Integrated Impact Assessment Report for Clinical Commissioning Policies

Policy Reference Number	B14X07		
Policy Title	Surgical sperm retrieval for male infertility		
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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 is to **routinely commission** surgical sperm retrieval for patients with obstructive and non-obstructive azoospermia as described in K1.2. It is estimated that c.1% of all men in England suffer from azoospermia[i]. Applying this to the adult/adolescent male population in England[ii], the prevalent population could be c. 220,000[iii]. Of these, an estimated 80% would have non-obstructive azoospermia (NOA) and 20% obstructive azoospermia (OA).[iv]	

	K1.2 What is the number of patients currently eligible for the treatment under the proposed policy?	K1.2 The size of the eligible patient group is difficult to estimate as it depends on the individual patient and their partner's circumstances, and the criteria for commissioning propose that patients have confirmed funding from CCGs for subsequent stages in the pathway.[v]
		
		As such, the prevalent population is a subset of those identified in K1.1. The total number of patients eligible for surgical sperm retrieval is estimated based on:
		
		• In the UK in 2013, there were c. 11,700 fresh cycles of intracytoplasmic sperm injection (ICSI) due to only male infertility factors[vi]. This relates to an estimated 9,290 patients. [vii]
		  • Of these it is estimated that 10% **(929)** would suffer from azoospermia[viii].
		  • Of these, an estimated 10% **(93)** of patients would likely have had Y chromosome deletions and therefore not have been eligible for surgical sperm retrieval[ix]; and
		  • An estimated 10-20% **(93 – 186)** of patients will have chosen not to undertake surgical sperm retrieval or have looked for alternative fertility treatments[x].
		  • This therefore relates to **650 to 743** patients in the UK in 2013.
		
		Adjusting this for just the population in England leads to an estimated **550 to 630** patients who would have been eligible for surgical sperm retrieval in 2014/15.[xi]
		
		The patient numbers above could, however, be an under-estimate as they are only based on patients who were successful throughout the different stages of the pathway (i.e. those that have gone on to receive IVF/ICSI). Please refer to K1.5 for current patient activity or this group.

	K1.3 What age group is the treatment indicated for?	K1.3 This treatment is indicated for all age groups although the majority of men are expected to be over 18 years.[xii]
	K1.4 Describe the age distribution of the patient population taking up treatment?	K1.4 As described in K1.3, the vast majority of patients will be over the age of 18. The only exceptions are cases of adolescents who are due to undergo chemotherapy or surgery which would result in azoospermia and who are unable to provide ejaculated semen prior to receiving treatment.[xiii] An upper age limit is not placed on the patient themselves, but rather the age and fertility of their partner.[xiv]
	K1.5 What is the current activity associated with currently routinely commissioned care for this group?	K1.5 The five main procedures for surgical sperm retrieval include: • Percutaneous epididymal sperm aspiration (PESA) • Microsurgical epididymal sperm aspiration (MESA) • Testicular sperm aspiration (TESA) • Testicular sperm extraction (TESE) • Microdissection TESE (mTESE) In Hospital Episode Statistics (HES) for 2014/15, there were **c.725 episodes**[xv] relating to the above procedures. This covers all NHS funded activity, whether it was undertaken in the NHS or in a private clinic.[xvi] For information, data from a Secondary Uses Services (SUS) extract suggests this could relate to broadly **650 unique patients;** however there is some uncertainty around this.[xvii]
	K1.6 What is the projected growth of the	K1.6 No change in the future prevalence rate is expected going

	disease/condition prevalence (prior to applying the new policy) in 2, 5, and 10 years?	forwards, so the number of men with azoospermia is expected grow in line with the adult male population in England. The future prevalent population could therefore be in the region of:[xviii] • ~ 220,000 in 2016/17 (year 1) • ~ 220,000 in 2017/18 (year 2) • ~ 225,000 in 2020/21 (year 5) Factors that could affect this growth rate are identified in K2.2.
	K1.7 What is the associated projected growth in activity (prior to applying the new policy) in 2,5 and 10 years	K1.7 In the 'do-nothing' it is expected that the indicative activity reported in K1.5 would grow in line with demographic growth. The future number of surgical sperm retrievals could therefore be estimated to be in the region of :[xix] • ~ 735 in 2016/17 (year 1) • ~ 740 in 2017/18 (year 2) • ~ 755 in 2020/21 (year 5)
	K1.8 How is the population currently distributed geographically?	K1.8 Across England, no evidence of geographical variation for this condition has been identified in this review.
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 This procedure is currently commissioned locally and offered by fewer than 5 centres in the UK as well as private fertility clinics[xx]. If the policy is adopted, it will become routinely commissioned by NHS England for the target population group.

	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 Lifestyle factors such as smoking and excess alcohol consumption could affect the growth in the population[xxi]. Moreover, increased obesity rates, increased patient awareness of surgical sperm retrieval techniques and increased access of patients to radiotherapy treatments, which increases the likelihood of oligozoospermia, could lead to an increase in patients taking up treatment.[xxii]
	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 such changes have been 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 policy is estimated to have the following two impacts on the number of surgical sperm retrieval procedures: 1. For the current number of patients, under the policy they would receive the most appropriate procedure in the first instance. Although patient numbers (compared to the current situation) would remain constant in this case, this is expected to[xxiii]: a. Reduce the number of repeat procedures; and b. Increase success rates, and therefore the likelihood to progress down the pathway. Under the policy **OA patients** would first have a PESA, MESA, TESA or TESE depending on their characteristics and choice[xxiv]. Where insufficient sperm is retrieved a second attempt at mTESE can be tried. It is expected that this pathway is currently being followed for this patient group, and as such there would be little change as a result

		of the policy.[xxv] Under the policy **NOA patients** would receive an mTESE in the first instance, and where insufficient sperm is retrieved a second attempt at mTESE can be tried.[xxvi] For NOA patients, mTESE has an estimated success rate of c. 50%.[xxvii] In the current situation, it is expected that not all NOA patients follow this pathway. That is, they may inappropriately receive a TESA or TESE, which have an associated success rate of c. 35%.[xxviii] In NOA patients, or less commonly a MESA or PESA with success rates closer to 0%.[xxix] By all NOA patients receiving an mTESE straight away under the policy, there could be a decrease in the total number of retrievals undertaken in the NHS (due to the higher success rates and therefore fewer patients requiring a repeat procedure). This, however, could not be quantified as data coverage is incomplete and it is uncertain how many 'unnecessary' procedures are currently undertaken.[xxx] 2. Given significant variation in local commissioning[xxxi], there could be unmet need in the system that is currently: a. **Being serviced privately.** This is expected to be minimal as the main constraint is CCG fertility criteria rather than access to surgical sperm retrieval itself[xxxii]; or b. **Not in the system.** As above, this is expected to be minimal as commissioning criteria depend on the patient having confirmed funding for subsequent stages of the pathway.[xxxiii] Although patient numbers are likely to remain unchanged under the policy, there could be a shift in where the activity is serviced and the

		total number of procedures. Patients with NOA who are NHS funded, but currently receive inappropriate procedures such as MESA, PESA, TESA or TESE in private fertility clinics would instead receive an mTESE in NHS secondary care under the policy.[xxxiv] This could: • Increase the number of mTESE provided in NHS secondary care; and • Decrease the number of MESA, PESA, TESA or TESE provided in private fertility clinics but funded by the NHS. This is expected to lead to an overall decrease in the number of procedures due to the reduction in unnecessary repeats (as mTESE has a greater success rate in these patients). [xxxv] Given the split of activity serviced in the NHS or privately is unknown, this cannot be estimated, however is expected to be low.[xxxvi] Further to the impact on the number of surgical sperm retrievals, an increase in success rates, as described in 1b above, could lead to an increase in the number of CCG funded IVF / ICSI treatments. The impact of this however is difficult to quantify as how the patient would have been treated in the 'do-nothing' is uncertain. For example they could have progressed down the IVF route with donor sperm, chosen to adopt a child, or done nothing.
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 Activity is estimated as described in K1.5.

	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 Given the 'do-nothing' in K1.7 and the change in activity under the policy in K2.4, the change in total number of surgical sperm retrievals undertaken under the policy is difficult to estimate, though likely to be small. As described in K2.4, it is expected that there is no, or only minimal, unmet need in the system that would now be eligible under the policy.[xxxvii] The number of patients is therefore assumed to be the same under the policy and in the current state. As described in K2.4, total activity undertaken in future could not be quantified, but it is expected that there could be a decrease in the number of procedures under the policy, as well as a potential shift in where activity is serviced, with more patients receiving an mTESE in NHS secondary care, rather than a needle aspiration in a private fertility clinic that was funded by the NHS.[xxxviii]
	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' activity is as described in K1.7
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 will see their GP and are offered an initial assessment, including a semen analysis. If the result of the first semen analysis is abnormal, a repeat confirmatory test will be offered in an accredited laboratory either locally or at a hospital. If a gross spermatozoa deficiency (azoospermia or severe oligozoospermia) has been detected the repeat test will be undertaken as soon as possible. The GP refers the patient to a fertility clinic for treatment for diagnosis of azoospermia and the treatment

		options are discussed. The fertility clinic may conduct surgical sperm retrieval, or refer the patient to an urologist. If sperm retrieval is successful, IVF/ICSI would follow. Surgical sperm retrieval is currently funded by CCGs.
	K4.2. What are the current treatment access criteria?	K4.2 The MDT at the fertility centre or the urologist as part of an MDT within a specialised urology centre will recommend the patient for surgical sperm retrieval, and, the patient's CCG agrees to fund SSR and fertility pathway following successful surgical sperm retrieval.
	K4.3 What are the current treatment stopping points?	K4.3 For patients diagnosed with azoospermia, the stopping point would come after numerous failed attempts at sperm retrieval, or successful pregnancy.
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 There are no direct alternatives to surgical sperm retrieval, infertile couples where the male has azoospermia could consider using donor sperm or adoption.
	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	K5.2 Semen analysis does not identify azoospermia, patient referred back to fertility centre. Patient opts for donor sperm or adoption.

	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 • GP diagnoses fertility problem via two semen analyses. • GP refers patient to fertility clinic for treatment. MDT makes decision about onward referral. • Patient then referred to urologist to make azoospermia diagnosis and discuss treatment options. • If successful, ICSI would follow. The number of men with azoospermia requiring surgical sperm retrieval is expected to rise slightly in future years due to increased obesity rates, greater patient awareness of surgical sperm retrieval techniques and increased access of patients to cancer treatments which result in azoospermia.
	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.	K6.2 Semen analysis does not identify azoospermia, and the patient is referred back to the fertility centre. Men with AZFa or AZFb Y chromosome deletions or men with obstructive azoospermia caused by vasectomy. Patient opts for donor sperm or adoption, or the patient's CCG does not agree to fund the subsequent steps in the fertility pathway.
K7 Treatment Setting	K7.1 How is this treatment delivered to the patient? o Acute Trust: Inpatient/Daycase/	K7.1 MESA is typically delivered as an inpatient surgical procedure while PESA, TESE, mTESE and TESA are delivered as a daycase procedure.[xxxix]

	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*	K7.2 No change in delivery settling. Extra capacity may be required of urologists to diagnose azoospermia and discuss treatment options with patients earlier in the patient pathway.
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 Activity is recorded in SUS central data collections. These procedures are already carried out at the moment and activity data is regularly recorded in SUS. K8.2 Activity related to the patient pathway can be identified with the relevant OPCS codes within SUS.[xl] Furthermore, this can be combined with the relevant ICD10 code to identify activity by diagnosis.[xli]
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?	K9.1 No K9.2 N/A

	K9.3 What analytical information /monitoring/ reporting is required?	K9.3 As per national quality standards and HFEA audit requirements.
	K9.4 What contract monitoring is required by supplier managers? What changes need to be in place?	K9.4 Contract monitoring is managed by the Commissioning Support Unit (CSU) and the necessary information is then shared with supplier managers (commissioners).
	K9.5 Is there inked information required to complete quality dashboards and if so is it being incorporated into routine performance monitoring?	K9.5 No.
	K9.6 Are there any directly applicable NICE quality standards that need to be monitored in association with the new policy?	K9.6 No.
	K9.7 Do you anticipate using Blueteq or other equivalent system to guide access to treatment? If so, please outline. *See also linked question in M1 below*	K9.7 No
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	L1.1 The service is organised with fertility centres providing surgical

	organised? (i.e. tertiary centres, networked provision)	sperm retrieval, and urology centres providing surgical sperm retrieval. There is a limited link between fertility centres and urology centres.
	L1.2 How will the proposed policy change the way the commissioned service is organised?	L1.2 The policy would ensure consistent access to surgical sperm retrieval across England, and the services would be available in all areas
L2 Geography & Access	L2.1 Where do current referrals come from?	L2.1 GPs refer to local fertility centre that sometimes perform surgical sperm retrieval and IVF, or they will refer the patient to a urologist or specialised urological MDT for further diagnosis of azoospermia and surgical sperm retrieval and ICSI fertility treatment.
	L2.2 Will the new policy change / restrict / expand the sources of referral?	L2.2 The new source of referral will be from GP to urologist, rather than GP to fertility centre to urologist.
	L2.3 Is the new policy likely to improve equity of access	L2.3 Yes, rather than treatment being dependant on CCG commissioning, all patients across England will have access to treatment through specialised commissioning, providing that the patient's CCG will fund the further stages of the patient's fertility pathway.
	L2.4 Is the new policy likely to improve equality of access / outcomes?	L2.4 Should ensure consistent access and improve consistency of outcomes due to patients being seen by an expert in male infertility and receiving the most suitable treatment.
L3 Implementation	L3.1 Is there a lead in time required prior to implementation and if so when could	L3.1 No lead in time.

	implementation be achieved if the policy is agreed?	
	L3.2 Is there a change in provider physical infrastructure required?	L3.2 While the patient pathway will change to use urology centres earlier in the pathway, these centres are already in place and this policy will not result in a change to physical infrastructure.
	L3.3 Is there a change in provider staffing required?	L3.3 No change expected.
	L3.4 Are there new clinical dependency / adjacency requirements that would need to be in place?	L3.4 No change expected.
	L3.5 Are there changes in the support services that need to be in place?	L3.5 No change expected.
	L3.6 Is there a change in provider / inter-provider governance required? (e.g. ODN arrangements / prime contractor)	L3.6 Specialist fertility MDTs will have a greater role in the governance arrangements. HFEA will continue to provide fertility governance.
	L3.7 Is there likely to be either an increase or decrease in the number of commissioned providers?	L3.7 No change expected.

	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)	L3.8As per L1.2, publication of new service specification.
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 No
Section M - Finance Impact		
Theme	**Questions**	**Comments** (Include source of information and details of assumptions made and any issues with the data)
M1 Tariff	M1.1 Is this treatment paid under a national prices*, and if so which?	M1.1 No, please refer to M1.3.
	M1.2 Is this treatment excluded from national prices	M1.2 Yes, please refer to M1.3.
	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 There is no national tariff for this procedure. For this analysis, the national average reference cost for the 'collection of sperm[xlii]' has been taken as a proxy for a national tariff[xliii]. HRG code: MC06Z, with a cost of £1,531[xliv]. There are storage costs of approximately £300 per patient in the first year and £100 in subsequent years[xlv] which are additional to the 'price' identified in M1.1. These may be borne by providers or CCGs,

		but may sometimes be non-NHS funded.[xlvi] There is no reason to believe that that the price paid for by the NHS to private fertility clinics would be different to the proxy tariff estimate above.[xlvii]
	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 Yes
	M1.6 Do you envisage a prior approval / funding authorisation being required to support implementation of the new policy?	M1.6 No
M2 Average Cost per Patient	M2.1 What is the revenue cost per patient in year 1?	M2.1 Following an initial assessment by the patient's GP, the costs[xlviii] per patient are comprised of:[xlix] • A confirmatory test in an accredited laboratory or at a hospital (if necessary) at a cost of £88;[l] • An appointment with a urologist with an interest in male infertility with a cost of £138;[li] • The consideration of a couple's case at a specialist fertility MDT

		with an estimated cost of £108;[lii] • The £1,531 for the procedure, as identified in M1.3; • Storage costs of £300 per year (where applicable); and • Post-surgery follow-up to discuss the patient's options. The cost for this attendance is c £76.[liii] This leads to an estimated cost per patient in year 1 in the region of **£2,240**.
	M2.2 What is the revenue cost per patient in future years (including follow up)?	M2.2 Where storage is required, this could cost c. £100 per year as mentioned in M1.3.
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 Note: w*hilst this would be specialised commissioning activity, it is acknowledged that the current specialised identification rules may not trigger the spell and it therefore could be being paid for by CCGs.[liv] Where this is the case, the baseline spend would move as part of the national baseline alignment of the identification rules, and this would be cost neutral to NHS England.[lv]* As described in K2.4, the impact of the policy on the number of retrievals undertaken, and therefore the financial impact of the policy, is uncertain (please see M3.2 for more detail). Under the policy, NOA patients would receive the most appropriate procedure in the first instance. Therefore, there is likely to be a reduction in 'unnecessary' first-line and repeat aspirations. This could lead to cost saving, however, the magnitude of these savings could not be quantified, but is expected to be low given the activity volumes and cost.[lvi] *As a point of reference, were unnecessary repeats to account for 10% of activity, the savings would be in the region of £0.1m[lvii] each year. This however is provided for reference only.*

		As such it is estimated that this policy would be broadly cost neutral to NHS England, or cost saving to the extent to which unnecessary repeat procedures are reduced.
	M3.2 Where this has not been identified, set out the reasons why this cannot be measured	M3.2 It could not be estimated what fraction of total activity is due to (unnecessary) aspirations and what fraction is due to mTESE. This is due to a multitude of factors: • Firstly, it is unknown what fraction of current activity identified in K1.5 is apportioned to privately serviced (but NHS funded) patients; • Secondly, it is unknown to what extent the proposed policy is currently being followed. Therefore, the change to current practice, in terms of activity, under the policy is uncertain. In the data, it could not be identified how many NOA patients incorrectly receive aspiration procedures that would receive mTESE in the future; and • Finally, the extent to which there is unmet need in the system could not be quantified; however it is expected to be minimal.[lviii]
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 *As described in M3.1, this activity could currently be being paid for by CCGs, but this baseline spend would be transferred to NHS England as part of the national baseline alignment of the identification rules. This would be cost neutral to CCGs.* As described in K2.4, the extent to which the policy impacts upon the number of patients progressing onto IVF/ICSI, which is CCG funded, could have a cost impact to CCGs. The impact of this however is difficult to quantify as how the patient would have been treated in the 'do-nothing' is uncertain, for example they could have progressed

		down the IVF route with donor sperm or chosen to adopt a child.
	M4.2 Indicate whether this is cost saving, neutral, or cost pressure to the NHS as a whole	M4.2. Based on M3.1 and M4.1, this is expected to be broadly cost neutral or cost saving, to the extent to which repeat procedures would reduce under the policy, to the NHS as a whole. As described in M4.1, there could be cost impacts to CCGs were the number of patients progressing to CCG funded IVF/ICSI, however this is uncertain.
	M4.3 Where this has not been identified, set out the reasons why this cannot be measured	M4.3 Please refer to M3.2.
	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 To be discussed at CPAG.
M6 Financial Risks Associated with Implementing this Policy	M6.1 What are the material financial risks to implementing this policy?	M6.1 No material financial risks have been identified.

	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 as cost impacts are uncertain.
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 The evidence review has not provided any literature on cost effectiveness of the intervention.
	M7.2 What issues or risks are associated with this assessment? *e.g. quality or availability of evidence*	M7.2 The evidence review has not provided any literature on issues or risks of the intervention as it was only based on published peer reviewed journals.
M8 Cost Profile	M8.1 Are there non-recurrent capital or revenue costs associated with this policy? *e.g. Transitional costs, periodical costs*	M8.1 There are no such costs anticipated unless this service will be offered more widely than currently. In this case, it would depend whether the proposed site currently met the required service criteria, such as having a fertility lab and storage unit on site.[lix]
	M8.2 If so, confirm the source of funds to meet these costs	M8.2 Not applicable.

[i] Source: Cocuzza et al. (2013). "The Epidemiology and Etiology of Azoospermia." *Clinics* 68.Suppl 1 (2013): 15–26. [Online] Available from http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3583160/ [Accessed: 23/10/2015].

[ii] Based on ONS population estimates for 2014 for males in England aged 15 and older [Source: Population Estimates for UK, England and Wales, Scotland and Northern Ireland, Mid-2014.].

[iii] This includes men with secondary infertility and also all age ranges and as such the target population will therefore only be a subset of this [Source: Based on conversations with the clinical and commissioning working group].

[iv] Based on discussions with clinicians in the policy working group.

[v] Please refer to the policy proposition

[vi] Human Fertilisation and Embryology Authority (HFEA) (2014). Fertility treatment in 2013: trends and figures

[vii] Based on the relative number of overall cycles to patients as reported in: Human Fertilisation and Embryology Authority (HFEA) (2014). Fertility treatment in 2013: trends and figures.

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

[ix] Based on discussion with the policy working group.

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

[xi] This UK figure is adjusted to cover only the population in England and grown by demographic growth of the male population of reproductive age (aged 15 and above) [Based on: Office for National Statistics (ONS) (2015). Population Estimates for UK, England and Wales, Scotland and Northern Ireland, Mid-2014; and ONS (2012). Populations projections]

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

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

[xiv] Older population will not be seen for infertility as partners are likely to be older and not fertile (based on discussions with the policy working group).

[xv] Based on HES (2014/15), all procedures relating to OPCS codes N342, N344, N345 and N346.

[xvi] Based on HSCIC. *What HES data are available?*. [Online] Available from http://www.hscic.gov.uk/hesdata [Accessed: 08/02.2016].

[xvii] The number of unique patients could be overestimated if a patient changed GP practice or due to age being calculated as at the treatment date. (Source: NHS England Informatics)

[xviii] Based on ONS population projections (2012) for men aged 15 and over. The Compound Annual Growth Rate (CAGR) between 2015/16 and 2020/21 is c. 0.7%.

[xix] Based on the number of episodes identified in K1.5 and grown with the demographic growth rate (Source: ONS Population projections, 2012).

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

[xxi] British Association of Urological Surgeons. Fertility Problems. [Online] Available from http://www.baus.org.uk/patients/conditions/4/fertility_problems [Accessed: 16/11/2015].

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

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

[xxiv] Policy proposition.

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

[xxvi] Policy proposition

[xxvii] Bernie, Aaron M.; Mata, Douglas A.; Ramasamy, Ranjith; Schlegel, Peter N.. Comparison of microdissection testicular sperm extraction, conventional testicular sperm extraction, and testicular sperm aspiration for nonobstructive azoospermia: a systematic review and meta-analysis. Fertil. Steril.. 2015,

[xxviii] Bernie, Aaron M.; Mata, Douglas A.; Ramasamy, Ranjith; Schlegel, Peter N.. Comparison of microdissection testicular sperm extraction, conventional testicular sperm extraction, and testicular sperm aspiration for nonobstructive azoospermia: a systematic review and meta-analysis. Fertil. Steril.. 2015,

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

[xxx] Based in discussions with the policy working group.

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

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

[xxxiii] Based in the policy proposition.

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

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

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

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

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

[xxxix] University Hospitals Coventry and Warwickshire. Surgical Sperm Retrieval (SSR). [Online] Available from http://www.uhcw.nhs.uk/ivf/treatments/ssr [Accessed: 26/11/2015] and South West Centre for Reproductive Medicine. Patient information – surgical sperm retrieval; [Online] Available from

http://www.plymouthhospitals.nhs.uk/ourorganisation/foundationtrust/Documents/PI%202.6%20Patient%20Information%20Surgical%20Sperm%20Retrieval(V2).pdf [Accessed: 26/11/2015]; and Manchester Fertility. Surgical Sperm Retrieval. [Online] Available from https://www.manchesterfertility.com/treatments/specialist-procedures/surgical-sperm-retrieval [Accessed: 26/11/2015].

[xl] The OPCS codes are: N342, N344, N345, N346.

[xli] N46X: male infertility.

[xlii] HRG code MC06Z

[xliii] As suggested by the NHS England Finance Lead for this policy.

[xliv] Based on discussions with NHS England finance lead. This is inclusive of MFF.

[xlv] Based on discussions with NHS England finance lead.

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

[xlvii] Based on discussions with the NHS England Finance Lead. These would be determined through local price arrangements.

[xlviii] The cost figures bellow all take 2014/15 tariff price, an uplift for MFF (10%) and apply the 2015/16 efficiency (-3.5%) and inflation (1.9%) to determine 2015/16 prices. These are then assumed constant going forward.

[xlix] Policy proposition.

[l]Based on 2014/15 National Tariff (General surgery, follow-up - single-professional outpatient appointment) with a cost of £81.

[li] Based on 2014/15 National Tariff (Urology, first attendance - single professional, outpatient appointment) with a cost of £127.

[lii] Based on 2013/14 Reference costs for '-Other Cancer MDT Meetings' at a cost of £99. It is assumed that the costs for a specialist urology MDT is similar.

[liii] Based on 2014/15 National Tariff (Urology Outpatient follow-up appointment with a single professional) with a cost of £70.

[liv] Based on discussions with the NHS England Finance Lead.

[lv] Based on discussions with NHS England Finance Lead.

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

[lvii] This assumes only the procedure cost, as in M2.1, would be borne by NHS England.

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

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