATS currently.

[xviii] Based on the views of the policy working group.

[xix] NCIN. (2010).

[xx] Cancer Research UK – Lung cancer risks and causes [Online]. Available at: http://www.cancerresearchuk.org/about-cancer/type/lung-cancer/about/lung-cancer-risks-and-causes [Accessed: 03 November 2015].

[xxi] As set out in response to question K1.6, surgery is more common with early stage cancers.

[xxii] OPCS codes in relation to lung resection surgery would be relevant, as well as ICD-10 in relation to lung cancer.

[xxiii] Based on a business case from a trust in northern England.

[xxiv] Based on a business case from a trust in northern England.

[xxv] Average of 2014/15 tariff weighted by the number of non-emergency admissions (based on 2014/15 HES data) for the HRG codes DZ02A, DZ02B, DZ02C (based on a business case study from a hospital in northern England). A market forces factor of 10% is applied.

[xxvi] Based on a business case from a trust in northern England..

[xxvii] The number of lung resections is estimated to have increase substantially in the last year based on discussions with those familiar with the area. The estimate noted is based on c. 250 patients undergoing robotic procedures in the current year.

xxviii However, there are reports of some cost reducing features of RATS for trusts: Based on a business case outline provided by the members of the policy working group. Benefits may include reduced high dependency unit stay, reduced overall length of stay, improved recovery, less analgesia, and less blood according the case.