QUALITY IMPACT ASSESSMENT (QIA)

Bedfordshire, Luton and Milton Keynes Clinical Commissioning Group

Name of Scheme	Specialist Fertility
Scheme Lead (and author of this QIA if different to scheme lead)	Specialist Fertility Task and Finish Group
Organisation	BLMK CCG
Date & Version	Oct 2021 Version **0.4 DRAFT covering option 1**&2
Brief Description of Scheme	The merger of Bedfordshire, Luton and Milton Keynes CCGs has led to the need for a single specialist ferility policy. It has been identified that policy alignment for specialist fertility will require public consultation due to the variation in existing policies. Two options have been developed: **Option 1:** To reduce the current offer of three cycles of IVF to residents in Luton to one cycle for all eligible patients, in line with the current offering in Bedfordshire and Milton Keynes and extend access to the service to fund artificial insemination for same sex females couples, single females and transmen with uterus to ensure equity of access. **Option 2:** To increase the number of cycles available to couples in Bedfordshire and Milton Keynes, in line with the current Luton model and extend access to the service to fund artificial insemination for same sex females couples, single females and transmen with uterus to ensure equity of access.

Self-Assessment Criteria

Negative	**This development will have a negative impact**
Neutral	**There is no anticipated change in the impact of this development**
Positive	**This development will have a positive impact**
N/A	**This question is not relevant at this time**

OVERALL ASSURANCE

	No. Questions	Negative	Neutral	Positive	N/A
SAFETY	5	0	4	0	1

DRAFT

	No. Questions	Negative	Neutral	Positive	N/A
CLINICAL EFFECTIVENESS	2	0	0	1	1
PATIENT EXPERIENCE AND INVOLVEMENT	6	0	3	1	1

NAME OF MEMBER OF QUALITY TEAM SUPPORTING	Claire Flower

SCREENING SECTION

Is a full QIA required for this Scheme? Please colour "Yes" or "No" accordingly	**Yes**	→ **Proceed to the full QIA below**	
	No	→ **Explain why further analysis is not required, or who you have spoken to in the Quality Team in the box to the right**	n/a

FULL QIA-EQIA

	ID	What is the potential impact of the service development on patient safety	Use these prompts to help you comprehensively evaluate the plans	Information to inform Self-Assessment	Self-Assessment
	1a	What are the known patient safety issues within the current service? (as identified by national/local audits, SIs, incident trend analysis, complaints, CQC and other external inspections, staff observation/feedback)	Has the current safety of the service been evaluated and known patient safety risks identified? Prompts to consider: Specific safety issues within this pathway or service. Analysis of available data/information to identify themes and trends. The way in which the planned changes will address the identified patient safety issues. Impact on preventable harm. **Covid specific** - back log position, current patient wait in service. Has service prioritisation been considered	Offering fertility treatment to service users with particular modifiable /lifestyle factors (raised BMI, smokers, etc) would increase risk of maternal morbidity, mortality and negative fetal outcomes. Thus, these factors are addressed in the existing policies and would need to be in any new policy. No backlog has been flagged at contract review meetings with providers.	**Neutral**

	1b	Have staffing, skill mix and workload issues been considered within the plans?	What assurances have the service providers given with regard to assessing their workforce requirements to deliver this service/pathway safely? Prompts to consider: skill mix, recruitment activity, vacancy, training etc. **Covid specific** – what is impact on staff availability to work, numbers of staff shielding, vulnerable, having to work differently. How will required MDT working be addressed in order to offer service provision for patients who are shielding	If in **option 1** the number of cycles is aligned to one cycle across BLMK then a small reduction in demand is likely (those patients who currently undergo cycles 2 & 3 in Luton). Widening the access criteria however is likely to increase demand overall although we do not have data quantifying this demand. This may have a limited impact on workforce in fertility services and later maternity care (potentially leading to higher risk obstetric led care). If in **option 2** the number of cycles is increased to three cycles across BLMK then an increase in demand is likely (those patients who currently undergo one cycle in Bedfordshire and Milton Keynes would now be able to access up to 3). Widening the access criteria however is likely to also increase demand although we do not have data quantifying this demand. The increased demand would impact workforce in fertility services and later maternity care (potentially leading to higher risk obstetric led care).	**Neutral**

SAFETY	**1c**	Do the plans include changes to treatment involving medications, (including prescribing, administration or security)	What impact will the plans have on medicines security and have you received assurance as to how any risks will be mitigated? Prompts to consider: Patient safety. Competency in medicines administration. Systems in place to ensure appropriate monitoring of patient outcomes/safety. Have you sought support/advice from the Meds Management Team? **Covid specific** – treatment of patients including virtual assessments – OPD assessments for clinical presentations. What safety consideration are in place in using technology for assessment? What are positives for patient safety using technology?	No changes identified. Not applicable	**Neutral**
	1d	Explain any impact on the organisation's duty to protect children, young people and adults?	Protocols to consider include: The NHS Constitution, Partnership working, Safeguarding children or adults Have you sought support/advice from the Safeguarding Team? **Covid specific** – How will safeguarding be considered in virtual assessment settings? Digital technology – has robustness and safety of service been assessed to prevent against any safeguarding concerns.	All the existing policies state: "Providers must meet the national statutory requirements to ensure the welfare of the child. This includes HFEA's Code of Practice which considers the 'welfare of the child which may be born' and takes into account the importance of a stable and supportive environment for children as well as the pre-existing health status of the parents." See also www.hfea.gov.uk. This would need to be included in any new policy so the impact is neutral	**Neutral**
	1e	Explain how the planned changes will be ratified through a governance process?	In the event of a legal challenge, how thorough is the ratification process? Where is clinical leadership and decision making? Prompts to consider Current statutes / professional standards E.g. Mental Capacity Act, Mental Health Act, Dangerous Drugs Act, Children's' Act, No Secrets, GMC, NMC etc. Involvement of the appropriate specialist Responsible committees within each organisation and across the pathway (Please note these may be outlined within the NICE Guidance) Overview and Scrutiny Committee; who and how will the changes/KPI's be monitored; what early warning flags will be monitored/reviewed and by whom? **Covid specific** Where is governance agreement across BLMK commissioning and provision? Has clinical leadership and involvement been sought? Has there been any feedback through incident management cell regarding service provision? Infection prevention and Control response requires cautious consistent consideration and adherence to specific Public health England guidance. How has this been considered?	A governance process which requires ratification is required due to a risk of legal challenge. Legal advice has been sought: No legal obligation for the CCGs to fund Artificial Insemination with Sperm Donor (AID) for any cohort of patients (2.1.) Commissioning it for some cohorts and not for others may carry a risk of discrimination and/or public law claims (2.1.) Restrictions would need to be supported by a strong rationale Restricting access for all three cohorts (same sex females, single females and transmen with a uterus) would carry the same level of risk of challenge Not funding treatement would be a breach to the Equalities Act (all policies currently support access) We did not seek legal advice regarding fertility support for same sex males as we do not fund surrogacy, in line with national guidance. The Task and Finish Group made up of primary and secondary care clinical leads has reviewed the existing policies and provided challenage around planned changes.	**N/A**

	ID	What is the potential impact of the service development on clinical effectiveness?	Use these prompts to help you comprehensively evaluate the plans	Information to inform Self-Assessment	Self-Assessment
CLINICAL EFFECTIVENESS	**2a**	How are the planned changes or service re-design in line with the most up-to-date guidance ensuring the business case is evidence- based? NICE baseline assessment tool can be accessed from: www.nice.org.uk Has the NICE commissioning Costing Tools been used? What plans are in place for clinical audit or evaluation	Has a baseline assessment against recommendations/indicators been undertaken? Does the plan reflect the Quality Standard Indicators? Are there gaps? If there are gaps, how will these be addressed? Use NICE costing tools alongside the guidance, where available. These can be accessed from: www.nice@org.uk Audit against standards outlined in NICE guidance or professional standards. Use the NICE clinical audit tool where available www.nice@org.uk **Covid specific** If this is a service delivery change or service change, due to Covid impact, how will this service and how quickly be evaluated? What are timelines and where will this evaluation be shared	Benchmarking against NICE guidance has been employed, but rationale based on funding and likely outcomes has been considered locally in line with clinical indicators and public consultion. Guidance from HFEA has also been consulted. https://www.hfea.gov.uk/media/2920/commissioning-guidance-may-2019-final-version.pdf	**N/A**

CL	**2b**	What are the Health Outcomes for patients?	What are the expected health outcomes for patients? How will the success against your expected health outcomes be measured? How do these compare with other available treatment or care pathway alternatives? **Covid Specific** If this is a service delivery change or service change, due to Covid impact, how will this service and how can the same outcomes for patients be achieved? Will outcomes be improved? Will this affect access to services? Could this have impact on health outcome is access is different	Infertility can have a real impact on individuals' mental health. Failure to address infertility and commission appropriate treatments can lead to a significant burden on the health sector. Commissioning fertility treatment can have positive health outcomes because it: • Reduces rates of mental health issues relating to infertility • Reduces the incidence of multiple births (reproductive tourism, where people travel abroad for fertility treatment, often leads to health complications or multiple births absorbed by the NHS) We expect the planned changes to widen the access criteria will achieve the above outcomes for a larger proportion of our population. This would be measured by the number of patients accessing the service and treatment outcomes. Noting in relation to option 1: Some patients in Luton	**Positive**

	ID	What is the potential impact of the service development on patent experience and involvement?	Use these prompts to help you comprehensively evaluate the plans	Information to inform Self-Assessment	Self-Assessment
PATIENT EXPERIENCE AND INVOLVEMENT	**3a**	What do patients and carers say about the current service?	Use positive and negative feedback from: PALS and complaints, patient opinion, surveys Real time feedback, focus groups, LINk/Healthwatch **Covid Specific** What feedback has been received from service users since commencement of business contingency and incident management for Covid in health services	Case studies to be added (inc complaints)? Can Fertility UK or Health Watch help us to reach out to patient groups to get feedback? FFT and quality schedule also to be added.	
	3b	How will patients, carers and key stakeholders be involved in the decision-making process around the development of this service?	At what point in the decision-making process will patients and public have a chance to influence the service development? What methods will be used to involve patients, public and stakeholders? Has advice been sought from the Strategic Public Involvement Group as to how best to manage this. **Covid specific** How have you engaged for co-production with service users /patients on Covid specific service change	The policy will be open to public consultation. Engagement with Service user groups List out the different foums, groups etc that we have planned?	**N/A**
	3c	How will the service development improve the patient experience?	How will this be captured?	Inclusion/exclusion criteria will be standardised across BLMK. The "Postcode lottery" across the system with be eliminated.	**Positive**
	3d	How will the patient experience of the new service be monitored?	How will feedback be collected? Who will be analysing it and when? **Covid specific** If covid specific service change how have you continued to engage with patient group	Patient experience will be monitored through existing mechanisms including: FFT, PALs/complaints and patient surveys.	**Neutral**
	3e	How will patient choice be affected?	Will choice be reduced, increased or stay the same? Do the plans support the compassionate and personalised care agenda? Have you sought specialist Equality and Diversity support and advice? **Covid specific** Choice may be affected due to impact on resource /workforce , how has this been communicated to patients	There are no planned changes which impact on patient choice.	**Neutral**
	3f	What level of public support for this service development is anticipated?	Do you expect people to be supportive, be a little concerned or contact their MP or the press as a result of their objections ? **Covid specific** Has there been any Covid specific feedback nationally/locally regarding service access?	Public support may be limited, with unknown proportions of the population being of the opinion that fertility should not be a key priority for the NHS. This will be gauged during public consultation.	**Neutral**

Quality Team Commentary, Recommendations & Sign-Off

To be completed by a member of the Quality team.

SAFETY	CLINICAL EFFECTIVENESS	PATIENT EXPERIENCE AND INVOLVEMENT
Commentary	**Commentary**	**Commentary**
By only offering 1 cycle there is potential for patients to seek fertility services by unregulated service providers overseas which are not regulated as per HFEA standards and can lead to high risk maternity complications, including multiple births.	Clinical effectiveness measures will need to be implemented to statistically determine success rates of one cycle.	Patient experience and involvement among users of fertility services will be optimised by ensuring equality of access across BLMK. Involvement with mental health services is paramount due to the recognised emotional impact fertility treatment can have (and conversely, the acceptance of infertility, on individuals and families).
Recommendation	**Recommendation**	**Recommendation**
Further Assurance Required	**Proceed**	**Proceed**

	Final Sign-Off	
	Name	**Date**
Signature of Senior Responsible Owner (SRO)	**Sarah Whiteman**	**TBC**
Signature of Quality Team Member	**Claire Flower**	**TBC**

EQUALITY ANALYSIS (EA) FORM

Name of Scheme	Specialist Fertility
Scheme Lead	Specialist Fertility Task and Finish Group
Organisation	BLMK CCG
Date & Version	Oct 2021 Version **0.4 DRAFT** **covering option 1**&2
Name of member of Arden & Gem E&D Team or HR Team supporting (if applicable)	Emma Richards

DRAFT

What is the aim of the scheme?	The merger of Bedfordshire, Luton and Milton Keynes CCGs has led to the need for a single specialist ferility policy. It has been identified that policy alignment for specialist fertility will require public consultation due to the variation in existing policies. Two options have been developed: **Option 1:** To reduce the current offer of three cycles of IVF to residents in Luton to one cycle for all eligible patients, in line with the current offering in Bedfordshire and Milton Keynes and extend access to the service to fund artificial insemination for same sex females couples, single females and any person with a uterus (including trans men and non-binary people) to ensure equity of access. **Option 2:** To increase the number of cycles available to couples in Bedfordshire and Milton Keynes, in line with the current Luton model and extend access to the service to fund artificial insemination for same sex females couples, single females and any person with a uterus (including trans men and non-binary people) to ensure equity of access.
Who will be affected by this work? e.g. staff, patients, service users, partner organisations etc.	Patients and provider organisations

SCREENING SECTION

Is a full EA required for this Scheme? Please colour "Yes" or "No" accordingly	**Yes**	**Proceed to the full EA below**	**No**	**Explain why further analysis is not required in the box to the right**	*n/a*

FULL EQUALITY ANALYSIS (EA) FORM

If at an initial stage further information is needed to complete a section this should be recorded and updated in subsequent versions of the EA. An Equality Analysis is a developing document, if you need further information for any section then this should be recorded in the relevant section in the form and dated

1	**Evidence used** What evidence have you identified and considered in determining the impact of this decision e.g. census demographics, service activity data, consultation responses

The following evidence has been identified in determining the impact of this decision, however analysis of consultation responses is not yet possible:
- Public consultation responses
- National guidance
- Service activity data
- Service user feedback
- National best practice e.g. Brighton and Sussex University Hospitals Gender Additive approach in perinatal services

2	**Impact of decision** In the following boxes detail the findings and impact identified (positive or negative) within the research detailed above; this should include any identified health inequalities which exist in relation to this work
2.1	**Age** Describe age-related impact and evidence. This can include safeguarding, consent and welfare issues

Clinically justified age limits are in line with NICE guidance.The most important factor in predicting the success of fertility treatment is age: birth rates from fertility treatment fall with increasing female (or egg donor's) age. The access criteria for fertility treatment for women aged 40-42 years is not referred to in the existing Bedfordshire policy. This should be alighned to include age up to 42 and the paternal age limit of 55 years should be removed.

2.2	**Disability** Describe disability-related impact and evidence. This can include attitudinal, physical, communication and social barriers as well as mental health/learning disabilities, cognitive impairments

No restrictions according to disability. Access to fast-tracked assisted conception /treatment where a known disability prevents intercourse will be promoted. Parenting capacity assessments may need to be considered in cases of severe physical/mental health/ learning disabilities.

2.3	**Gender reassignment (including transgender)** Describe any impact and evidence in relation to transgender people. This can include issues such as privacy of data and harassment

Consideration to ensure we are compliant with our duties under the Equality Act 2010 to ensure our fertility treatment crieria include any person with a uterus (including trans men and non-binary people). There is a risk of an impact on how trans men & non-binary people plan any wider gender specialist care in line with the 3 year requirement to show unexplained fertility, this may cause some patients to delay the taking on of hormones or hormone blockers which may lead to increase distress and an an impact on mental wellbeing.

2.4	**Marriage and civil partnership** Describe any impact and evidence in relation to marriage and civil partnership. This can include working arrangements, part time working and caring responsibilities

Access to investigations and treatment has been addressed in terms of civil partnership status, with equality provisions for single sex female couples, single individuals and any person with a uterus (including trans men and non-binary people).

2.5	**Pregnancy and maternity** Describe any impact and evidence in relation to marriage and civil partnership. This can include working arrangements, part time working and caring responsibilities

This policy excludes potential service users who have previous children from current or previous relationships, irrespective of residency of the child(ren).

2.6	**Race** Describe race-related impact and evidence. This can include information on different ethnic groups, Roma gypsies, Irish travellers, nationalities, cultures and language barriers

This policy will be applied equally, irrespective of race. Language barriers to be addressed by ensuring the availabiliity of information in other languages. It is also noted that BMI figures vary based on ethnicity. In the existing policy for Milton Keynes CCG area there is no maximum BMI for male partners, however in Luton and Bedfordshire CCG areas the maximum is 35. There is potential for male partners from certain ethnic groups to be inpacted by this change. The rationale for expanding the maximum to include Milton Keynes area is based on reduced fertility of male partners with a BMI over 30 as set out in NICE guidelines: "Men who have a BMI of 30 or over should be informed that they are likely to have reduced fertility".

2.7	**Religion or belief** Describe any impact and evidence in relation to religion, belief or no belief on service delivery or patient experience. This can include dietary needs, consent and end of life issues

No potential service user will be advantaged or disadvantaged based on religion or belief.

2.8	**Sex** Describe any impact and evidence in relation to men and women. This could include access to services and employment

Criteria for investigations for male and female partners are included in the policy. Male only partnerships are not include in this policy due to the exclusion of surrogacy. However, infertility investigations will still be offered in line with criteria. We have considered the need to ensure language is inclusive including in relation to specifiying gender and sex.

2.9	**Sexual orientation** Describe any impact and evidence in relation to heterosexual people as well as lesbian, gay and bisexual people. This could include access to services and employment, attitudinal and social barriers

Equal access to fertility investigations, irrespective of sexual orientation (see above). It is also noted that BMI figures vary based on sexual orientation. In the existing policy for Milton Keynes CCG area there is no maximum BMI for male partners, however in Luton and Bedfordshire CCG areas the maximum is 35. There is potential for male partners from certain ethnic groups to be inpacted by this change. The rationale for expanding the maximum to include Milton Keynes area is based on reduced fertility of male partners with a BMI over 30 as set out in NICE guidelines: "Men who have a BMI of 30 or over should be informed that they are likely to have reduced fertility".

2.10	**Carers** Describe any impact and evidence in relation to part-time working, shift-patterns, general caring responsibilities. (Not a legal requirement but a CCG priority and best practice)

Not applicable to this policy.

2.11	**Other disadvantaged groups** Describe any impact and evidence in relation to groups experiencing disadvantage and barriers to access and outcomes. This can include socio-economic status, resident status (migrants, asylum seekers), homeless people, looked after children, single parent households, victims of domestic abuse, victims of drug/alcohol abuse. This list is not finite. This supports the CCG in meeting its legal duties to identify and reduce health inequalities

Socio-economic: positive, single parent: positive, other groups: neutral.

3	**Human rights** The principles are Fairness, Respect, Equality, Dignity and Autonomy

Will the proposal impact on human rights? *Please colour "Yes" or "No" accordingly*		**No**
Are any actions required to ensure patients' or staff human rights are protected? *Please colour "Yes" or "No" accordingly*	**Yes**	

If so what actions are needed? Please explain below.

Consideration of:
The 1969 United Nations declaration on social progress and development which states "Ensure that family planning, medical and related social services aim not only at the prevention of unwanted pregnancies but also at the elimination of involuntary sterility and subfecundity in order that all couples may be permitted to achieve their desired number of children, and that child adoption may be facilitated". https://www.un.org/en/development/desa/population/theme/rights/index.asp

The World Health Organisation defines infertility as a disease and as a national health service there is a duty of care for any illness. "Infertility is a disease of the male or female reproductive system defined by the failure to achieve a pregnancy after 12 months or more of regular unprotected sexual intercourse." https://www.who.int/news-room/fact-sheets/detail/infertility#:~:text=Infertility%20is%20a%20disease%20of,on%20their%20families%20and%20communities.

4	**Health Inequalities.** e.g. patients with a learning disability were accessing cancer screening in substantially smaller numbers than other patients. By revising the pathway the CCG is able to show increased take up from this group, this a positive impact on this health inequality

Health inequalities have been identified in the existing policies for access by single females, same sex couples and other people with a uterus (including trans men and non-binary people). This will need to be addressed in the new policy.

5	**Engagement/consultation** What engagement is planned or has already been done to support this project?

Engagement activity	With whom? e.g. protected characteristic/group/community	Date
Planned engagement	With relevant patient groups	
	Engagement with wider communities and potential service users	

Please summarise below the key finding / feedback from your engagement activity and how this will shape the policy/service decisions e.g. patient told us, so we will… (If a supporting document is available, please provide it or a link to the document)

This will need to be populated once analysis of consultation has been done.

6	**Mitigations and changes** If you have identified mitigations or changes, summarise them below. E.g. restricting prescribing over the counter medication. It was identified that some patient groups require high volumes of regular prescribing of paracetamol, this needs to remain under medical supervision for patient safety, therefore an exception is provided for this group which has resolved the issue

Extending access to the service to fund artificial insemination for same sex females couples, single females and any patient with a uterus (including trans men and non-binary people) ensuring equity of access. Aligning the age limit for fertility treatment to 42 and removing the paternal age limit. We have also taken a gender additive approach to ensuring inclusive language and when describing equity of access criteria to ensure no erasure of identity and any acknowledge inequalities occures. This means we have sought to add language and be explicit when discussing the inclusion of patients other than women who have a uterus rather than seeking more general gender neutral language throughout.

7	**Is further work required to complete this EA?** Please state below what work is required and to what section e.g. additional consultation or engagement is required to fully understand the impact on a particular protected group (e.g. disability)

Work Needed	Section	When	Date Completed
Further pre-engagement to help develop this EA and ensure the gender additive approach to delivering equity and ensuring inclusive language has not excluded any specific group	All	Aug / Sept	
Further review once the analysis from the public consultation is availble	All	Jan	

8	**Development of the Equality Analysis** If the EA has been updated from a previous version please summarise the changes made and the rationale for the change, e.g. Additional information may have been received – examples can include consultation feedback, service Activity data

Version	Change and Rationale	Version Date
e.g. Version 0.1	The impact on wheelchair users identified additional blue badge spaces are required on site to improve access for this group.	23-Aug-20

9	**Final Sign off** Completed EA forms must be signed off by the completing manager. They will be reviewed as part of the decision making process. Service lines should maintain an up to date log of all Eas

Version Approved:	TBC	
	Name	**Date**
Signature of Senior Responsible Owner (SRO)	Sarah Whiteman	TBC
Signature of HR Team Member	Emma Richards	TBC