Mid and South Essex Integrated Care System

NHS Mid and South Essex Integrated Care Board

Meeting of the Mid and South Essex Integrated Care Board

Thursday, 9 February 2023 at 3.00 pm – 4.00 pm

Marconi Room, Chelmsford Civic Centre, Duke Street, Chelmsford, Essex CM1 1JE

Part I Agenda

No	Time	Title	Action	Papers	Lead	Page No
		Opening Business				
1.	3.00 pm	Welcome and Apologies for Absence	Note	Verbal	Professor M Thorne	-
2.	3.02 pm	Review of Register of Interests and Declarations of Interest	Note	Attached	Professor M Thorne	2
3.	3.05 pm	Questions from the Public	Note	Verbal	Professor M Thorne	-
4.	3.10 pm	Minutes of ICB Board meeting held 19 January 2023 and matters arising.	Approve	Attached	Professor M Thorne	4
5.	3.12 pm	Review of Action Log	Note	Attached	Professor M Thorne	14
		Items for Decision				
6.	3.15 pm	Harmonisation of Commissioning Policies: • Bariatric Surgery • Breast asymmetry • Breast reduction • Female Sterilisation. • Vasectomy • Tertiary Fertility Services.	Approve	Attached	Dr R Fenton	15
		Items For Noting				
7.	3.59 pm	Any Other Business	Note	Verbal	Professor M Thorne	-
8.	4.00 pm	Date and time of next Part I Board meeting: Thursday, 16 March 2023 at 3.00 to 5.00 pm, to be held in Committee Room 1, Southend Civic Centre, Victoria Avenue, Southend-on-Sea, Essex SS2 6ER	Note	Verbal	Professor M Thorne	-

Agenda Item 2

MID AND SOUTH ESSEX INTEGRATED CARE BOARD
Register of Board Members' Interests - February 2023

First Name	Surname	Job Title / Current Position	Declared Interest (Name of the organisation and nature of business)	Type of Interest Declared			Is the interest direct or indirect?	Nature of Interest	Date of Interest		Actions taken to mitigate risk
				Financial	Non-Financial Professional Interest	Non-Financial Personal Interest			From	To	
Les	Billingham	Local Authority Partner Member for Thurrock Council	Thurrock Council	x			Direct	Interim Director of Adults Social Care		Ongoing	Interest included in Board register of Interests. To be declared if and when necessary so that appropriate arrangements can be made to manage any conflict of interest.
Frances	Bolger	Interim Chief Nursing Officer	Suffolk and North East Essex ICB	x			Direct	Director of Midwifery	03/01/23	Ongoing	I will declare this interest as necessary so that appropriate arrangements can be made if required.
Hannah	Coffey	ICB Partner Member	Mid and South Essex NHS Foundation Trust				Direct	Interim Chief Executive		Ongoing	I will declare this interest as necessary so that appropriate arrangements can be made if required.
Anna	Davey	GP Partner Member	Coggeshall Surgery Provider of General Medical Services	x			Direct	Partner in Practice providing General Medical Services	09/01/17	Ongoing	I will not be involved in any discussion, decision making, procurement or financial authorisation involving the Coggeshall Surgery or Edgemead Medical Services Ltd
Anna	Davey	GP Partner Member	Colne Valley Primary Care Network	x			Direct	Partner at The Coggeshall Surgery who are part of the Colne Valley Primary Care Network - no formal role within PCN.	01/06/20	Ongoing	I will declare my interest if at any time issues relevant to the organisation are discussed so that appropriate arrangements can be implemented and will not participate in any discussion, decision making, procurement or financial authorisation involving the Colne Valley PCN.
Anna	Davey	GP Partner Member	Essex Cares	x			Indirect	Close relative is employed	06/12/21	On-going	I will declare my interest if at any time issues relevant to the organisation are discussed so that appropriate arrangements can be implemented
Peter	Fairley	ICB Partner Member (Essex County Council)	Director for Strategy, Policy and Integration, at Essex County Council (ECC)	x	x		Direct	Essex County Council (ECC) holds pooled fund arrangements with NHS across Mid and South Essex. I am the responsible officer at ECC for the Better Care Fund pooled fund. ECC commissions and delivers adults and childrens social care services and public health services. ECC has some arrangements that are jointly commissioned and developed with NHS and local authority organisations in Mid and South Essex. ECC hosts the Essex health and wellbeing board, which co-ordinates and sets the Essex Joint Health and Wellbeing Strategy	01/07/22	Ongoing	Interest declared to MSE ICB and ECC. If in potential conflict take the advice of the Chair/ Monitoring Office and if need be absent one's self from the vote/ discussion.
Peter	Fairley	ICB Partner Member (Essex County Council)	Suffolk and North East Essex (SNEE) Integrated Care Partnership	x	x		Direct	ECC representative	01/07/22	Ongoing	Interest declared to MSE ICB and ECC. If in potential conflict take the advice of the Chair/ Monitoring Office and if need be absent one's self from the vote/ discussion.
Ronan	Fenton	Medical Director	Mid and South Essex Foundation Trust	x	x		Direct	Employed as Consultant Anaesthetist	20/06/05	Ongoing	I will declare my interest if at any time issues relevant to MSEFT or anaesthetic services are discussed so that appropriate arrangements can be implemented.
Ronan	Fenton	Medical Director	Mid and South Essex Foundation Trust	x			Indirect	My wife is employed by MSEFT as a Consultant Anesthetist.	24/06/05	Ongoing	I will declare my interest if at any time issues relevant to MSEFT or anaesthetic services are discussed so that appropriate arrangements can be implemented.
Ronan	Fenton	Medical Director	Springfield Hospital/Ramsay Healthcare	x			Direct	I carryout Private Medical Services at Springfield Hospital	20/06/05	Ongoing	I will declare my interest if at any time issues relevant to Springfield Hospital or Private anaesthetic services are discussed so that appropriate arrangements can be implemented.

Agenda Item 2

MID AND SOUTH ESSEX INTEGRATED CARE BOARD
Register of Board Members' Interests - February 2023

First Name	Surname	Job Title / Current Position	Declared Interest (Name of the organisation and nature of business)	Type of Interest Declared			Is the interest direct or indirect?	Nature of Interest	Date of Interest		Actions taken to mitigate risk
				Financial	Non-Financial Professional Interest	Non-Financial Personal Interest			From	To	
Ronan	Fenton	Medical Director	Springfield Hospital/Ramsay Healthcare	x			Indirect	My wife carries out private medical services at Springfield hospital	26/06/05	Ongoing	I will declare my interest if at any time issues relevant to Springfield Hospital or Private anaesthetic services are discussed so that appropriate arrangements can be implemented.
Ronan	Fenton	Medical Director	Fentons Limited	x			Direct	I ama a registered officer of "Fentons Ltd" which is a company which offer general and specialist medical services	22/06/05	Ongoing	I will declare my interest if at any time issues relevant to this company or private anaesthetic services are discussed so that appropriate arrangements can be implemented.
Joseph	Fielder	Non-Executive ICB Board Member	Four Mountains Limited	x			Direct	Director	01/05/17	Ongoing	No conflict of interest is anticipated
Joseph	Fielder	Non-Executive ICB Board Member	North East London Foundation Trust	x			Indirect	Personal relationship with Director of Operations for North East London area.	01/01/19	Ongoing	As above.
Joseph	Fielder	Non-Executive ICB Board Member	NHS England and Improvement	x			Indirect	Close family member employed as senior manager in strategy	01/01/23	Ongoing	As above.
Neha	Issar-Brown	Non-Executive ICB Board Member	Queen's Theatre Hornchurch (QTH)			x	Direct	QTH often works with local volunteer sector including Healthwatch, Social care sector for various community based initiatives, which may or may not stem from or be linked to NHS (more likely BHRUT than MSE).		Ongoing	No immediate action required. Interest to be declared if a conflict of interest is identified.
Ruth	Jackson	Executive Chief People Officer	Nil								
Jennifer	Kearton	Executive Director of Resources	Nil								
Benedict	Leigh	ICB Partner Board Member	Southend City Council	x			Direct	Senior Member of Staff	01/07/22	Ongoing	No immediate action required. Interest to be declared if a conflict of interest is identified.
Benedict	Leigh	ICB Partner Board Member	Sense		x		Direct	Trustee	01/07/22	Ongoing	Will recuse myself from any procurement or commissioning decision that may involve the award of contracts to Sense or the negotiation of fee rates for services. Will recuse myself from discussions within Sense board if these involve Commercial relationships with MSE ICS
Benedict	Leigh	ICB Partner Board Member	Migrant Help	x			Indirect	Partner is a member of staff	01/07/22	Ongoing	Will not discuss commercial matters relating to either Migrant Help or MSE ICS with partner. Interest to be declared if and when a conflict of interest arises.
Anthony	McKeever	Chief Executive of the Mid & South Essex Integrated Care Board	MACS et al Ltd	x			Direct	Director of wholly owned company through which I contract with the NHS for interim and other services.	02/03/20	On-going	As of 3/10/2020 I am employed and paid through NHS payroll for my role in Mid and South Essex. However, I will declare my interest in MACS et al Ltd if and where required so that appropriate arrangements can be implemented.
Anthony	McKeever	Chief Executive of the Mid & South Essex Integrated Care Board	Royal Society of Medicine (RSM)		x		Direct	Fellow	02/03/20	On-going	No immediate action required.
Anthony	McKeever	Chief Executive of the Mid & South Essex Integrated Care Board	Faculty of Medical Leadership & Management (FMLM)		x		Direct	Fellow	02/03/20	On-going	No immediate action required.
Paul	Scott	ICB Partner Member	Essex Partnership University NHS Foundation Trust	x			Direct	Chief Executive Officer	01-Jul-23	Ongoing	I will declare this interest as necessary so that appropriate arrangements can be made if required.
Mike	Thorne	ICB Chair	Nil								
George	Wood	Non-Executive ICB Board Member	Princess Alexandra Hospital	x			Direct	Senior Independent Director, Chair of Audit Committee, Member of Board, Remuneration Committee and Finance & Performance Committee	01/07/19	Ongoing	Clear separation of responsibilities and conflicts.
George	Wood	Non-Executive ICB Board Member	Barking, Havering and Redbridge University Hosptals NHS Trust (BHRUT)	x			Direct	Chairman of hospital charity.	01/01/15	Ongoing	Interest to be declared if and when any matters relevant to BHRUT are discussed so that appropriate arrangements can be implemented.

Minutes of the Part I Board Meeting

Held on 19 January 2023 at 3.00 pm – 5.00 pm

Gold Room, Prince Charles Avenue, Orsett Hall, Thurrock, Essex, RM16 3HS

Attendance

Members

- Professor Michael Thorne (MT), Chair of Mid and South Essex Integrated Care Board (MSE ICB).
- Anthony McKeever (AMcK), Chief Executive of MSE ICB.
- Dr Ronan Fenton (RF), Medical Director, MSE ICB.
- Jennifer Kearton (JK), Director of Resources, MSE ICB.
- Frances Bolger (FB), Interim Chief Nurse, MSE ICB.
- Dr Ruth Jackson (RH), Chief People Officer, MSE ICB.
- Joe Fielder (JF), Non-Executive Member.
- Dr Neha Issar-Brown (NIB), Non-Executive Member.
- George Wood (GW), Non-Executive Member.
- Hannah Coffey (HC), Partner Member, Mid and South Essex NHS Foundation Trust.
- Les Billingham (LB), Partner Member, Thurrock Council.
- Peter Fairley (PF), Partner Member, Essex County Council.
- Dr Anna Davey (AD), Primary Care Board Member.

Other attendees

- Jacqui Van Rossum (JVR), Acting Chief Executive of North East London NHS Foundation Trust (on behalf of Paul Scott).
- Jo Cripps (JC), Executive Director of Strategy and Partnerships.
- Dr Tiffany Hemming (SH), Interim Executive Director of Oversight and Delivery, MSE ICB.
- Dan Doherty (DD), Alliance Director (Mid and South Essex) MSE ICB.
- Pam Green (PG), Alliance Director (Basildon & Brentwood) MSE ICB.
- Aleksandra Mecan (AM), Alliance Director (Thurrock), MSE ICB.
- Mike Thompson (MTh), Chief of Staff, MSE ICB.
- Claire Hankey (CH), Director of Communications and Engagement, MSE ICB.
- Gemma Hickford (GH), Consultant Midwife, MSE ICB.
- Sara O'Connor (SO), Head of Governance and Risk (minute taker).

Apologies

- Paul Scott (PS), Partner Member, Essex Partnership University NHS Foundation Trust.
- Benedict Leigh (BL), Partner Member, Southend City Council

1. Welcome and Apologies (presented by Prof. M Thorne).

MT welcomed everyone to the meeting and noted apologies as listed above. JVR advised she was attending on behalf of PS.

2. Amendment to Board Meeting Conduct and Etiquette Protocol.

MT drew members' attention to the amendment to the Board Meeting Conduct and Etiquette Protol regarding the use of mobile phones during meetings. No comments were received.

Resolved: The Board approved the amendment to the Board Meeting Conduct and Etiquette Protocol regarding the use of mobile phones.

3. Declarations of Interest (presented by Prof. M Thorne).

MT reminded everyone of their obligation to declare any interests in relation to the issues discussed at the beginning of the meeting, at the start of each relevant agenda item, or should a relevant interest become apparent during an item under discussion, in order that these interests could be managed.

JF advised that his declaration of interest would be updated because one of his son's had moved roles from Guys and St Thomas Hospital to NHS England and Improvement.

RF advised that he was in the process of updating his declaration of interest.

SO confirmed the register of interests would be updated accordingly.

Declarations made by ICB Board and committee members are listed in the Register of Interests and available on the ICB website**.**

ACTION: SO to update the register of Board members' interests to reflect revised declarations from JF and RF and then upload the new register to the website.

4. Questions from the Public (presented by Prof. M Thorne).

Peter Blackman (Chair of South Woodham Ferrers Health & Social Care Group), who was present at the meeting, had submitted the following question:

"Given the present situation, what please is your message to the local communities in places like South Woodham Ferrers about the levels of services they can expect today and how they can help you to make those services work as well as possible? In particular as examples, what can they expect and should do if people seem likely to be having a cardiac arrest, a heart attack, a stroke, be involved in a serious accident where there seems to be a major trauma patient, and a serious accident where someone seems to have an open fracture or broken pelvis."

CH provided the following response to Mr Blackman:

The NHS was under extreme pressure as highlighted within the national and local news. There were number of key messages that the ICB would like to convey to the public at this time.

Firstly, when faced with an accident or major emergency such as those described in the question, it was imperative the public dialled 999 to seek professional advice and support. Despite the pressures faced by the ambulance service they were still prioritising the most urgent cases and would advise patients accordingly.

However, there are many things the public can do to ease pressure on local services.

The Do Your Bit campaign toolkit has previously been shared and remained accessible on the ICB website to guide the public in accessing services; for example by calling 111 for health advice; by using the pharmacist for help with basic health complaints; by stocking up appropriately on prescription and non-prescription medication during public holiday periods; and by taking up the vaccinations on offer for flu and COVID in the eligible population.

Outpatient and elective services were also under pressure. Where appropriate, patients could access the referral support service rather than contacting their GP when appointments were changed or cancelled.

Mr Blackman asked that the response was also emailed to him.

MT advised that a question relating to in-vitro fertlisation (IVF) services had been passed to the relevant team dealing with the harmonisation of commissioning policies.

Action: NA to arrange for the ICB's response to Mr Blackman to be emailed to him.

5. Minutes of the ICB Board Meeting held 17 November 2022 and matters arising (presented by Prof. M Thorne).

MT referred to the draft minutes of the ICB Board meeting held on 17 November 2022 and asked members if they had any comments or questions. No comments were submitted.

There were no matters arising.

Resolved: The Board approved the minutes of the ICB Board meeting held on 17 November 2022 as an accurate record.

6. Review of Action Log (presented by Prof. M Thorne).

The updates provided on the action log were noted.

LB referred to Action 2 and advised that he and AM had agreed draft Terms of Reference for Thurrock Alliance, subject to some minor amendments.

Resolved: The Board noted the updates on the action log.

Action: LB and AM to submit draft Terms of Reference for Thurrock Alliance to the ICB Board on 16 March 2023 for approval.

7. Local Maternity and Neonatal System (LMNS) Consultant Midwife Update (presented by G Hickford)

GH presented a set of slides providing an update on action being taken to improve maternity services within mid and south Essex (MSE). The recently published Care Quality Commission (CQC) report on Mid and South Essex Hospitals NHS Foundation Trust (MSEFT) had identified that maternity services required improvement. The LMNS was sighted on progress against the associated action plan which also incorporated recommendations made via other national or local reports.

GH and other stakeholders, including service users, participated in monthly quality assurance visits. Engagement with maternity staff enabled them to provide anonymous feedback. A dashboard supported the monitoring of key safety and quality indicators. The Trust would be establishing a data intelligence committee which GH would participate in on behalf of the system. The Serious Incident (SI) process supported the identification of themes and learning.

The results of the CQC annual maternity survey, published the previous week, confirmed an improvement in the majority of scores given by women who gave birth in 2022. The MSE LMNS also engaged with the Suffolk and North East Essex LMNS to share expertise. The MSE LMNS had been audited to ensure that its implementation of the Ockenden review recommendations was robust, with 'reasonable' assurance identified.

GH advised that key actions included improving the culture within MSEFT. Professional behaviours workshops already held would be rolled out further. Birthrights training would also be provided. Work was also ongoing to support maternity staff, with additional leadership posts in place, and to listen to and learn from those using maternity services by involving them in the co-production of services. The CQC report had confirmed there was evidence of good teamworking. The Trust also aimed to reduce staff sickness rates and improve appraisal rates.

MSEFT, the LMNS and NHSE/I participated in a multi-disciplinary thematic review of stillbirths over the preceding twelve months, following which an action plan was developed including a review of maternity services governance. The Perinatal Policy Surveillance Model implemented by the LMNS in 2022 provided a framework whereby concerns were escalated and intelligence shared. New roles of Senior Professional Advocate and Consultant Obstetrician to work with the LMNS were being filled to ensure that external oversight of MSEFT services was available.

In response to a query from NIB regarding the triangulation of data, GH advised that the LMNS, which was a collective of stakeholders, reviewed the maternity dashboard monthly via either its safety forum or the LMNS Board. GH then identified any areas of concern, such as the recruitment and retention of midwives, for escalation to the ICB Quality Committee.

RJ welcomed the rigour being applied to maternity services and noted that in the last year 100% of undergraduate midwives had transitioned into roles within MSEFT which was a very positive indicator.

HC acknowledged that despite recent progress, further work was required to improve services and asked how the LMNS interacted with other partner organisations. GH

confirmed there were good relationships with local authorities and public health colleagues, including collaboration on the smoke-free pregnancy pathway. The LMNS also linked with HealthWatch and other organisations.

AMcK welcomed the independent professional scrutiny being applied and asked for an update on progress against the last three Ockenden review recommendations.
GH confirmed that all three remained open as MSEFT and the LMNS were taking a cautious approach to ensure robust evidence was available before closing them, but all were on-track.

Resolved: The Board noted the Local Maternity and Neonatal System Consultant Midwife Update.

8. Quality Report (presented by F Bolger)

FB highlighted that Clostridium Difficuile Infection (CDI) rates continued to decline.

The Health and Safety Executive would visit MSEFT the following week to investigate the maternity nitrous oxide SI at Basildon Hospital. Two other Trusts had identified similar problems and a national review was being taken forward by NHSE/I.

Following issues identified by the Channel 4 'Dispatches' programme, the CQC undertook an inspection at Essex Partnership University NHS Foundation Trust (EPUT), the results of which were awaited. A Rapid Quality Review meeting was held to gain assurance regarding action being taken by EPUT and agree any additional support required. Monthly oversight meetings would monitor progress. The independent inquiry of mental health services was ongoing although it was understood some timelines might be delayed.

FB noted the outcome of the recent CQC report of MSEFT and confirmed the ICB's working relationship with the Trust was very positive, open and transparent.

A trajectory for completion of SI investigations by May 2023 had been agreed in preparation for transition to the new Patient Safety Incident Response Framework (PSIRF) by August 2023. An extension to a change in the cancer harm review process to free up clinicians' time to treat patients and reduce the backlog was being considered by NHSE/I.

In response to a query from GW, it was confirmed that information on the severity of incidents together with any worrying trends and details of communication plans with patients and their families, was provided to the ICB Quality Committee. In response to a further query from GW, FB confirmed that long stays in hospital was a potential contributory factor for pressure ulcers and falls incidents.

HC advised that declared SIs were considered by MSEFT's Executive Review Panel within 48 hours to identify any immediate learning, mitigating action required, and to ensure appropriate application of the Duty of Candour. The implementation of PSIRF would help organisations to more easily identify themes to support a quality improvement approach. MSEFT continued to work with regional and national experts to investigate the nitrous oxide SI, but acknowledged that the Trust did not resolve the problem on a timely basis, for which she had unreservedly apologised.

JF commented that it would be helpful to include the ICB's ambitions in relation to patient safety and quality in future reports.

Resolved: The Board:

- **Note the key quality concerns and escalations as identified by Quality Committee and the assurances provided regarding mitigating actions.**
- **Agreed that Clostridium Difficult Infection rates would continue to be monitored via Quality Committee with an update provided after the end of 2022/23.**
- **Noted the recent adverse media attention received by MSEFT resulting from the nitrous oxide serious incident; the recent Channel 4 Dispatches programme which featured Essex Partnership NHS Trust (EPUT); the resulting potential impact on confidence in services by the public and staff; and the consequent remedial actions being undertaken by the Trusts and, where appropriate, the ICB.**
- **Note the MSEFT Care Quality Commission report publication, findings and ICB oversight processes for supporting improvement of services.**
- **Agreed that the overdue SI and cancer harm reviews would continue to be monitored via the Quality Committee, with ICB oversight of MSEFT actions via formal meetings held with the Trust.**

9. Performance (presented by T Hemming)

TF confirmed that mental health standards were mainly being achieved, although improvements were required on second appointment times.

However, other constitutional standards were not met. The festive period was very challenging due in part to several child deaths caused by Streptococcus A infections reported in the national media, which had resulted in high rates of attendance in emergency departments (EDs) and primary care. Winter monies were therefore used to provide additional paediatric resources at the three EDs.

Southend Hospital had recently seen improvements in ambulance handover times as a result of new processes which should be reflected in the data for January 2023. January data should also highlight improvements against the ED 4 hour wait standard.

Diagnostic waiting times remained problematic, complicated by the backlog. A capacity and demand review would be undertaken to ensure sufficient capacity on an ongoing basis.

Significant work had been undertaken to reduce cancer backlogs, including a ‘Day Zero’ patient tracking list for skin cancer to ensure patients received appropriate treatment as quickly as possible. Teledermatology was also being implemented to speed up the two-week wait pathway in particular.

Referral to Treatment times had improved, with only one patient in December waiting 104+ weeks due to patient choice. Significant work was being taken to reduce the number of patients waiting 78+ weeks to zero by March 2023.

Additional community beds at Mountnessing and Halstead had made a positive impact and the volunteer network had provided support to patients discharged from hospital.

AMcK advised that he and Andrew Pike, MSEFT, recently met to review 78+ week waits to ensure they were eliminated by the end of March. This would involve outsourcing some procedures.

TF advised that although cancer performance remained below standard, there was an improving trajectory and backlogs should be eradicated within six months.

RF confirmed that national money was available for two Community Diagnostic Centres (CDCs) to be located in Thurrock and Braintree. There was confidence that money would be forthcoming for two further CDCs for which business cases were being developed. The CDCs should be established by 2025. RF outlined action being taken to address diagnostic capacity in the interim.

In response to comments by MT and LB regarding use of winter monies, PF advised that local authorities had been concerned with the national focus on putting patients into care homes which was not always the right setting.

HC thanked staff and partners for their hard work during a particularly challenging winter period. HC also explained that work to improve diagnostics, developing new pathways and using the workforce differently should reduce cancer/elective backlogs significantly.

Resolved: The Board noted the ICB performance report.

10. Fuller Stocktake Report (presented by Dr A Davey).

AD highlighted the progress made against plans to implement the Fuller Stocktake and 'Our Plan for Patients' locally as set out in the report.

AD noted that 46% more home visits had been provided than before the pandemic and MSE performance against the national ambition for patients to be seen within two weeks of contacting primary care was only slightly below national performance which, given current local challenges, was encouraging. Practices had made good progress with implementing and using digital solutions, including ordering of repeat prescriptions online.

In response to a request by LB, AD agreed to provide information regarding access to primary care services relating to each Alliance in future reports.

AD advised that a very small number of practices might remain resistant to digital solutions, although the ICB would encourage and support them to do so. MT thanked the primary care team and Alliance Directors for their ongoing work in this regard.

DD cautioned that the national ambition for patients to be seen within two weeks might not necessarily be the right target due to demographics, patient preferences and other factors. AD acknowledged that the target was controversial as primary care was not considered an emergency service and deliver against targets was affected by the way different cohorts of patients preferred to interact with GPs.

Resolved: The Board noted the Fuller Stocktake Report update report.

Action: AD to provide information regarding access to primary care services relating to each Alliance in future reports.

11. Finance Report Month 8 (presented by J Kearton)

JK confirmed that the month 8 (M8) position showed a break-even position for the ICB. The year-to-date position for the system was a deficit of £55.7 million, although data for M9 indicated the run rate had reduced to circa £5 million.

JK explained that the ICB was forecasting break-even as part of consolidated accounts. If the ICB wished to amend the forecast, regional and national discussions were required to support the effective management of NHS finances. Consequently, regular updates had been provided to negotiate a suitable forecast outturn for the system and it was likely that a deficit of circa £50 million would be forecast for 2023/23. The position would be clarified in more detail when M9 financial data was analysed and report to the Finance and Investment Committee and Board.

JK highlighted that the ICB position included an in-year System Risk Reserve which would be released. Consequently, no commitments had been reduced to-date. There was a cost pressure associated with use of bank and agency staff. Action was being taken to reduce this in line with the agency cap. However, despite the challenging financial position, MSE had been recognised for the collaborative approach being taken to address its financial position.

MT advised that as a result of the large deficit MSE would lose some autonomy and would have to abide with national financial rules and oversight requirements, although he was confident partner organisations would continue to work collaboratively to improve the financial situation. MT also asked that the full Board was made aware of and agreed any changes required to the forecast outturn position. JK confirmed that arrangements were in train to ensure this occurred.

JF mentioned the importance of ensuring there was evidence that approved business cases delivered anticipated improvements and savings.

Resolved: The Board noted the Month 8 Finance Report.

12. Approach to Operational Planning 2023/24 (presented by J Kearton and J Cripps)

JK advised that the report outlined the approach to be applied for the NHS operational planning round. Templates for completion had now been received from NHSE/I and a robust process had been put in place. The timeline within the report would be updated to reflect a submission to Finance and Investment Committee on 1 February 2023.

JC advised that the Joint Forward Plan (JFP) was a five year plan for the ICB and its NHS partner organisations which would respond to the Integrated Care Strategy signed off by the Integrated Care Partnership, to run alongside operational planning requirements.

AMcK advised that once proposals for ground rules between partner organisations had been agreed, a workshop should be held to help the Chief Executive Forum agree what was practicable and feasible. This would ensure that combined MSE resources of £3.9 billion were used effectively to create investment and development opportunities to save money in the long term.

JC advised that prior to submission of the final draft of the JFP, engagement was required with stakeholders and suggested that a workshop in February could be used to progress this.

LB highlighted that several strategies were being developed and although similar in content, it was important to ensure they reflected a unified set of objectives. LB also advised that Thurrock Council would be holding elections in May, with purdah commencing in March until the end of May 2023. The new cabinet would then be formed in June and asked that this was considered when seeking views. JC noted this and explained that although the JFP was technically a plan for the NHS, local authorities' views were valued.

GW advised that it was important that increased productivity, for example by maximising use of theatres, estates, and digital solutions was considered within the JFP.

HC asked that capacity was clearly defined, along with a longer-term approach to workforce planning, and to articulate what would happen if progress was not achieved as this could help to drive behaviours.

PG mentioned that the Alliances had shared the background to the JFP work with their committees to provide local engagement on the ICB's longer term plans.

Resolved: The Board noted the approach to operational planning 2023/24.

13. General Governance

13.1 Approved Minutes of Committee meetings

The Board received copies of the latest approved minutes of the following main committees:

- Quality Committee, 30 September 2022
- System Oversight and Assurance Committee (SOAC), 14 December 2022.
- Primary Care Commissioning Committee, 16 November 2022.

Resolved: The Board noted the latest approved minutes of the Quality Committee, System Oversight and Assurance Committee and Primary Care Commissioning Committee.

13.2 Decisions taken in between Board Meetings

MT advised that the Board was asked to ratify the decisions taken since the last Board meeting held on 17 November 2022 to approve three business cases as set out in the report.

Resolved: The Board ratified the decisions taken to approve the following business cases made in between Board meetings:

- **Alternative Provider Medical Service Procurement.**
- **Business Intelligence Procurement.**
- **Independent Sector Contracts for additional elective capacity.**

13.3 Adoption of new ICB Policies

MT advised that the Board was asked to ratify three new ICB policies which had received prior approval by the relevant committees as set out in the report.

Resolved: The Board ratified the following new ICB Policies:

- **MSEICB 003 - Procurement and Contracting Policy.**
- **MSEICB 076 - Individual Funding Request Policy.**
- **MSEICB 078 - Reimbursement of Staff Expenses Policy.**

14. Any Other Business

There was no other business discussed.

15. Date and Time of Next Part I Board meeting:

Thursday, 9 February 2023 at 3.00 pm to 4.00 pm in Marconi Room, Chelmsford Civic Centre, Duke Street, Chelmsford, Essex, CM1 1JE.

Action No.	Meeting Date	Agenda Item No.	Agenda Item Title and Action Required	Lead	Deadline for completion	Update / Outcome	Status
2	01/07/2022 and 17/01/2023	7 6	**Establishment of Committees** Advise of proposed amendments to the Thurrock Alliance Terms of Reference, for submission to the ICB Board meeting on 15 September 2022.	L Billingham / A Mecan	31/08/2022	Draft Terms of Reference for Thurrock have been developed and will be submitted to ICB Board on 16 March 2023 for approval.	In progress
4	01/07/2022	9	**Appointment of Lead Roles** Include appointment of Deputy Chair of the ICB to the agenda of a future Board meeting.	M Thompson	31/08/2022	Deferred until future Board meeting.	In progress
9	13/10/2022	8	**Digital Strategy and Investment Priorities** Secure investment requirements over future years.	System Leaders Finance Group/ J Kearton	Ongoing	Digital priorities discussed at System Finance Leaders Group, deep dive planned for 7 February 2023.	In progress
14	13/10/2022	12	**Finance Report:** Clarify budgetary pressures within the hospital relating to the use of interim staff.	J Kearton	17/11/2022	There is a cost pressure associated with use of bank and agency staff. Action is being taken to reduce this in line with the agency cap and system financial plans.	Complete
18	17/11/2022	3	**Board Assurance Framework** Consider how mental health services should be articulated within the BAF.	A McKeever/ M Thompson	16/03/2022	To be reflected as appropriate in future iteration of the BAF.	In progress
19	19/01/2023	10	**Fuller Stocktake** Provide information regarding access to primary care services relating to each Alliance in future reports.	A Davey E Cox	16/03/2023	To be included in next Fuller Stocktake update.	In progress

Part I ICB Board meeting, 9 February 2023

Agenda Number: 6

Service Harmonisation Business Case

Summary Report

1. Purpose of Report

To set out the proposed harmonisation of service restriction policies for six services, from five sets of legacy policies to one single policy for each, and the likely impact of doing so in the way proposed.

The six services are:

- Bariatric Surgery.
- Breast asymmetry.
- Breast reduction.
- Female Sterilisation.
- Vasectomy (male sterilisation).
- Tertiary Fertility Services – including intra-uterine insemination (IUI), in vitro fertilisation (IVF), with or without intra-cytoplasmic sperm injection (ICSI) and sperm and oocyte donation.

2. Executive Lead

Dr Ronan Fenton, System Medical Director, Mid and South Essex Integrated Care System (MSE ICS)

3. Report Author

Dr Peter Scolding, Assistant Medical Director, MSE ICS

4. Responsible Committees

- Clinical and Multi-Professional Congress
- Finance and Investment Committee
- Quality Committee

5. Impact Assessments

Equality and health inequality impact assessments have been undertaken and included within the business case.

6. Financial Implications

Using reasonable assumptions, we can expect the harmonisation of service restriction policies as per the preferred option set out in this document to create an annual cost pressure of up to £1.076m. Given the potential for latent demand, there is likely to be a

spike in activity in the first few years following policy implementation. This is anticipated to be up to c. 50% of the total annual cost, i.e. up to circa £1.614m.

Non-recurrent transitional costs (i.e. supporting patients currently referred for, or receiving, treatment that they would no longer be eligible for under new recommendations), could cost up to c.£ 150K during year one.

Members should be aware that by implementing these proposed changes, the ICB is pre-committing this recurrent increase in cost from its growth funding for 2023/24, thus the ability to fund any new investments may be limited accordingly.

7. Details of patient or public engagement or consultation

A public consultation was carried out between 31 October to 19 December 2022, with a final report delivered in January 2023.

8. Conflicts of Interest

None identified.

9. Recommendations

This paper asks the ICB Board to approve the service harmonisation business case pertaining to harmonisation of 6 service area policies and the transitional arrangements necessary for specific populations affected, to be effective from 1 April 2023.

1. Introduction

The service harmonisation business case is intended to support a decision by the Mid and South Essex Integrated Care Board (MSE ICB) on whether to adopt the proposed, harmonised service policies across Mid and South Essex. In moving from five Clinical Commissioning Groups (CCGs) to one Integrated Care Board we must ensure that commissioning policies are harmonised so that services are provided consistently across(MSE. This is a requirement placed on the ICB by NHS England. Up to now, service offers have differed for six clinical treatment areas:

- Bariatric Surgery.
- Breast asymmetry.
- Breast reduction.
- Female Sterilisation.
- Vasectomy (male sterilisation).
- Tertiary Fertility Services – including intra-uterine insemination (IUI), in vitro fertilisation (IVF), with or without intra-cytoplasmic sperm injection (ICSI) and sperm and oocyte donation.

This process is founded on an intention to provide services equitably to those who may gain significant benefit, in line with the national evidence base and local system context. This is an opportunity to deliver on our core purposes as an Integrated Care System (ICS), including addressing previous variation and inequality of access, and to continue a focus on sustainability and value for money.

Currently, the ICS is an outlier in continuing to have varying policies across previous CCG localities after July 2022. This position continued, with the agreement of NHS England, whilst the service harmonisation process developed proposals.

This process has, since February 2022, brought together clinical, financial and resident perspectives in reviewing how these procedures should be provided in MSE. The options for how each service should be provided include continuing previous funding policies; moving to Group Prior Approval (GPA); to Individual Prior Approval (IPA); or to not routinely funding the service (full definitions in glossary). The different components of the process bring together different views to deliver nationally guided, locally informed recommendations.

2. Main content of Report

Vision for Commissioning policies:

Harmonisation of service policies across the ICB is a requirement from NHS England. Commissioning policies within MSE must result in access to treatments and procedures for those who may gain significant benefit, in line with the national evidence base and local system context. As national guidance changes, including Evidence Based Intervention guidance, we will continue to review and update our policies within MSE.

These policies are an important part of delivering on our duties as an ICS to improve outcomes in population health and healthcare, to tackle inequalities in outcomes, experience and access and to enhance productivity and value for money. Perpetuating the historic differences in CCG commissioning policies would prevent MSE ICS from delivering on these purposes.

Service Harmonisation process:

The Service Harmonisation process took place between February 2022 to January 2023, guided by:

- Multi-professional clinical and professional in-depth review and advice via the MSE Clinical and Multi-professional Congress (CliMPC) and expert clinical panels.
- Engagement and consultation with residents via public consultation.
- An assessment of the financial consequences of any decision made led by the ICB Resources Directorate.
- An assessment of service capacity and capability to deliver any future changes to the service restriction policy.
- Equality and health inequality impact assessment.
- Service Harmonisation programme board with executive and senior leadership team input.
- Service Harmonisation working group, bringing together the System Clinical lead for SRPs, ICB funding team, service harmonisation programme lead and others.

Funding policy recommendations:

This process has yielded the following recommendations for service provision (a summary of the threshold criteria is available in **Appendix 1** below):

- Bariatric surgery – group prior approval, using National Institute for Health and Care Excellence (NICE) threshold criteria.
- Tertiary fertility services – individual prior approval, using MSE threshold criteria based on NICE guidance.
- Breast reduction – individual prior approval, using threshold criteria based on national Evidence Based Intervention (EBI) criteria.
- Breast asymmetry - individual prior approval, using threshold criteria based on national EBI criteria.
- Male sterilisation – vasectomy under local anaesthetic (LA) should be routinely funded, vasectomy under general anaesthetic (GA) should be provided via group prior approval based on MSE threshold criteria.
- Female sterilisation – group prior approval, using threshold criteria based on guidance from the Faculty of Sexual and Reproductive Health.

The full wording of service policies is available within the business case.

Consultation:

The consultation ran between 31 October 2022 and 19 December 2022. During this time, a programme of activities sought participation from those groups most likely to be impacted by any change. These were well promoted both online via our social media platforms, and through all the local media outlets. We worked hard with all our partners, especially those with strong links to our health inequality groups to share and promote all our materials.

People were encouraged to use an online feedback questionnaire to submit their views but could also feedback in a variety of other ways: by letter or email to the ICB central ‘get involved’ email; or by attending a meeting or focus group, where we undertook structured notes and feedback. Along with the meetings and focus groups we produced the main consultation document and questionnaire both online and paper versions, plus an easy read

version of the consultation document. Copies of the documentation were made available at libraries across MSE.

All the information was shared with the three Health Oversight and Scrutiny Committees (HOSCs) both in person and via papers, and at the Mid and South Essex Hospitals NHS Foundation Trust (MSEFT) Governors' meeting.

A total of 210 people responded to the online survey with one hard copy response. Twenty people participated in public events or focus groups. The consultation analysis and report were prepared by Stand, who are independent engagement practitioners.

Most online survey respondents supported the proposed policy updates. The highest levels of support were for special fertility services (78%), bariatric surgery (74%) and vasectomy (72%). For the other clinical service areas – breast asymmetry, breast reduction and female sterilisation - approximately two thirds expressed support for the changes.

Overall, it was felt that the policy changes would enable equitable access for all residents in MSE and remove the 'postcode lottery' that currently exists. Further, for some clinical areas i.e., bariatric surgery, breast asymmetry, breast reduction, it was thought that the changes would result in improved quality of life for patients, whilst reducing associated costs for the NHS (see separate Consultation Report document for full details).

Consultation commentary:

A range of specific concerns were highlighted through the consultation, the most common are highlighted below, along with outline responses (fuller commentary is available within the business case.

- **The use of BMI within threshold criteria**: BMI is a commonly used threshold criterion in guidance and recommendations in the UK from NICE, EBI, as well as other national and international bodies. There is no validated alternative measure or set of thresholds to use in its place. Until such time as an alternative evidence base is developed and national recommendations change, BMI should continue to be used within threshold criteria.
  In the case of female sterilisation specifically, BMI less than 35 was recommended as a threshold criterion by our expert clinical panel due to the associated clinical risk. However given the feedback in the consultation, and the lack of a specific BMI threshold in Faculty of Reproductive Health guidance, this has been changed in the final recommended policy wording, from a referral criterion to a guidance note to the referrer, that where an individual patient's BMI is above 35, this will be reviewed carefully at surgical assessment, and options for appropriate weight management may be considered prior to a decision on surgery.

- **The requirement to be a non-smoker** (with no corresponding requirement to **demonstrate** abstinence from alcohol or drug use): The reasons for this distinction is due to the impact that smoking has on wound healing, a significant factor in breast reduction and breast asymmetry surgeries specifically.

- **Parity in the role of counselling** within assessment for male and female sterilisation (with the concern that people pursuing male sterilisation do not have to undergo the same counselling **processes** as people pursuing female sterilisation): We have now added standard guidance from the Faculty of Reproductive Health within the full policy wording for both female and male sterilisation.

- **The omission of gynaecomastia from the breast asymmetry policy**. Gynaecomastia is covered by a separate service policy within the full SRP document available via our website.

- Tertiary **fertility service threshold criteria**, including:

  - *"Opportunity for the criteria to be more inclusive and provide more equitable access for same sex couples":* The recommendations would improve female same-sex couple access via funding in localities where IVF was not previously funded (e.g. ME, B&B), and would harmonise the number of cycles available to heterosexual and same-sex couples where there was a difference previously (e.g. Thurrock). We note the Government's intention to work with NHS England (NHSE) to implement commitments in the Women's Health Strategy fully over the next 10 years. We await further detail from NHSE and will at that stage consider any changes in national approach and the implications for ICB policies.

  - *"Criterion re: same sex couples having to have had six cycles of privately funded intrauterine insemination".* IUI may be part of a pathway for two reasons (i) treatment or (ii) diagnosis of 'unexplained infertility'. As regards use of treatment, our expert clinical panel recommended prioritising available funding on increasing access to IVF, and not funding IUI for treatment, due to its limited clinical effectiveness.
    In order to access funding for IVF, patients must either have a specific diagnosed cause of infertility or demonstrate 'unexplained infertility'. In male-female couples, this is demonstrated via 1-2 years of being unable to get pregnant, depending on age. For female same-sex couples, who are unable to demonstrate infertility in the same way, inability to get pregnant despite 6 rounds of IUI is used as the alternative standard. This is also noted in the Equality and Health Inequalities Impact Assessment (EHIIA). Funding IUI for diagnosis of 'unexplained infertility' for female same-sex couples only would raise the query of whether this unfairly excludes all other populations who might wish to access IUI for treatment purposes. Undertaking to fund IUI for both treatment and diagnosis of 'unexplained infertility' would be a more financially costly option, and therefore has the potential to negatively impact funding, access and outcomes associated with other clinical services. Therefore, the recommended option is not to fund IUI.
    We will continue to review equalities impact via audit of activity and referral equity, to understand the impact our policies over time.

Financial case overview:

Working in partnership with the Clinical and Professional Leadership Directorate, the Resources Directorate have undertaken a level of analysis that helps to identify the potential recurrent cost increases for the ICB should changes to service provision be agreed as part of this process.

Using reasonable assumptions, we can expect the harmonisation of service restriction policies as per the preferred options set out in this document to create an annual cost pressure of up to £1.076m. Given the potential for latent demand, there is likely to be a spike in activity in the first few years following policy implementation. This is anticipated to be up to c. 50% of the total annual cost, i.e. up to circa £1.614m.

Non-recurrent transitional costs (i.e. supporting patients currently referred for, or receiving, treatment that they would no longer be eligible for under new recommendations), could cost up to c.£150K during year one.

Members should be aware that by implementing these proposed changes, the ICB is pre-committing this recurrent increase in cost from its growth funding for 2023/24, thus the ability to fund any new investments will be limited accordingly. The ICB's initial financial drafts for 2023-24 now make provision for this increased cost.

If approved this business case will enter a mobilisation period leading up to a go-live date of the 1 April 2023.

3. Findings/Conclusion

MSE ICB must harmonise service policies for bariatric surgery, breast asymmetry, breast reduction, female sterilisation, male sterilisation (vasectomy) and tertiary fertility services, in order to meet national responsibilities and core ICB purposes, including addressing inequalities.

The service harmonisation business case has been developed over the past 12 months through a significant, robust process of clinical, resident and resources engagement and assessment, to arrive at the recommendations delivered.

The recommended service funding options and threshold criteria would create an annual cost pressure of up to £1.076m, with potential for latent demand to create a spike of up to circa £1.614m over the next few years. Non-recurrent transitional costs could cost up to c.£150K during year one.

4. Recommendation(s)

This paper asks the ICB Board to agree the recommendations for harmonised provision of each of the six services, and the transitional arrangements necessary for specific populations affected (funding options and recommended threshold criteria listed in **Appendix 1** below, full policy wording available in business case).

5. Appendices

Appendix 1 - Summary of recommended service policy funding options and threshold criteria.

The full wording of service policies is available in the full business case.

Appendix 1 - Summary of recommended service policy funding options and threshold criteria.

1. Bariatric surgery

Recommended funding option: GPA

Recommended threshold criteria

- The person has a BMI of 40 kg/m2 or more, or between 35 kg/m2 and 40 kg/m2 and other significant disease (for example, type 2 diabetes or high blood pressure) that could be improved if they lost weight.
- All appropriate non-surgical measures have been tried but the person has not achieved or maintained adequate, clinically beneficial weight loss.
- The person has been receiving or will receive intensive management in a tier 3 service.
- The person is generally fit for anaesthesia and surgery.
- The person commits to the need for **long-term follow-up**.

2. Tertiary Fertility Services

Recommended funding option: IPA, using NICE criteria with additional local criteria

Recommended threshold criteria:

IVF:

- **A full cycle** is defined as up to one fresh and one frozen embryo transfer. This will include the cost of freezing and storage. For patients who do not achieve a live birth with the fresh embryo transfer, the transfer of one frozen embryo will be funded. Any previous IVF cycles, whether self- or NHS-funded, will count towards the total number offered by the ICB.
- The age of mother at the time that the embryos are frozen is required to be within the age limits set out in the policy. This also applies to the age at transfer.
- Patients younger than 23 will be considered where investigations have shown conception would be impossible without fertility treatment.
- Cause of infertility: Couples who have been diagnosed as having a male factor or female factor problems or have had unexplained infertility for at least 2 years, taking into consideration both age and waiting list times. Where the partner receiving IVF is 40-42, the period of unexplained infertility should be at least 1 year.
- Eligible Couples will be offered: a maximum of 2 full cycles of IVF+/-ICSI (local definition of a full cycle) where the partner receiving treatment is between the age of 23 and 39.
  Where the partner is between the age of 40-42, a maximum of 1 full cycle (local definition) will be offered.
- **Registration**: The partner receiving IVF should have been registered to an MSE practice for at least 12 months preceding referral to IVF services.
- **BMI**: Women will only be considered for treatment if their BMI is between 19-30 (Kg/m2). Women with BMI >30 should be referred to the appropriate obesity management pathway. Men with a BMI of >35 will not be considered for treatment and should be referred to appropriate obesity management pathway.
- **Smoking**: Couples must not be non-smoking at the time of treatment.

- **Same Sex Couples**: If six cycles of privately funded IUI have been unsuccessful, demonstrating infertility, the couple will be eligible for IVF as above.

Donor gametes:

- Up to one batch (usually 6) of donor oocytes and one batch of sperm will be funded. Where more than two viable embryos are generated, up to two transfers will be funded in line **with** the rest of the policy. Any remaining embryos will be subject to the same criteria as if the oocytes were the couple's own. Fertility products will be stored in line with relevant national guidance.

Living Children:

Fertility treatment will only be offered to couples where the following two criteria are met: a) where there are no living children in the current relationship b) where neither partner has children from previous relationships. This includes any adopted child within their current or previous relationship

Intrauterine insemination (IUI) will not be funded.

3. Breast reduction

Recommended funding option: IPA

Recommended threshold criteria

Patients will be eligible if all the following are confirmed:

- The patient is suffering from **neck ache or backache**. Clinical evidence will need to be produced to **rule out any other medical/physical problems** to cause these symptoms,
- OR The patient has persistent **intertrigo** for at least one year and confirmed by GP OR another serious **functional impairment** for at least one year,
- AND Full evidence is provided of all **conservative management options** that have been attempted, including engaging with weight management services where appropriate, and that the wearing of a professionally fitted brassiere has not relieved the symptoms,
- AND The patient has a **BMI <27** and evidence that the weight has been **stable** for 12 months,
- AND The patient is a **non-smoker**
- AND At least **1kg** is planned to be removed from each breast.

Patients who have predictable breast changes due to pregnancy are excluded.

Initial assessment should be done the by referrer prior to appointment with consultant plastic surgeon to ensure criteria are met. Assessment of the thorax should be carried out, including any indicated diagnostics. Written information on risks and benefits should be provided to enable informed decision-making. Patients informed that smoking increases post-op complications, and patient must be a non-smoker. Women informed that breast surgery for macromastia can cause permanent loss of lactation.

4. Breast asymmetry

Recommended funding option: IPA

Recommended threshold criteria

The goal of surgery is to correct a significant deformity which is causing an impact on health. Patients will be eligible if all the following are confirmed:

- Clinical evidence rules out any **other medical/physical problems** to cause these symptoms.
- AND full evidence is provided of all appropriate **conservative management options** that have been attempted.
- AND there is a **difference of at least 2 cup sizes** (e.g. C and DD cup size differential) OR evidence of another serious functional impairment for at least one year.
- AND the patient is a **non-smoker**
- AND patient has had **no change in cup size for 1 year**, and has reached end of **puberty**. Referral should be delayed if end of puberty has not been reached.

Only unilateral breast **reduction** (not unilateral breast augmentation) will be funded. This policy does not cover **gynaecomastia**.

Procedures for cosmetic purposes only will not be funded. Contour irregularities and moderate asymmetry (including dog-ears, nipple direction or position, breast size and shape disparity) are predictable following surgery. Any post-surgical cosmetic irregularities will not be funded by the ICB in revision surgery.

5. Male Sterilisation (vasectomy)

Recommended funding option: routinely funded (for sterilisation under LA)

Recommended funding option: GPA (for sterilisation under GA)

Recommended threshold criteria:

- Previous documented adverse reaction to local anaesthesia.

  OR

- Scarring or deformity distorting the anatomy of the scrotal sac or content making identification and/or control of the spermatic cord through the skin difficult to achieve.

6. Female sterilisation

Recommended funding option: GPA.

Recommended threshold criteria:

Family complete: The woman is certain that her family is complete or that she never wants children in the future.

Contraception: AND there is an absolute clinical **contraindication** to Long-Acting Reversible Contraception (LARC) or has severe **side effects** to the use of LARC or

declines a trial of LARC after counselling from a healthcare professional experienced in fitting these devices.

Capacity: AND the woman has **mental capacity** OR all necessary arrangements have been completed to either support her to a position of having capacity or where appropriate advocacy arrangements are in place, in compliance with latest capacity guidance.

Counselling: AND she aware that the procedure is permanent but has a failure rate, that reversal is not funded on the NHS (except via Individual Funding Requests), that **other forms of LARC** have a similar success rate, with **lower risk profile**. Counselling must also include consideration of **vasectomy** for her partner where appropriate.

Exemptions: women who have a **medical condition** making pregnancy dangerous or where LARC is **contra-indicated** or inappropriate will be exempt from these criteria and female sterilisation will be routinely funded.

Guidance note on BMI: there is an increased clinical risk associated with BMI of 35 and above, and patients are likely to be advised regarding weight management support services at surgical assessment.

7. **Transitional arrangements:**

The ICB should implement transitional arrangements for those who are already on, or have been referred to, a treatment pathway.

If approved by the ICB Board, from April 2023 the 6 new policies would replace the relevant legacy policies across Mid and South Essex However, where an individual is undergoing or has already been referred for NHS-funded treatment on any of the relevant pathways prior to that date, transitional arrangements will be applied.

In either of these cases, the individual should experience no disadvantage as a result of the new MSE policies. Therefore:

- where a **new policy disadvantages** the patient, the **legacy policy will apply (see below)**; and
- where a **new policy is advantageous** to the patient, the **new MSE policy** will apply.

These transitional arrangements **will apply** to relevant patients **until the course of treatment** specified in the relevant policy is **complete**, or until the patient is **no longer eligible** for NHS funded treatment.

The populations identified to whom this may apply include:

i. Tertiary fertility services: Thurrock **-** female-male couples eligible for IVF, who could access 3 rounds of IUI under Thurrock CCG policy.
ii. Breast reduction: BB, CPR, Southend, Thurrock - people who would have been eligible to have between 500-999g removed per breast under CCG policies. And people who smoke.
iii. Breast asymmetry: CPR, Southend, Thurrock: people who smoke
iv. Female sterilisation: CPR, Southend, Thurrock: access may be slightly reduced due to shift from routinely funded to GPA (likely minimal impact).

Service harmonisation business case

Document Control:

Date: 31/01/2023
Version: 0.9

Date: 24.01.2023

Prepared by: Peter Scolding

Sponsoring workstream / Stewardship Group: Service Harmonisation

Implementation Trajectory: April 2023

Contents

1 Executive Summary

This business case is intended to support a decision by the Mid and South Essex ICB Board (MSE / ICB) on whether to adopt the proposed, harmonised service policies across mid and south Essex. In moving from five Clinical Commissioning Groups (CCGs) to one Integrated Care Body in July 2022, we must ensure that commissioning policies are harmonised so that services are provided consistently across mid and south Essex. This is a requirement placed on the ICB by NHS England (NHSE).

Service offers differed for six clinical treatment areas:

1. Bariatric surgery
2. Breast asymmetry
3. Breast reduction
4. Female sterilisation
5. Male sterilisation (vasectomy)
6. Tertiary fertility services – including intra-uterine insemination (IUI), in vitro fertilisation (IVF), with or without intra-cytoplasmic sperm injection (ICSI) and sperm and oocyte donation.

This process is founded on an intention to provide services equitably to those who may gain significant benefit, in line with the national evidence base and local system context. This is an opportunity to deliver on our core purposes as an Integrated Care System (ICS), including addressing previous variation and inequality of access, and to continue a focus on sustainability and value for money.

Currently, the ICS is an outlier in continuing to have varying policies across previous CCG localities after July 2022. This position continues whilst the service harmonisation process develops proposals.

This process has, since February 2022, brought together clinical, financial and resident perspectives in reviewing how these procedures should be provided in mid and south Essex. The options for how each service should be provided include continuing previous funding policies, moving to Group Prior Approval (GPA), to Individual Prior Approval (IPA) or to not routinely funding the service (full definitions in glossary). The different components of the process bring together different views to deliver nationally-guided, locally-informed recommendations.

Using reasonable assumptions we can expect the harmonisation of service restriction policies as per the preferred option set out in this document to create an annual cost pressure of up to £1.076m. Given the potential for latent demand, there

is likely to be a spike in activity in the first few years following policy implementation. This is anticipated to be up to c.50% of the total annual cost i.e. up to £1.614m.

Non-recurrent transitional costs (i.e. supporting patients currently referred for or receiving treatment that they would no longer be eligible for under new recommendations), could cost up to c.£150K during year one. If approved this business case will enter a mobilisation period leading up to a go-live date of the 1 April 2023.

The Service Restriction Policies (SRP) for each of the services can be found in full in Appendix 1.

Existing or new budget: Existing commissioning budget

Senior Responsible Officer: Ronan Fenton

Fit with MSE Strategy: Yes

Legal requirement: No. It is national policy requirement

Director of resources (DOR) Agreement: Yes

Project manager: Peter Scolding

Key stakeholder: MSE ICB, patients and population

Service specialty: As in the Executive Summary (six clinical areas)

1.1 Bariatric surgery

Bariatric surgery is usually considered as part of a four-tier weight management service after individuals have trialled treatments in tiers one to three. Bariatric surgery includes options such as gastric banding, gastric bypass, duodenal switch, sleeve gastrectomy and Roux-en-Y gastric bypass. Clinical criteria will be used to guide which option is most appropriate for any individual.

In 2019/20 there were 39 bariatric surgeries for patients in MSE, the financial year prior to COVID was chosen to avoid any impact of the pandemic. Patients in MSE requiring bariatric surgery are often transferred outside of Mid and South Essex NHS Foundation Trust (MSEFT).

Financial Year	Number of cases	Cost (£)
2018/19	41	206,863
2019/20	39	223,960
2020/21	26	122,103
2021/22	40	206,220

Financial Year	Number of cases	Cost (£)
Average	37	189786.5
Average cost per case		5200

Table 1 Average number of bariatric surgeries and cost across MSE, Apr 2018-Mar 2022

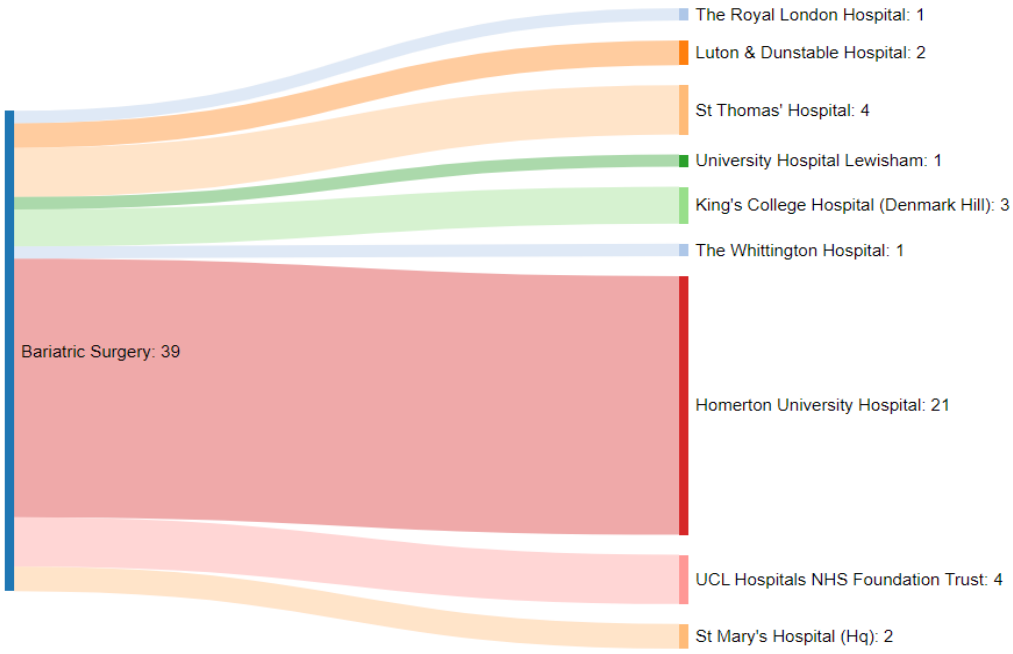


Figure 1 Total no. of bariatric surgeries 19/20, and hospital attended

1.1.1. Variation in previous CCG commissioning policies:

- Basildon & Brentwood: Individual prior approval (using The National Institute for Health and Care Excellence (NICE) criteria)
- Mid-Essex: Individual prior approval (NICE criteria plus additional local criteria)
- Southend and Castle Point and Rochford: Group prior approval (NHS England policy criteria)
- Thurrock: Group prior approval (NHS England policy criteria)

1.1.2. Proposal for service provision policy

Group prior approval using NICE criteria e.g.:

- They have a BMI of 40 kg/m2 or more, or between 35 kg/m2 and 40 kg/m2 and other significant disease (for example, type 2 diabetes or high blood pressure) that could be improved if they lost weight.

- All appropriate non-surgical measures have been tried but the person has not achieved or maintained adequate, clinically beneficial weight loss.
- The person has been receiving or will receive intensive management in a tier 3 service.
- The person is generally fit for anaesthesia and surgery.
- The person commits to the need for long-term follow-up.

1.2 Tertiary Fertility services

Tertiary Fertility Services includes intra-uterine insemination (IUI), in vitro fertilisation (IVF), with or without intra-cytoplasmic sperm injection (ICSI) and sperm and oocyte donation. Other services are out of scope for this business case, including:

- Surgical sperm retrieval, which is funded nationally by NHS England Specialised Commissioning.
- Sperm, oocyte and embryo cryopreservation (for patients undergoing cancer treatment or other therapies likely to affect their fertility) as this funded by all MSE CCGs on an individual prior approval basis with no variation across the system.
- Tertiary fertility services for the Armed Forces, commissioned directly by NHS England.
- Surrogacy and preimplantation genetic screening.

1.2.1. Variation in previous CCG commissioning policies

- Basildon and Brentwood: Not funded
- Mid-Essex: Not funded
- Southend, and Castle Point and Rochford: Individual prior approval (local criteria – see Appendix 1)
- Thurrock: Individual prior approval (local criteria – see Appendix 1)

1.2.2. Proposal for service provision policy:

Individual prior approval, using NICE criteria with additional local criteria as below.

CCG Name	PCN	2018/19*	2019/20*	2020/21*	2021/22*
Castle Point and Rochford CCG	Benfleet	6	5	3	5
	Canvey	4	4	3	4
	Rayleigh and District	5	6	7	6
	Rochford	4	8	3	1
	Unknown	2			
Castle Point and Rochford CCG Total		21	23	16	16
Southend CCG	Southend East	3	3	2	3
	Southend Victoria	7	13	7	11
	SS9	9	12	7	7
	West Central	8	4	6	5
	Unknown		1		
Southend CCG Total		27	33	22	26
Thurrock CCG	Aveley, South Ockenden and Purfleet	12	7	5	11
	Grays	15	18	10	15
	Stanford-le-Hope	9	9	8	7
	Tilbury & Chadwell	3	6	5	2
	Unknown	5	4	2	1
Thurrock CCG Total		44	44	30	36
Grand Total		92	100	68	78

Table 2 Assisted Fertility Approvals

*Financial year by application date.

1.2.3. Recommended threshold criteria:

IVF: A full cycle defined as up to one fresh and one frozen embryo transfer. This will include the cost of freezing and storage. For patients who do not achieve a live birth with the fresh embryo transfer, the transfer of one frozen embryo will be funded. The

age of mother / birthing parent at the time that the embryos are frozen is required to be within the age limits set out in the policy. This also applies to the age at transfer.

Cause of infertility: Couples who have been diagnosed as having a male factor or female factor problems or have had unexplained infertility for at least 2 years, taking into consideration both age and waiting list times. Where the partner receiving IVF is 40-42, the period of unexplained infertility should be at least 1 year.

Eligible couples will be offered a maximum of 2 full cycles of IVF+/-ICSI (local definition of a full cycle) where the partner receiving treatment is between the age of 23 and 39.
Where the partner is between the age of 40-42, a maximum of 1 full cycle (local definition) will be offered.

Patients younger than 23 will be considered where investigations have shown conception would be impossible without fertility treatment.

Any previous IVF cycles, whether self- or NHS-funded, will count towards the total number offered by the ICB.

The partner receiving IVF should have been registered to a mid and south Essex practice for at least 12 months preceding referral to IVF services.

BMI: Women and people assigned female at birth will only be considered for treatment if their BMI is between 19-30 (Kg/m2). Women and people assigned female at birth with BMI >30 should be referred to the appropriate obesity management pathway.

Men and people assigned male at birth with a BMI of >35 will not be considered for treatment and should be referred to appropriate obesity management pathway.

Smoking: Couples must be non-smoking at the time of treatment.

Same sex couples: If six cycles of privately funded IUI have been unsuccessful, demonstrating infertility, the couple will be eligible for IVF as above.

Donor gametes: Up to one batch (usually 6) of donor oocytes and one batch of sperm will be funded. Where more than two viable embryos are generated, up to two transfers will be funded in line with the rest of the policy. Any remaining embryos will be subject to the same criteria as if the oocytes were the couple's own. Fertility products will be stored in line with relevant national guidance.

Living children: Fertility treatment will only be offered to couples where the following two criteria are met: a) where there are no living children in the current relationship b) where neither partner has children from previous relationships. This includes any adopted child within their current or previous relationship.

Intrauterine insemination (IUI) will not be funded.

1.3 Breast reduction surgery

Breast reduction (reduction mammoplasty) is a surgical procedure performed on patients with macromastia (commonly referred to as hypermastia), large breasts, for symptom relief.

In 2019/20 there were 36 breast reduction procedures carried out in MSE. The majority (26) were performed at Broomfield Hospital.

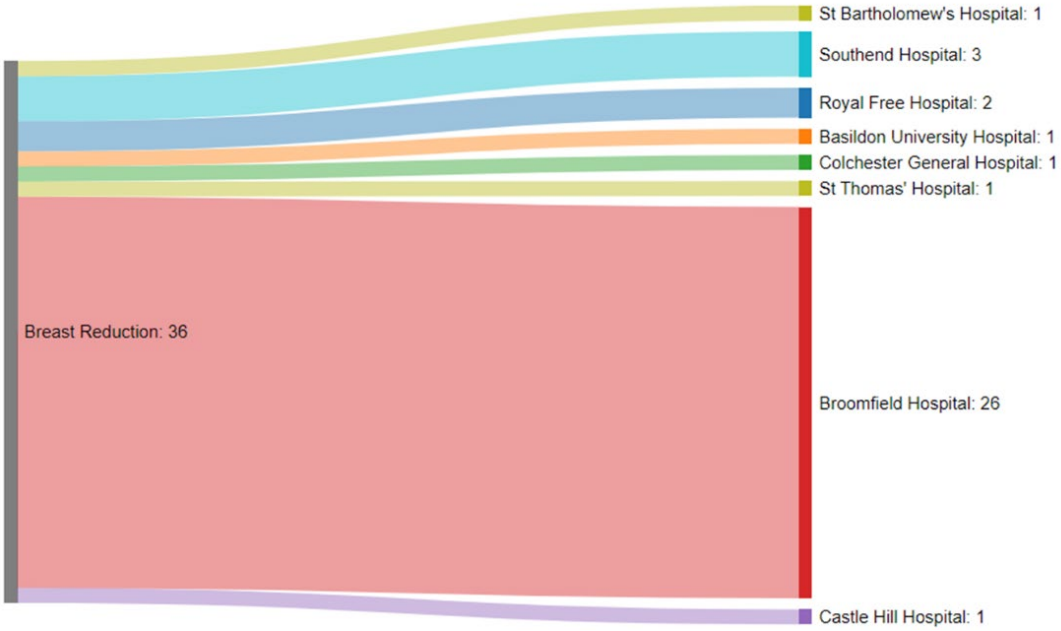


Figure 2 Number of reduction mammoplasties procedures performed in each hospital

1.3.1. Variation in previous CCG commissioning policies

- Basildon and Brentwood: Individual prior approval
- Mid-Essex: Not funded
- Southend, and Castle Point and Rochford: Individual prior approval
- Thurrock: Individual prior approval

Same individual prior approval criteria across 4 CCGs with individual prior approval policy.

1.3.2. Proposal for service provision policy

Individual prior approval.

1.3.3. Recommended threshold criteria:

Patients will be eligible if all the following are confirmed:

- The patient is suffering from neckache or backache. Clinical evidence will need to be produced to rule out any other medical/physical problems to cause these symptoms.
- OR The patient has persistent intertrigo for at least one year and confirmed by GP OR another serious functional impairment for at least one year.
- AND Full evidence is provided of all conservative management options that have been attempted, including engaging with weight management services where appropriate, and that the wearing of a professionally fitted brassiere has not relieved the symptoms,
- AND The patient has a BMI <27 and evidence that the weight has been stable for 12 months,
- AND The patient is a non-smoker
- AND At least 1kg is planned to be removed from each breast.

Patients who have predictable breast changes due to pregnancy are excluded.

Initial assessment should be done the by referrer prior to the appointment with consultant plastic surgeon to ensure criteria are met. Assessment of the thorax should be carried out, including any indicated diagnostics. Written information on risks and benefits should be provided to enable informed decision-making. Patients should be informed that smoking increases post-op complications, and the patient must be a non-smoker. Patients should be informed that breast surgery for hypermastia can cause permanent loss of lactation.

1.4 Breast asymmetry surgery

Breast asymmetry can be due to developmental disorders and acquired conditions secondary to trauma, infection or surgery. A degree of breast asymmetry is common, however significant (more than 2 cups sizes) difference is less common. Breast asymmetry corrective surgery reduces the size of, or enlarges, one breast resulting in a similar size of both breasts. Broadly, the NHS in England have not funded unilateral breast enlargement (only unilateral reduction) for breast asymmetry.

We are unable to differentiate from the data how many procedures for breast reduction were unilateral vs bilateral. From speaking to local surgeons we suspect the number for unilateral reductions is small.

1.4.1. Variation in previous CCG commissioning policies

- Basildon and Brentwood: Not funded
- Mid-Essex: Not funded
- Southend, and Castle Point and Rochford: Individual prior approval
- Thurrock: Individual prior approval

Same individual prior approval criteria across CCGs with individual prior approval policy.

1.4.2. Proposal for service provision policy

Individual prior approval.

1.4.3. Recommended threshold criteria

The goal of surgery is to correct a significant deformity which is causing an impact on health. Patients will be eligible if all the following are confirmed:

- Clinical evidence rules out any other medical/physical problems to cause these symptoms.
- AND full evidence is provided of all appropriate conservative management options that have been attempted.
- AND there is a difference of at least 2 cup sizes (e.g. C and DD cup size differential) OR evidence of another serious functional impairment for at least one year.
- AND the patient is a non-smoker.
- AND patient has had no change in cup size for 1 year and has reached the end of puberty. Referral should be delayed if end of puberty has not been reached.

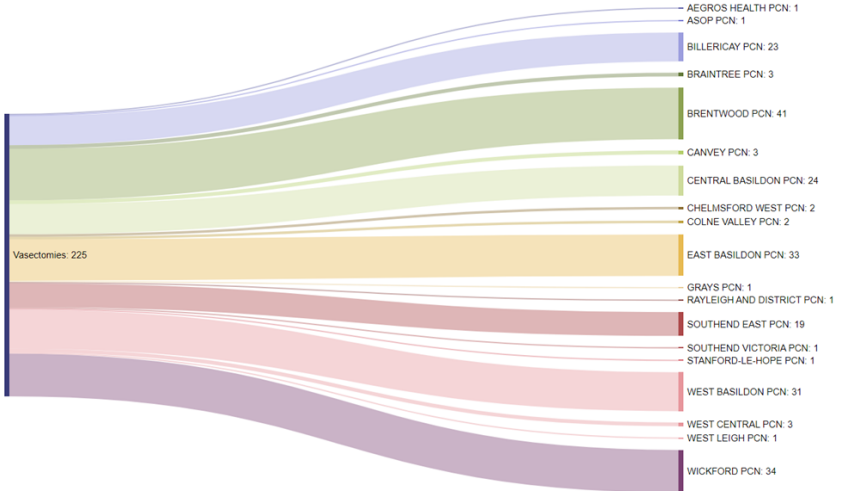
Only unilateral breast reduction (not unilateral breast augmentation) will be funded. This policy does not cover gynaecomastia.

Procedures for cosmetic purposes only will not be funded. Contour irregularities and moderate asymmetry (including dog-ears, nipple direction or position, breast size and shape disparity) are predictable following surgery. Any post-surgical cosmetic irregularities will not be funded by the ICB in revision surgery.

1.5 Male sterilisation (vasectomy)

Vasectomy is an operation to sterilise a man or person assigned male at birth; this can be achieved by the interruption of the vas deferens, preventing sperm from entering the ejaculate. The procedure is usually performed under local anaesthesia (LA) in primary care. But in exceptional circumstances it is carried out under general anaesthesia (GA) in an acute setting.

In 2019 there were a total of 225 vasectomies carried out in MSE under LA. Activity data from the calendar year prior to COVID has been used to avoid any impact of the pandemic. Figure 3 provides a breakdown of the activity by Primary Care Network (PCN). The majority were for patients in Brentwood, Wickford, East Basildon, West Basildon and Basildon Central PCNs (all PCNs are in Basildon and Brentwood CCG).



PCN	Total Vasectomies
BRENTWOOD PCN	41
WICKFORD PCN	34
EAST BASILDON PCN	33
WEST BASILDON PCN	31
CENTRAL BASILDON PCN	24
BILLERICAY PCN	23
SOUTHEND EAST PCN	19
CANVEY PCN	3
WEST CENTRAL PCN	3
BRAINTREE PCN	3
COLNE VALLEY PCN	2
CHELMSFORD WEST PCN	2
RAYLEIGH AND DISTRICT PCN	1
STANFORD-LE-HOPE PCN	1
AEGROS HEALTH PCN	1
WEST LEIGH PCN	1
ASOP PCN	1
SOUTHEND VICTORIA PCN	1
GRAYS PCN	1

Figure 3 Total number of vasectomies carried out in 2019 by PCN

1.5.1. Variation in previous CCG commissioning policies

- Basildon and Brentwood: Group prior approval
- Mid-Essex: Not funded
- Southend, and Castle Point and Rochford: Group prior approval
- Thurrock: Group prior approval

1.5.2. Proposal for service provision policy

Vasectomy under Local anaesthetic: Routinely funded

Vasectomy under General anaesthetic: Group prior approval

1.5.3. Recommended threshold criteria

Previous documented adverse reaction to local anaesthesia.

OR

Scarring or deformity distorting the anatomy of the scrotal sac or content making identification and/or control of the spermatic cord through the skin difficult to achieve.

1.6 Female sterilisation

Female sterilisation is a permanent method of contraception which can involve sealing the fallopian tubes (by clipping, tying or applying rings), cutting, or even removing them. The procedure usually requires a general anaesthetic. From April 2019 to March 2020 there were 79 procedures carried out in MSE.

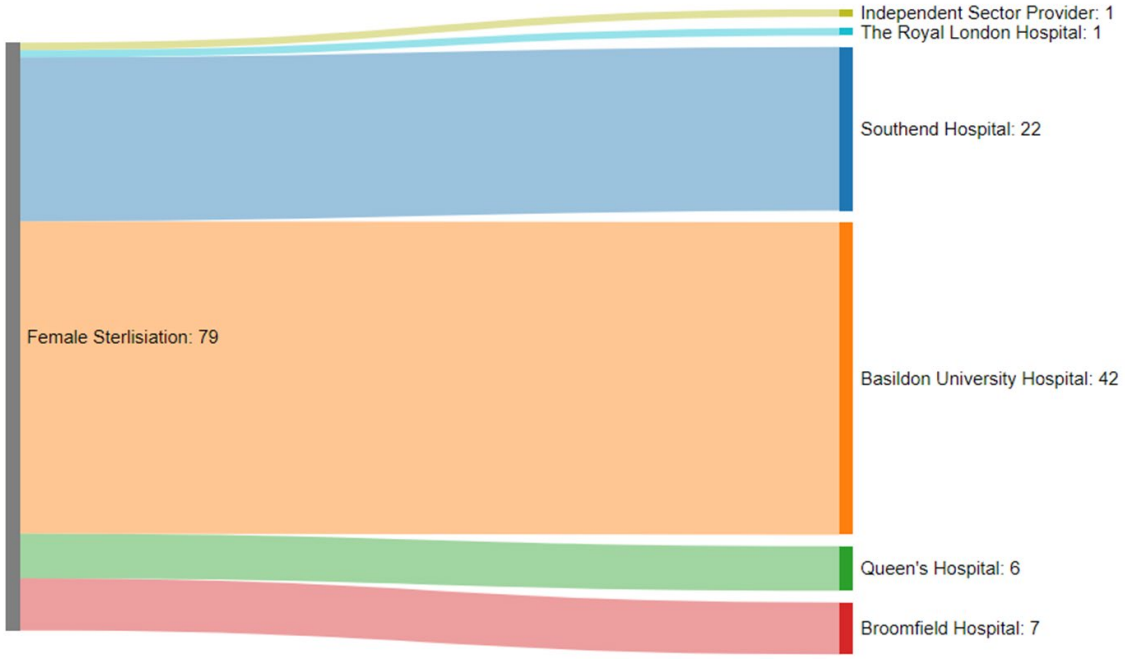


Figure 4 Female sterilisation procedures (19/20) performed by hospital

1.6.1. Variation in previous CCG commissioning policies

- Basildon and Brentwood: Group prior approval
- Mid-Essex: Not funded
- Southend, and Castle Point and Rochford: Routinely funded
- Thurrock: Routinely funded

1.6.2. Proposal for service provision policy

Group prior approval.

1.6.3. Recommended threshold criteria

Family complete: The patient is certain that their family is complete or that they never want children in the future.

Contraception: AND there is an absolute clinical contraindication to Long Acting Reversible Contraception (LARC) or has severe side effects to the use of LARC or declines a trial of LARC after counselling from a healthcare professional experienced in fitting these devices.

Capacity: AND the patient has mental capacity OR all necessary arrangements have been completed to either support them to a position of having capacity or where appropriate advocacy arrangements are in place, in compliance with latest capacity guidance.

Counselling: AND they are aware that the procedure is permanent but has a failure rate, that reversal is not funded on the NHS (except via Individual Funding Requests), that other forms of LARC have a similar success rate, with lower risk profile. Counselling must also include consideration of vasectomy for their partner where appropriate.

Exemptions: patients who have a medical condition making pregnancy dangerous or where LARC is contra-indicated or inappropriate will be exempt from these criteria and female sterilisation will be routinely funded.

2 Strategic fit

2.1 Overview

2.1.1. Vision for commissioning policies

Commissioning policies in mid and south Essex must result in access to treatments and procedures for those who may gain significant benefit, in line with the national evidence base and local system context. As national guidance changes, including Evidence Based Intervention guidance, we will continue to review and update our policies within mid and south Essex.

These policies are an important part of delivering on our duties as an ICS to improve outcomes in population health and healthcare, to tackle inequalities in outcomes, experience and access and to enhance productivity and value for money.

The Service Harmonisation process is guided by:

- multi-professional clinical and professional advice
- engagement and consultation with residents
- an assessment of the financial consequences of any decision made
- an assessment of service capacity and capability to deliver any future changes to the service restriction policy
- an equality and health inequality impact assessment

The absence of provision in some areas, and specific disparities between others must be addressed, while ensuring the ICB can fulfil its four key, nationally stated, purposes to:

- improve outcomes in population health and healthcare
- tackle inequalities in outcomes, experience and access
- enhance productivity and value for money
- help the NHS support broader social and economic development

Perpetuating the historic differences in CCG commissioning policies would prevent MSE ICS from delivering on these purposes.

There is no earmarked funding to address historical disparities.

2.1.2. Overview of commissioning policy categories

The Integrated Care Board (ICB) has adopted the predecessor CCG commissioning policies with regard to treatments / interventions / devices / procedures (hereafter known as procedures) which are not currently included in established care pathways (as identified for example in the schedules to the service agreements with acute care providers) or identified as being routinely funded. The commissioning policies set out approval processes for access to a range of procedures. Process options include routine funding, group prior approval (GPA), individual prior approval (IPA) and not routinely funded, where an individual funding request (IFR) is required (see Appendix 2 for the glossary for full definitions).

2.2 Statutory responsibilities

The ICB has a responsibility to set commissioning policies.

The Standing Rules, which remain in force post 1 July 2022, require an ICB to *"have in place arrangements for making decisions and adopting policies on whether a particular health care intervention is to be made available for persons for whom the relevant body has responsibility."* (Regulations 34 to 35, National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012.)

It must do so in accordance with its statutory duties, including those under the NHS Act 2006:

- s. 14Z32 Duty to promote NHS Constitution
- s. 14Z33 Duty as to effectiveness, efficiency etc
- s. 14Z34 Duty as to improvement in quality of services
- s. 14Z35 Duties as to reducing inequalities
- s. 14Z38 Duty to obtain appropriate advice (e.g. clinical advice)
- s. 14Z39 Duty to promote innovation
- s. 14Z43 Duty to have regard to wider effect of decisions (i.e. the Triple Aim)
- s. 14Z45 Duty to involve the public

And s. 149 of the Equality Act 2010: The Public Sector Equality Duty

2.2.1. Liability

There is no automatic right for individuals who have been affected by a change of policy to be compensated because they have been impacted by a change of policy.

If liability was to arise, it would arise out of a successful challenge in the courts which affected individuals would need to bring by way of judicial review. To ensure that the service harmonisation process is as robust as possible, there are two focal procedural areas of note – the consultation process, and transitional arrangements for those individuals already on, or who have been referred to a treatment pathway.

2.2.2. Consultation

The ICB should ensure fair procedure via robust, inclusive, meaningful consultation, with those affected having sufficient material and time to intelligently engage, and the consultation product being conscientiously taken into account in finalising statutory proposals.

2.2.3. Transitional arrangements

The ICB should implement transitional arrangements for those who are already on, or have been referred to, a treatment pathway.

From April 2023, the six new policies will replace the relevant legacy policies across mid and south Essex. However, where an individual is undergoing or has already been referred for NHS-funded treatment on any of the relevant pathways prior to that date, transitional arrangements will be applied.

In either of these cases, the individual should experience no disadvantage as a result of the new MSE policies. Therefore:

- Where a new policy disadvantages the patient, the legacy policy will apply; and
- Where a new policy is advantageous to the patient, the new MSE policy will apply.

These transitional arrangements will apply to relevant patients until the course of treatment specified in the relevant policy is complete, or until the patient is no longer eligible for NHS funded treatment.

See Section 5 for business case costing model.

Transitional arrangements

These would apply to the following groups:

Policy	Populations whose access could reduce under proposed ICB policies
Bariatric surgery	None identified

Policy	Populations whose access could reduce under proposed ICB policies
Tertiary fertility services	Thurrock: IUI - reduction in access for female-male couples eligible for IVF who might previously have accessed IUI, from 3 funded cycles to none.
Breast reduction	Basildon and Brentwood, Castle Point and Rochford, Southend, Thurrock: people who could have 500-999g removed per breast (proposed minimum tissue weight for removal rising from 500g to 1kg), and for people who smoke (likely minimal impact).
Breast asymmetry	Castle Point and Rochford, Southend, Thurrock: people who smoke (minimal impact expected).
Vasectomy	None identified
Female sterilisation	Castle Point and Rochford, Southend, Thurrock: access may be slightly reduced due to shift from routinely funded to Group prior approval (likely minimal impact).

2.2.4. Equalities and health inequalities

Draft Equality and Health Inequality Impact Assessments (EHIIAs) have been completed for all six areas in July 2022 by a panel with expertise in inequalities, public health, Place (Alliance), primary care, clinical and procurement. Full EHIIAs are available in Appendix 3).

These draw upon the Clinical and Multi-Professional Congress' (CLiMPC) service provision recommendations and the threshold criteria recommended by expert clinical panels, as well as points highlighted during public consultation.

2.3 Overview of the consultation process

2.3.1. Pre-consultation engagement

Based on the desk-top review and the pre-consultation engagement process, the following points appeared across all six treatment areas:

- fairness and equity
- affordability (particularly about fertility services)
- impact on mental health
- potential for legal challenge

Two clear and consistent themes were fairness and equity, ensuring that anyone in mid and south Essex should be able to access services without restriction.

Affordability, keeping a service free, was also essential to provide those on lower income or those with an inability to pay access to services.

When it comes to making decisions about access to services, people wanted there to be greater consideration of the emotional impact of infertility, dealing with larger and/or uneven breasts and obesity.

2.3.2. Consultation

The consultation ran between 31 October and 19 December 2022. During this time there was a programme of activities with an emphasis on seeking participation from those groups most likely to be impacted by any change. These were well promoted throughout the period both online via our social media platforms, and through all the local media outlets. We worked hard with all our partners, especially those with strong links to our health inequality groups to share and promote all our materials.

People were encouraged to use an online feedback questionnaire to submit their views but could also feed back in a variety of other ways: by letter, by email to the ICB central 'get involved' email, by attending a meeting or focus group where we undertook structured notes and feedback. Along with the meetings and focus groups we produced the main consultation document and questionnaire, both online and paper versions, and an easy read version of the consultation document. Copies of the documentation were made available at all mid and south Essex libraries.

All the information was shared with the three Health Overview and Scrutiny Committees (HOSCs), both in person and via papers, and at the MSEFT governors meeting.

A total of 210 people responded to the online questionnaire with one hard copy response. Twenty people participated on public events or focus groups. The consultation analysis and report was prepared by Stand, who are independent engagement practitioners, the full report including the exec summary can be found in Appendix 4.

2.3.3. Commentary on consultation outcomes

Overview:

Most online questionnaire respondents supported the proposed policy updates. The highest levels of support were for special fertility services (78%), bariatric surgery (74%) and vasectomy (72%). For the other clinical service areas – breast asymmetry, breast reduction and female sterilisation - approximately two thirds expressed support for the changes.

Overall, it was felt that the policy changes would enable equitable access for all residents in mid and south Essex and remove the 'postcode lottery' that currently exists. Further, for some clinical areas i.e. bariatric surgery, breast asymmetry, breast reduction, it was thought that the changes would result in improved quality of life for patients, whilst reducing associated costs for the NHS.

The full Consultation Report document can be found at Appendix 4.

Reasons for opposing policies proposed in the consultation and responses

1. BMI

- Concerns were expressed that BMI is not valid for individuals with high proportion of muscle mass which disproportionately contributes to weight, leading to a high BMI despite potentially having lower body fat. Additionally, that the recommended BMI threshold (BMI 27) for breast reduction did not sufficiently account for the contribution of large breasts to BMI, and more broadly discriminated against people with BMI above the relevant thresholds in different policy recommendations.
- Use of BMI as a threshold criterion: BMI is a commonly used threshold criterion in guidance and recommendations in the UK from NICE, Evidence Based Interventions, as well as other national and international bodies. There is no validated alternative measure or set of thresholds to use in its place. Until such time as an alternative evidence base is developed and national recommendations change, BMI should continue to be used within threshold criteria. Specific considerations relating to particular service areas are outlined below.
- Bariatric surgery: It is considered unlikely that individuals with high muscle mass would seek to access bariatric surgery, and such individuals would be unlikely to comply with other threshold criteria.
- Tertiary fertility: evidence shows lower IVF success rates outside a BMI range of 19-30[1].
- Breast reduction: The healthy weight reference range of BMI is 18.5-24.9. The threshold criteria of BMI 27 for breast reduction was chosen to reflect health weight plus the contribution, to a BMI up to 27, of disproportionately large breasts.
- Female sterilisation: BMI less than 35 was recommended as a threshold criterion by our expert clinical panel (see Section 4.2), due to the associated

[1] Nice Fertility problems: assessment and treatment, 20 February 2013 Last updated: 06 September 2017

clinical risk. However given the feedback in the consultation, and the lack of a specific BMI threshold in Faculty of Reproductive Health guidance, this was changed in the final recommended policy wording from a referral criterion to a guidance note to the referrer: that where an individual patient's BMI is above 35, this will be reviewed carefully at surgical assessment, and options for appropriate weight management may be considered prior to a decision on surgery (see Service Restriction Policy: Female Sterilisation in Appendix 1).

2. Non-smoking used as a threshold criterion

- A concern was raised that "*Care* [is] *being denied to smokers, with no mention of drug / alcohol use*", with regards to breast reduction and breast asymmetry surgery.
- The reasons for this distinction (as outlined in Section 4.3.2) is due to the impact that smoking has on wound healing, a significant factor in these surgeries specifically.

3. Parity of counselling in male and female sterilisation

- A small number additionally considered it unfair how people pursuing male sterilisation do not have to undergo the same counselling processes as people pursuing female sterilisation, with feeling that the criterion around this should be comparable.
- As a result, the following guidance from the Faculty of Reproductive Health guidance has been reproduced within the full policy wording for both female and male sterilisation (see Appendix 1). "*Vasectomy, tubal occlusion and other methods of contraception should be discussed with all men and women requesting sterilisation. They should be advised that vasectomy is safer, quicker to perform and is associated with less morbidity than laparoscopic sterilisation for women*."

4. Tertiary fertility service threshold criteria

- "*Disagreement with criterion re: no living children in the current relationship / neither partner has children from previous relationships*" – this criterion is in place in order to ensure funding is prioritised for those couples who have no children.
- "*Concerns about costs to the NHS / feeling that this is a non-essential service which should be privately funded*" – the provision of the tertiary fertility services included within policy recommendations are recommended by NICE. Non-provision would make us a national outlier. Overall, although 12% of respondents (17 people) expressed this concern, 78% (120 people) expressed support for the proposed tertiary fertility policy update overall.

- "*Disagreement with criterion re: previously privately funded IVF cycles being considered within the total number of cycles offered by the ICB*" – all previous cycles, whether self-funded or via the NHS, are counted in line with national evidence base which shows declining clinical effectiveness of IVF treatment with increasing cycle numbers. NICE guidance on Fertility problems: assessment and treatment (Point 1.10.2.1) states that "*the overall chance of a live birth following IVF treatment falls as the number of unsuccessful cycles increases*.".
- "*Disagreement with criterion re: same sex couples having to have had six cycles of privately funded IUI"* – IUI may be part of a pathway for two reasons (i) treatment, (ii) diagnosis of 'unexplained infertility'.
    (i) As regards use of treatment, our expert panel recommended prioritising available funding on increasing access to IVF, and not funding IUI for treatment, due to is limited clinical effectiveness.
    (ii) In order to access funding for IVF, patients must either have a specific diagnosed cause of infertility (see Service Restriction Policy for Tertiary fertility services in Appendix 1) or demonstrate 'unexplained infertility'. In male-female couples, this is demonstrated via 1-2 years of being unable to get pregnant, depending on age (see full wording in Appendix 1). For female same-sex couples, who are unable to demonstrate infertility in the same way, inability to get pregnant despite six rounds of IUI is used as the alternative standard. This is also noted in the Equality and Health Inequalities assessment (see Appendix 3). Funding IUI for diagnosis of 'unexplained infertility' for female same-sex couples only would raise the query of whether this unfairly excludes all other populations who might wish to access IUI for treatment purposes. Undertaking to fund IUI for both treatment and diagnosis of 'unexplained infertility' would be a more financially costly option, and therefore has the potential to negatively impact funding, access and outcomes associated with other clinical services. Therefore the recommended option is not to fund IUI.

5. The omission of gynecomastia from the Breast asymmetry Policy

Gynaecomastia is covered by a separate service policy available on the MSE ICS website.

2.4 Bariatric surgery

2.4.1. National

Harmonising service policies in the manner proposed in the Executive Summary, would bring policy into greater alignment with NICE guidance[1], where eligibility criteria are defined as below:

- BMI of 40 kg/m2 or more, or between 35 kg/m2 and 40 kg/m2 and other significant that could be improved if they lost weight.
- All appropriate non-surgical measures have been tried but the person has not achieved or maintained adequate, clinically beneficial weight loss.
- The person has been receiving or will receive intensive management in a tier 3 service.
- The person is generally fit for anaesthesia and surgery.
- The person commits to the need for long-term follow-up.

Perpetuating historic differences in CCG commissioning policies would prevent MSE ICS from delivering on its core purposes or the triple aim, as it would perpetuate inequalities, failing to equitably improve population health.

2.4.2. Local

Changes in prevalence / patient population: In mid and south Essex, there is an average number of 37 bariatric surgery cases per year. Nationally and in mid and south Essex, the number of bariatric surgeries decreased during the pandemic. In mid and south Essex numbers have now already reached pre-COVID levels[2] (Table 3). Given the continued rise in obesity nationally, we need to have a robust, single service policy[3].

Financial Year	National Cases	MSE Cases
2018/19	6056	41
2019/20	5741	39

[1] Recommendations, Obesity: identification, assessment and management, NICE, updated 08 September 2022
[2] Bariatric surgical procedures, 2021/22 (provisional)– National Obesity Audit [Management Information] - NDRS (digital.nhs.uk)
[3] Obesity Profile: short statistical commentary, Office for Health Improvements and Disparities July 2022

Financial Year	National Cases	MSE Cases
2020/21	1596	26
2021/22	4035	40
Average	4357	37

Table 3 The average number of bariatric surgeries performed nationally vs across MSE

2.4.3. Proposed changes in bariatric surgery

Bariatric Surgery	Service policy	Differences in threshold criteria vs NICE criteria	Change for residents under harmonised policy
Basildon and Brentwood CCG	Individual prior approval (using NICE criteria)	Nil	Move from Individual prior approval to Group prior approval may result in more people having access overall.
Mid-Essex CCG	Individual prior approval (NICE criteria plus additional local criteria)	Additional local criteria, including: 1. Patient is a non-smoker at the time of referral (as confirmed by CO monitor- for adults reading of 6 COppm (1.59%COHb) or less) and maintains this status. 2. GP has addressed and optimised management of any underlying social circumstances or clinical conditions which may be affecting weight management in the patient e.g. hormone problems such as underactive thyroid, Cushing's syndrome, polycystic ovarian syndrome (PCOS); substance misuse 3. Patient has BMI ≥ 35 for at least 5 years with significant co-morbidities, OR Patients with BMI ≥	1. Removal of non-smoking requirement may increase access for people who smoke. 2. Removal of 5 year time requirement may increase timeliness of access. 3. Move from Individual prior approval to Group prior approval may result in more people having access overall.

Bariatric Surgery	Service policy	Differences in threshold criteria vs NICE criteria	Change for residents under harmonised policy
		40 for at least 5 years without co-morbidities.	
Southend & Castle Point and Rochford CCGs	Group prior approval (NHS England policy criteria[1])	Additional threshold criterion present: 1. Morbid/severe obesity has been present for at least five years.	Removal of 5 year time requirement may increase timeliness of access.
Thurrock CCG	Group prior approval (NHS England policy criteria1)	Additional threshold criterion present: 1. Morbid/severe obesity has been present for at least five years.	Removal of 5 year time requirement may increase timeliness of access.
Proposed MSE ICB harmonised policy	Group prior approval (using NICE criteria)	Nil	See rows above

2.5 Tertiary fertility services

2.5.1. National

Legal duties pertaining to tertiary fertility services also include:

- The National Health Service Act 2006, including the ICB's financial duties under Chapter 6, specifically section 223GC, which provides that "*An integrated care board must exercise its functions with a view to ensuring that expenditure incurred by the board in a financial year does not exceed the sums received by it in that year".*
- The Human Rights Act 1998 ("the HRA"), particularly Articles 8 and 14 of the European Convention of Human Rights ("ECHR"), which the HRA adopts. Article 8 of the ECHR provides for the right to a private and family life, while Article 14 provides that the rights and freedoms in the ECHR apply equally and without discrimination.
- The Equality Act 2010.

[1] NHS commissioning Board: Clinical Commissioning Policy: Complex and Specialised Obesity Surgery April 2013

Harmonising service policies in the manner proposed in the Executive Summary would bring policy across MSE closer to NICE guidance[1], where eligibility criteria are defined as below:

IVF

NICE guidance states that women under the age of 40 should be offered three full cycles of IVF IF:

- They have been trying to conceive (through regular unprotected intercourse) for two years OR
- They have not become pregnant after 12 cycles of artificial insemination (six of which have been IUI) OR
- There is no chance of conceiving naturally and IVF is the only treatment which is likely to help.
- Women aged between 40 and 42 should be offered one full cycle of IVF if all of the following apply:
- They have been trying to conceive (through regular unprotected intercourse) for two years OR They have not become pregnant after 12 cycles of artificial insemination (six of which have been IUI)
- They have never had IVF before. The ovaries are likely to respond well to stimulation. The risks of IVF in patients aged over 40 has been discussed.

One full cycle is defined as one episode of ovarian stimulation and the transfer of any resultant fresh and frozen embryo(s).

IUI

NICE guidance states that IUI should be considered in the following circumstances:

- People who are unable to, or would find it very difficult to, have vaginal intercourse because of a clinically diagnosed physical disability or psychosexual problem who are using partner or donor sperm.
- People with conditions that require specific consideration in relation to methods of conception (for example, after sperm washing where the man is HIV positive)
- People in same-sex relationships.

[1] Recommendations | Fertility problems: assessment and treatment | Guidance | NICE

For patients who have not conceived following six IUI cycles (donor or partner sperm) with evidence of normal ovulation, tubal patency and semen analysis offer a further six unstimulated cycles of IUI before IVF is considered.

IUI should not be offered to those with unexplained subfertility, mild endometriosis or mild male factor infertility unless there are extenuating circumstances (e.g. religious or spiritual objections to IVF).

ICSI

NICE guidance states the following indications for ICSI:

- severe deficits in semen quality
- obstructive and no-obstructive azoospermia
- ICSI should be considered when a previous IVF treatment cycle has resulted in failed or very poor fertilisation.

Donor insemination

The use of donor insemination is considered effective in managing fertility problems associated with the following conditions:

- obstructive azoospermia
- non-obstructive azoospermia
- severe deficits in semen quality in couples who do not wish to undergo ICSI. [2004, amended 2013]

Donor insemination should be considered in conditions such as:

- Where there is a high risk of transmitting a genetic disorder to the offspring.
- Where there is a high risk of transmitting infectious disease to the offspring or woman from the man.
- Severe rhesus isoimmunisation.

Oocyte donation

The use of donor oocytes is considered effective in managing fertility problems associated with the following conditions:

- premature ovarian failure
- gonadal dysgenesis including Turner syndrome
- bilateral oophorectomy

- ovarian failure following chemotherapy or radiotherapy
- certain cases of IVF treatment failure.

Oocyte donation should also be considered in certain cases where there is a high risk of transmitting a genetic disorder to the offspring.

Women's Health Strategy[1]

Implementing the recommended approach would bring mid and south Essex closer to the undertakings in the Women's Health Strategy regarding fertility, e.g. "*to address the current geographical variation in access to NHS-funded fertility services across England. Female same-sex couples are able to access NHS-funded fertility services in a more equitable way. There is an end to non-clinical eligibility criteria, through an assessment of current criteria and updated commissioning guidance.*"

The recommendations harmonise provision, removing geographical variation within MSE. They improve female same-sex couple access via funding in localities where IVF was not previously funded (e.g. Mid-Essex, Basildon and Brentwood), and would harmonise the number of cycles available to heterosexual and same-sex couples where there was a difference previously (e.g. Thurrock).

We note the Government's intention to work with NHS England to implement these commitments fully over the next 10 years, and await further detail from NHS England and will at that stage consider any changes in national approach and the implications for ICB policies.

2.5.2. Local

Changes in prevalence

The fertility regulator's annual Fertility Trends[2] report, published in the organisation's 30th anniversary year, highlights advances and changes in fertility treatment over the past three decades, showing IVF cycles increased from 6,700 in 1991 to over 69,000 in 2019.

Financial Year	National Cycles	MSE Cases
2018/19	85786	92
2019/20	84394	100

*Table 4 The average number of assisted fertility approvals performed nationally vs across MSE**

[1] Women's Health Strategy for England, Department of Health and Social Care, Update 30 August 2022

[2] Human Fertilisation and Embryology Authority: State of the fertility sector 2019/2020. Published: November 2020

*data is only available for Southend, Castle Point and Rochford and Thurrock as they are the only CCGs that currently fund assisted fertility.

Summary

The proposed funding approach and threshold criteria for tertiary fertility services balance this national guidance, along with two of the ICS's core purposes of improving outcomes and tackling with inequalities, against its core purpose of enhancing productivity and value for money. This recognises the financial position of the ICS, along with its intent to expand tertiary fertility services to provide improved, equitable access across MSE.

2.5.3. Proposed changes in tertiary fertility services

Tertiary Fertility	Service policy	Differences in threshold criteria vs NICE criteria	Change for residents under harmonised policy

Southend and COR CCGs	Individual prior approval	**IVF/ICSI:**
		• Tighter definition of 'IVF cycle' – defined as up to 1 fresh and 1 frozen embryo transfer in CCG policy vs 1 episode of ovarian stimulation and the transfer of any resultant fresh and frozen embryo(s) in NICE guidance.
		• Reduced IVF cycles available for women under 40 years old - 2 cycles in CCG policy vs 3 cycles in NICE recommendations (both CCG and NICE guidance recommend for 1 cycle for women 40-42 yrs old).
		• Recommendation that any previous full IVF cycle, whether self-or NHS-funded, should count towards total cycles offered by NHS remains.
		• Additional CCG criteria including:
		  • BMI restriction (women must be 19-30; men must be <35). NICE guidance includes evidence of reduced efficacy where BMI is outside this range, but does not explicitly include in recommended eligibility criteria.
		  • Both of couple must be verified as non-smokers. NICE guidance includes evidence of reduced efficacy where either partner smokes, but does not explicitly include in recommended eligibility criteria.
		  • Living children: additional CCG criterion - couples ineligible if there are any living children from current or previous relationship, including adopted children.
			IVF:
			• Increased access due to reduction in period of unexplained fertility from 3 to 2 years in line with NICE guidance.
			• No change to number of cycles offered.
			
			IUI: no change.
			
			Egg donation:
			May increase access, as harmonised policy would fund batch of six eggs, with residents no longer needing to wait for altruistic donor. Criteria widened to include full range of NICE recommended indications.
			
			Donor insemination:
			No obvious impact on access, though harmonised policy would clarify limits:
			Provision will be up to a maximum of one batch of donor sperm.

Tertiary Fertility	Service policy	Differences in threshold criteria vs NICE criteria	Change for residents under harmonised policy
		• Couple should be registered with a GP in Southend or Castle Point and Rochford CCGs for 3+ years • Extended period of unexplained fertility – 3 years/ 12 cycles of IUI in CCG policy vs 2 years in NICE guidance. **IUI:** Not funded under CCG policy. NICE guidance is to consider unstimulated IUI in: • People who are unable to, or would find it very difficult to, have vaginal intercourse because of a clinically diagnosed physical disability or psychosexual problem who are using partner or donor sperm • People with conditions that require specific consideration in relation to methods of conception (for example, after sperm washing where the man is HIV positive) • People in same-sex relationships **Donor insemination/ donor sperm:** Funded under CCG policy for same sex couples as part of IVF/ ICSI treatment for same number of IVF cycles (therefore funded for a lower maximum number of embryo transfers in CCG vs NICE recommendations as per definition of a full cycle above). **Egg donation:** tighter criteria for CCG funding, including: • women who have undergone premature ovarian failure due to an identifiable pathological or iatrogenic cause before the age of 40 years	Previous maximum set at whatever quantity required for total cycles of IVF to which couple where eligible.

Tertiary Fertility	Service policy	Differences in threshold criteria vs NICE criteria	Change for residents under harmonised policy
		• Or to avoid transmission of inherited disorders to a child where the couple meet the other eligibility criteria NICE guidance recommends that donor oocytes are also considered effective in: • gonadal dysgenesis, including Turner syndrome, bilateral oophorectomy, certain cases of IVF treatment failure.	

Thurrock CCG	Individual prior approval	**IVF/ICSI**:
		• Tighter definition of 'IVF cycle' – defined as up to one fresh and one frozen embryo transfer in CCG policy vs one episode of ovarian stimulation and the transfer of any resultant fresh and frozen embryo(s) in NICE guidance.
		• Reduced IVF cycles available for women under 40 years old - two cycles in CCG policy vs three cycles in NICE recommendations
		• Reduced IVF cycles available for women 40-42 years old – no cycles under CCG policy vs one cycle in NICE recommendations).
		• Additional CCG criteria including:
		  • Couple should be registered with a GP in Thurrock CCG and live within Thurrock council boundary, or, if unregistered, their usual place of residence is within the Thurrock CCG boundary for minimum of 12 months.
		  • Couples should be living together.
		  • BMI restriction (women must be 19-30; men must be <35). NICE guidance includes evidence of reduced efficacy where BMI is outside this range
			IVF:
			• Increased access to IVF for women aged 40-42 from 0 to a maximum of one cycle.
			• Increased access for female same sex couples from a maximum of one cycle, to equal access as male-female couples.
			
			IUI: reduction in access for female-male couples eligible for IVF who might previously have accessed IUI, from three funded cycles to none.
			
			Egg donation:
			Increased access, from five to six oocytes, due to adjusted definition of 'one batch'.
			
			Donor insemination:

Tertiary Fertility	Service policy	Differences in threshold criteria vs NICE criteria	Change for residents under harmonised policy
		but does not explicitly include in recommended eligibility criteria. • Both of couple must be verified as non-smokers. NICE guidance includes evidence of reduced efficacy where either partner smokes, but does not explicitly include in recommended eligibility criteria. • There must be no other medical problems making the chance of success less than 20%. • Living children: additional CCG criterion - couples ineligible if there are any living children from current or previous relationship, including adopted children. • If three or more IVF cycles have been funded privately (a cycle defined as stimulation and egg collection) then couples would not be eligible for NHS funded IVF. • Female same sex couples eligible for one round of IVF after a minimum of six self-funded cycles of IUI under CCG policy, no specific recommendation in NICE guidance. **IUI**: • Up to three cycles IUI offered under CCG policy, where couple are eligible for IVF vs NICE recommendation to provide access to specific patient cohort as in Section 2.5.1. **Donor insemination/ sperm donation**: • CCG will fund one batch of donor sperm **Egg donation**: • CCG will fund one batch of oocytes (usually five)	No obvious impact on access.

Tertiary Fertility	Service policy	Differences in threshold criteria vs NICE criteria	Change for residents under harmonised policy
Basildon and Brentwood CCG	Not funded	N/A	Increased access to all tertiary fertility services for whole population defined under proposed threshold criteria.
Mid-Essex CCG	Not funded	N/A	Increased access to all tertiary fertility services for whole population defined under proposed threshold criteria.

Proposed MSE ICB harmonised policy	Individual prior approval	**IVF/ICSI**:
		• Tighter definition of 'IVF cycle' – defined as up to one fresh and one frozen embryo transfer in ICB policy vs one episode of ovarian stimulation and the transfer of any resultant fresh and frozen embryo(s) in NICE guidance.
		• Reduced IVF cycles available for women under 40 years old - two cycles in ICB policy vs three cycles in NICE recommendations (both ICB and NICE guidance recommend for one cycle for women 40-42 yrs old).
		• Additional ICB criteria including:
		  • Couple should be registered with a GP in MSE ICB for minimum of 12 months.
		  • BMI restriction (women must be 19-30; men must be <35). NICE guidance includes evidence of reduced efficacy where BMI is outside this range, but does not explicitly include in recommended eligibility criteria.
		  • Both of couple must be verified as non-smokers. NICE guidance includes evidence of reduced
			See rows above

Tertiary Fertility	Service policy	Differences in threshold criteria vs NICE criteria	Change for residents under harmonised policy
		efficacy where either partner smokes, but does not explicitly include in recommended eligibility criteria. • Living children: additional ICB criterion - couples ineligible if there are any living children from current or previous relationship, including adopted children. • If three or more IVF cycles have been funded privately (a cycle defined as stimulation and egg collection) then couples would not be eligible for NHS funded IVF. **IUI**: • Not funded under ICB policy. NICE guidance is to consider unstimulated IUI in specific populations listed in Section 2.5.1 **Donor insemination and egg/sperm donation**: • Greater clarity in quantity provided under policy e.g. one batch (usually six) oocytes, one batch sperm.	

2.6 Breast reduction

2.6.1. National

There is no published guidance from NICE on breast reduction surgery. Harmonising service policies in the manner proposed (see Section 1.3) would bring policy into greater alignment with national Evidence Based Intervention guidance[1], which states that breast reduction may only be provided for women if **all** the following criteria are met:

- The patient has received a full package of supportive care from their GP such as advice on weight loss and managing pain.
- In cases of thoracic / shoulder girdle discomfort, a physiotherapy assessment has been provided.
- Breast size results in functional symptoms that require other treatments / interventions (e.g. intractable candidal intertrigo; thoracic backache/kyphosis where a professionally fitted bra has not helped with backache, soft tissue indentations at site of bra straps).
- Breast reduction is planned to be 500gms or more per breast or at least four cup sizes.
- Body mass index (BMI) is <27 and stable for at least twelve months.
- The patient must be provided with written information to allow her to balance the risks and benefits of breast surgery.
- The patient should be informed that smoking increases complications following breast reduction surgery and should be advised to stop smoking.
- The patient should be informed that breast surgery for hypermastia can cause permanent loss of lactation.

2.6.2. Local

Changes in prevalence

- As many as 1-5% of the female population may have macromastia, although not all will suffer symptoms or a reduction of quality of life.[2]

[1] Breast reduction, Academy of Medical Royal Colleges
[2] Analysis of BAAPS Audit 2020-2021, The British Association of Aesthetic Plastic Surgeons

- In 2019/20 there were 36 breast reduction procedures carried out in MSE. Broomfield Hospital performed the majority (26). Four procedures were performed in hospitals within London.
- BAAPS audit in 2019/20[1] shows that 3949 female breast reductions were performed nationally (down from 2% the previous year).

Summary: there remains a population need for this service within mid and south Essex. Perpetuating historic differences in CCG commissioning policies would prevent MSE ICB from delivering on its core purposes or the ICS triple aim, as it would continue inequalities, failing to equitably improve population health. The new proposed service policy aims to harmonise the service approach across mid and south Essex, bringing practice closer to national standards and guidelines whilst enabling the ICB to improve historic inequalities, and to aim for sustainable, improved outcomes in the relevant population cohorts.

2.6.3. Changes in threshold criteria

Tertiary Fertility	Service policy	Differences in threshold criteria vs EBI criteria	Change for residents under harmonised policy
Basildon and Brentwood CCG	Individual prior approval*	BMI: CCG more restrictive than EBI. CCG policy was that patient must have a BMI <25 and evidence that the weight has been stable for 2 years vs EBI recommendation that BMI is <27 and stable for at least twelve months. Intertrigo: CCG policy was that this (or another serious functional impairment) should be present for at least 1 year vs no time requirement in EBI.	Reduction in access to surgery for those in whom <1kg would be removed (proposed minimum tissue weight for removal rising from 500g to 1kg). Reduction in access for people who smoke (minimal impact as expert experience shows that people who smoke are often declined for surgery during surgical assessment). Increase in access to those with BMI between 25-27 (previous CCG limit was BMI 25)
Mid-Essex CCG	Not funded	N/A	Increased access to breast reduction services for all eligible population.

[1] Analysis of BAAPS Audit 2020-2021, The British Association of Aesthetic Plastic Surgeons

Tertiary Fertility	Service policy	Differences in threshold criteria vs EBI criteria	Change for residents under harmonised policy
Southend & Castle Point and Rochford CCGs	Individual prior approval*	As per Basildon and Brentwood	As per Basildon and Brentwood
Thurrock CCG	Individual prior approval*	As per Basildon and Brentwood	As per Basildon and Brentwood
Proposed MSE ICB harmonised policy	Individual prior approval	Intertrigo: ICB policy would be that this (or another serious functional impairment) should be present for at least 1 year vs no time requirement in EBI. Smoking: ICB policy would require patient to be a non-smoker vs EBI recommendation to inform patient that smoking increases complications and should be advised to stop smoking. Breast reduction: must be at least 1kg per breast under ICB policy vs 500g per breast or at least 4 cup sizes in EBI.	See rows above

2.7 Breast asymmetry

2.7.1. National

There is no published guidance from NICE on breast reduction surgery for breast asymmetry. Harmonising service policies in the manner proposed (see Section 1.4) would bring policy into greater alignment with National Evidence Based Interventions[1], which states that breast reduction for women may only be provided if all the following criteria are met:

- The patient has received a full package of supportive care from their GP such as advice on weight loss and managing pain.
- In cases of thoracic / shoulder girdle discomfort, a physiotherapy assessment has been provided.

[1] Academy of Medical Royal Colleges. Breast reduction surgery. Accessed April 24, 2022

- Breast size results in functional symptoms that require other treatments / interventions (e.g. intractable candidal intertrigo; thoracic backache/kyphosis where a professionally fitted bra has not helped with backache, soft tissue indentations at site of bra straps).
- Breast reduction planned to be 500gms or more per breast or at least 4 cup sizes.
- Body mass index (BMI) is <27 and stable for at least 12 months. The patient must be provided with written information to allow her to balance the risks and benefits of breast surgery.
- The patient should be informed that smoking increases complications following breast reduction surgery and should be advised to stop smoking. Patients should be informed that breast surgery for hypermastia can cause permanent loss of lactation.

Unilateral breast reduction is considered for asymmetric breasts as opposed to breast augmentation if there is an impact on health as per the criteria above. Surgery will not be funded for cosmetic reasons. Surgery can be approved for a difference of 150 - 200gms size as measured by a specialist.

2.7.2. Local

Changes in prevalence

In 2019/20 there were 36 breast reduction procedures carried out in MSE, data on the number of these which were unilateral is not accessible. Expert opinion is that it will be a small percentage of the total number.

A degree of breast asymmetry is common, however significant (more than two cup sizes) difference is less common. It has been reported that of patients having breast augmentation surgery up to 88% had some degree of asymmetry in breast tissue and chest wall.[1]

Summary

There remains a population need for this service within mid and south Essex. Perpetuating historic differences in CCG commissioning policies would prevent MSE ICB from delivering on its core purposes or the ICS triple aim, as it would continue inequalities, failing to equitably improve population health. The new proposed service policy aims to harmonise the service approach across mid and south Essex, bringing practice closer to national standards and guidelines whilst enabling the ICB to

[1] Cosmetic Surgery Trends: Reduction in overall numbers as industry associations campaign for education and tighter regulation, The British Association of Aesthetic Plastic Surgeons, March 2020

improve historic inequalities, and to aim for sustainable, improved outcomes in the relevant population cohorts.

2.7.3. Changes in threshold criteria

Tertiary Fertility	Service policy	Differences in threshold criteria vs EBI criteria (EBI criteria for breast reduction)	Change for residents under harmonised policy
Basildon and Brentwood CCG	Not funded	N/A	Increased access to breast asymmetry services for all eligible population.
Mid-Essex CCG	Not funded	N/A	Increased access to breast asymmetry services for all eligible population.
Southend & Castle Point and Rochford CCGs	Individual prior approval*	**Assessment of asymmetry**: CCG policy specified funding considered where asymmetry is at least 2 cup sizes different on initial consultation with the patient's GP vs EBI recommendation that difference of 150 - 200gms in size, as measured by a specialist should be considered for funding. **BMI**: CCG more restrictive than **EBI**. CCG policy was that patient must have a BMI <25 and evidence that the weight has been stable for 2 years vs EBI recommendation that BMI is <27 and stable for at least twelve months. **Puberty**: CCG includes additional criteria that patient should be >18 years old and reached the end of puberty.	Increased access due to removal of physical symptom, BMI and stable weight criteria. **Smoking:** Reduction in access for people who smoke (minimal impact as expert experience shows that people who smoke are often declined for surgery during surgical assessment). **Puberty:** potentially increased access due to removal of requirement to be 18 yrs old, and shift towards stable breast size for 1 yr.
Thurrock CCG	Individual prior approval*	As per Southend & Castle Point and Rochford	As per Southend & Castle Point and Rochford

Tertiary Fertility	Service policy	Differences in threshold criteria vs EBI criteria (EBI criteria for breast reduction)	Change for residents under harmonised policy
Proposed MSE ICB harmonised policy	Individual prior approval	Assessment of asymmetry: ICB policy would specify asymmetry must be at least 2 cup sizes different vs EBI recommendation that difference of 150 - 200gms in size, as measured by a specialist. Smoking: ICB policy would require patients to be a non-smoker vs EBI recommendation to inform patients that smoking increases complications and should be advised to stop smoking. Puberty: ICB criteria that patient has had no change in cup size for 1 year and reached the end of puberty. Removed criteria: ICB policy would remove physical symptom criteria including neck ache or back ache and intertrigo, as well as BMI and stable weight requirements.	See rows above

2.8 Vasectomy

2.8.1. National

There is no NICE commissioning guidance or Evidence Based Interventions guidance on male sterilisation. The Faculty of Sexual and Reproductive Healthcare (FSRH) recommend that vasectomy should be performed under local anaesthetic where possible.[1] Additional care must be taken when counselling individuals under the age of 30 years or individuals without children who request sterilisation.

[1] FSRH Clinical Guideline: Male and Female Sterilisation (September 2014) - Faculty of Sexual and Reproductive Healthcare

Harmonising service policies in the manner proposed (see Section 1.5) would enable policy to remain in alignment.

2.8.2. Local

Changes in prevalence[1]

Nationally, prior to 2015/16 there had been a long term decline in the number of vasectomies performed, with the number falling by half (50%) between 2008/09 (22,156) and 2014/15 (11,113). Since then the number has remained at around 11 to 12 thousand per year.

In 2019, 225 vasectomies were performed in MSE, with 86% of these carried out for patients living in Basildon and Brentwood.

Summary

There remains an ongoing population need for this service within mid and south Essex. Perpetuating historic differences in CCG commissioning policies would prevent MSE ICB from delivering on its core purposes or the ICS triple aim, as it would continue inequalities, failing to equitably improve population health. The new proposed service policy aims to harmonise the service approach across mid and south Essex, bringing practice closer to national standards and guidelines whilst enabling the ICB to improve historic inequalities, and to aim for sustainable, improved outcomes in the relevant population cohorts.

2.8.3. Changes in threshold criteria

CCG	Service policy* (*same threshold criteria)	Change for residents under harmonised policy
Basildon and Brentwood CCG	Group prior approval*	No change
Mid-Essex CCG	Not funded	Increased access to vasectomy under GA for all eligible population.
Southend & Castle Point and Rochford CCGs	Group prior approval*	No change
Thurrock CCG	Group prior approval*	No change
Proposed MSE ICB harmonised policy	Vasectomy under Local anaesthetic: Routinely funded	See rows above

[1] Part 4: Sterilisations and vasectomies - NDRS (digital.nhs.uk)

CCG	Service policy* (*same threshold criteria)	Change for residents under harmonised policy
	Vasectomy under General anaesthetic: Group Prior Approval	

2.9 Female Sterilisation

2.9.1. National

There is no NICE commissioning guidance or Evidence Based Interventions guidance on female sterilisation. Guidelines from the Faculty of Sexual and Reproductive Health (FRSH) state that:[1]

- Counselling should be provided to women and men within the context of a service providing a full range of information about and access to other long-term reversible methods of contraception.
- Individuals should be informed that vasectomy carries a lower failure rate, and less risk associated with the procedure than sterilisation carried out by laparoscopy or laparotomy.
- Individuals should be made aware that some LARC methods are as effective as sterilisation.
- Hysteroscopic sterilisation, if available, should also be discussed as this has fewer contraindications than traditional methods, does not involve general anaesthetic, and can be performed as an outpatient.

Harmonising service policies in the manner proposed (see Section 1.6) would bring policy across MSE into closer alignment.

2.9.2. Local

Changes in prevalence

The number of sterilisations performed in NHS hospitals has fallen from 17,562 in 2008/09 to 12,918 in 2018/19, a decrease of 26%.[2]

In 2018/19, 79 female sterilisation procedures were carried out in MSE.

[1] FSRH Clinical Guideline: Male and Female Sterilisation (September 2014) - Faculty of Sexual and Reproductive Healthcare

[2] Sexual and Reproductive Health Services, England (Contraception) 2020/21 Part 4: Sterilisations and vasectomies - NDRS (digital.nhs.uk)

Summary:

There remains a population need for this service within mid and south Essex. Perpetuating historic differences in CCG commissioning policies would prevent MSE ICB from delivering on its core purposes or the ICS triple aim, as it would continue inequalities, failing to equitably improve population health. The new proposed service policy aims to harmonise the service approach across mid and south Essex, bringing practice closer to national standards and guidelines whilst enabling the ICB to improve historic inequalities, and to aim for sustainable, improved outcomes in the relevant population cohorts.

2.9.3. Changes in threshold criteria

CCG	Service policy	Differences in threshold criteria vs FRSH criteria	Change for residents under harmonised policy
Basildon and Brentwood CCG	Group prior approval	The woman is certain that her family is complete or that she never wants children in the future and is she aware that the procedure is permanent but has a failure rate, has information on the success rate for reversal and that reversal is not routinely funded on the NHS OR The woman has an absolute clinical contraindication to LARC or has severe side effects to the use of LARC or declines a trial of LARC after counselling from a healthcare professional experienced in fitting these devices AND	Increased support where mental capacity may be impaired. Clear information in counselling process that reversal not available on NHS, and highlighting increased risks of surgery vs other forms of long acting contraception. Reduction in access for people with BMI above 35 (minimal impact as expert experience shows that people with BMI >35 are often declined for surgery during surgical assessment).

CCG	Service policy	Differences in threshold criteria vs FRSH criteria	Change for residents under harmonised policy
		The woman has mental capacity	
Mid-Essex CCG	Not funded	N/A	Increased access to female sterilisation for all eligible population.
Southend & Castle Point and Rochford CCGs	Routinely funded	N/A	Access may be slightly reduced due to shift from routinely funded to Group prior approval – considered to be likely minimal impact.
Thurrock CCG	Routinely funded	N/A	Access may be slightly reduced due to shift from routinely funded to Group prior approval – considered to be likely minimal impact.
Proposed MSE ICB harmonised policy	Group prior approval	The patient is certain that their family is complete or that they never want children in the future and they are aware that the procedure is permanent but has a failure rate, has information on the success rate for reversal and that reversal is not routinely funded on the NHS. Counselling must also include consideration of vasectomy for their partner where appropriate. OR The patient has an absolute clinical contraindication to LARC or has severe side effects to the use of LARC or declines a trial of LARC after counselling from a healthcare professional experienced in fitting these devices AND The patient has mental capacity	See rows above

2.10 Populations whose access could increase under proposed ICB policies

Policy	Populations whose access could increase under proposed ICB policies
Bariatric surgery	Basildon and Brentwood: Move from Individual prior approval to Group prior approval may result in more people having access overall. Mid-Essex: • Removal of non-smoking requirement may increase access for people who smoke. • Removal of 5 year time requirement may increase timeliness of access. • Move from Individual prior approval to Group prior approval may result in more people having access overall. Castle Point and Rochford, Southend, Thurrock: Removal of 5 year time requirement may increase timeliness of access.
Tertiary fertility services	Basildon and Brentwood, Mid-Essex: Increased access to all tertiary fertility services for whole population defined under proposed threshold criteria. Castle Point and Rochford and Southend: IVF - increased access due to reduction in period of unexplained fertility from 3 to 2 years in line with NICE guidance. Egg donation - may increase access, as harmonised policy would fund batch of six eggs, with residents no longer needing to wait for altruistic donor. Criteria widened to include full range of NICE recommended indications. Thurrock: IVF - increased access to IVF for women and people assigned female at birth aged 40-42 from 0 to a maximum of 1 cycle, and for female same sex couples from a maximum of 1 cycle, to equal access as male-female couples. Egg donation - increased access, from 5 to 6 oocytes, due to adjusted definition of 'one batch'.
Breast reduction	Basildon and Brentwood, Castle Point and Rochford, Southend and Thurrock: people with BMI between 25-27 (previous CCG limit was BMI 25) Mid-Essex: Increased access to breast reduction services for all eligible population.
Breast asymmetry	Basildon and Brentwood, Mid-Essex: Increased access to breast asymmetry services for all eligible population. Castle Point and Rochford, Southend, Thurrock: Increased access due to removal of physical symptom, BMI and stable weight criteria. Potentially increased access due to removal of requirement to be 18 yrs old, and shift towards stable breast size for 1 yr.
Vasectomy	Mid-Essex: Increased access to vasectomy under GA for all eligible population.
Female sterilisation	Mid-Essex: Increased access to female sterilisation for all eligible population.

2.11 Populations whose access could reduce under proposed ICB policies

Policy	Populations whose access could reduce under proposed ICB policies
Bariatric surgery	None identified
Tertiary fertility services	Thurrock: IUI - reduction in access for female-male couples eligible for IVF who might previously have accessed IUI, from 3 funded cycles to none.
Breast reduction	Basildon and Brentwood, Castle Point and Rochford, Southend, Thurrock: people who could have 500-999g removed per breast (proposed minimum tissue weight for removal rising from 500g to 1kg), and for people who smoke (likely minimal impact).
Breast asymmetry	Castle Point and Rochford, Southend, Thurrock: people who smoke (minimal impact expected).
Vasectomy	None identified
Female sterilisation	Castle Point and Rochford, Southend, Thurrock: access may be slightly reduced due to shift from routinely funded to Group prior approval (likely minimal impact).

3 Economic case

3.1 Overview

Across mid and south Essex, different service restriction policies for the five CCGs resulted in unequal access to the six services.

For example those living in Mid-Essex or Basildon and Brentwood were not able to access tertiary fertility services or breast asymmetry surgery. Whilst those in Mid-Essex were also unable to access breast reduction surgery, vasectomy or female sterilisation services. More broadly, different threshold criteria used by different CCGs meant that certain individuals would have been able to access services in some CCGs but not in others e.g. female sterilisation.

To carry forward such policies and their resulting unequal access would go against one of the ICS's core purposes, i.e. to tackle inequalities in outcomes, experience and access.

At a high level, harmonising policy is necessary to reduce the previous postcode lottery and to equalise access to health benefits. The following sections outline the expected health and other associated benefits pertaining to each of the six service policies.

3.1.1. Bariatric surgery benefits

Health benefits

There are many well-known serious health consequences associated with obesity, including T2DM, cardiovascular disease, musculoskeletal disorders and certain cancers. Some of these may constitute the principal cause of death or lead to reduced life expectancy. Other health consequences may lead to a reduced quality of life e.g. obstructive sleep apnoea and infertility.[1] Surgery is associated with weight loss in the short term (with limited study evidence on long term effects), as well as reductions in comorbidities such as diabetes, metabolic syndrome and sleep apnoea.

In their review, The Clinical and Multi-professional Congress (CliMPC) noted that whilst both the average financial cost of bariatric surgery (£5200) and its inherent clinical risks, are higher than some other options within the weight management tier system, its impacts overall are significant, cost-effective for particular cohorts, and result in the greatest quality adjusted life year (QALY) gain relative to other weight

[1] Surgery for obesity, Cochrane, 8 August 2014

management options.[1,2] Individual health benefits include reducing the progression of co-morbidities, such as diabetes, cardiovascular disease and associated complications, whilst wider social gains include enhancing individuals' potential for beneficial societal contribution.

Societal benefits:

According to Public Health England, obesity has a serious impact on economic development, with the overall cost to wider society estimated at £27 billion – set to reach £49.9 billion by 2050. There is also an association with obesity and other factors such as income and ethnicity.[3] Improving access to clinically and cost-effective bariatric surgery therefore has a double societal benefit within mid and south Essex of addressing historically unequal access across CCG boundaries, as well as widening access to treatment for a condition associated with income and ethnicity-related inequalities.

3.1.2. Tertiary fertility services benefits

Health and other benefits

Assessing the impact of fertility services on population health is challenging. QALYs are used to capture improvements in a patient's health state from a particular intervention, however, "*they are not appropriate for placing a value on additional lives* [i.e. those created through fertility services]*. Additional lives are not improvements in health; preventing someone's death is not the same as creating their life and it is not possible to improve the quality of life of someone who has not been conceived by conceiving them*."[4] However cost effectiveness analysis has shown that IVF should be considered cost effective varying according to age, cause of infertility and number of cycles.[1] Clinical effectiveness, i.e. how likely different tertiary fertility measures are to result in a live birth, are outlined below in the Clinical / Technical case (see Section 4.3.2).

The health benefits described below therefore apply to the couple seeking treatment, rather than to any new life created. Both men and women who suffer with infertility are more likely to suffer from mental ill health.[5] IVF itself can cause stress and

[1] The clinical effectiveness and cost-effectiveness of bariatric (weight loss) surgery for obesity: a systematic review and economic evaluation NIHR, Sept 2009
[2] Cost-effectiveness of bariatric surgery and non-surgical weight management programmes for adults with severe obesity: a decision analysis model – PubMed, Oct 2021
[3] Health matters: obesity and the food environment - GOV.UK (www.gov.uk), March 2017
[4] Fertility: assessment and treatment for people with fertility problems. NICE Clinical Guideline. 2013.
[5] Karaca N., Karabulut A., Ozkan S., Aktun H., Orengul F., Yilmaz R., Ates S., Batmaz G. Effect of IVF failure on quality of life and emotional status in infertile couples. Eur J Obstet Gynecol Reprod Biol. 2016 Nov; 206:158-163. doi: 10.1016/j.ejogrb.2016.09.017. Epub 2016 Sep 20.

depression and anxiety symptoms. One study, observing women only, found more than 60% of women showed very few symptoms of anxiety or depression following IVF and women were less likely to show symptoms if the treatment was successful.[1] The risks associated with undergoing IVF are also described in Section 4.3.2. Therefore, overall there is a mixed picture in terms of health benefits to any given couple.

Clinical and Multi-professional Congress review

In their review, CliMPC noted that the complexity of this particular service area, with competing dimensions (e.g. limited clinical effectiveness or health benefits) set against the high social value placed upon the service by those who are seeking access. The low affordability of financially costly fertility services was also considered in the local context of a system under financial pressures, with any increase in funding for fertility services potentially affecting funding (and therefore residents' access) to other services. Providing access in line with NICE recommendations was the costliest option considered by CliMPC, and therefore had the greatest potential impact to negatively impact access to other clinical services.

CliMPC therefore recommended taking this the opportunity to harmonise policy, to broaden access to potential clinically effective services to those who lived in a CCG which did not previously fund it, or who had more limited access under CCG threshold criteria, and to use more restrictive threshold criteria than within the NICE guidance to reduce potential negative impact on access to other services due to funding implications.

3.1.3. Breast reduction benefits

Health benefits

Breast macromastia (enlarged breast tissue) may cause symptoms such as back ache, skin infections and loss of confidence. Musculoskeletal symptoms developing as a result of macromastia may lead to reduced exercise, weight gain and further ill health. Some of these symptoms may cause someone to take sick leave from work, reduce their social interactions and cause depression and anxiety. Loss of earnings, due to sick leave, was the greatest single cost to patients found in one study.[2]

The national Evidence Based Interventions guidance cites one systematic review and three non-randomised studies which show that surgery can improve patients'

[1] Rooney. K., Domar. A. The relationship between stress and infertility. Dialogues Clin Neurosci. 2018 Mar; 20(1): 41–47.
[2] Jud SM, Brendle-Behnisch A, Hack CC, et al. Macromastia: an economic burden? A disease cost analysis based on real-world data in Germany. Arch Gynecol Obstet. 2021;303(2):521-531. doi:10.1007/s00404-020-05841-7

quality of life, and reduce symptoms.[1] However, surgery is associated with risks and some complications may result in the permanent loss of function (e.g. loss of lactation, further details in Section 4.1.3).

Clinical and Multi-professional Congress review

In their review, CliMPC noted that whilst there was clear potential for health benefit at an individual level, there was limited impact at a population level overall.

As part of their review of cost effectiveness, Congress noted evidence on costs associated with care for individuals for macromastia prior to surgery, with a consensus that breast reduction surgery is cost-effective for a specific cohort of patients. Members were concerned that not funding breast reduction surgery could lead to an increase in health inequality in mid and south Essex, whilst noting that the current financial position of MSE limited its ability to fund all services for all residents. Balancing these considerations, Congress recommended that breast reduction surgery policies should be harmonised so that services are available via a process of Individual prior approval for the population defined in Section 1.3.

3.1.4. Breast asymmetry benefits

Health Benefits

Breast asymmetry may cause symptoms such as back ache, skin infections, loss of confidence, anxiety and depression (with some of these symptoms more relevant where unilateral macromastia is present – which is only the case in a proportion of patients). Physical and psychological improvements, such as reduced pain, increased quality of life and less anxiety and depression were found following breast reduction surgery (with physical health benefits likely to apply to patients with unilateral macromastia only, with psychological benefits potentially more widely relevant).[2] Some of the symptoms and problems associated with breast asymmetry, such depression and anxiety, may cause someone to take sick leave from work, reduce their social interactions and have an effect on relationships.

There is evidence that breast asymmetry corrective surgery improved emotional and mental health post operatively (although the study included breast augmentation as well as reduction, in contrast to widespread commissioning practice in the NHS).[3]

Benefits and risks associated with breast reduction and augmentation surgery for breast asymmetry were discussed by the Expert Clinical panel who reviewed

[1] Breast reduction, Academy of Medical Royal Colleges
[2] Academy of Medical Royal Colleges. Breast reduction surgery. Accessed April 24, 2022.
[3] Jud SM, Brendle-Behnisch A, Hack CC, et al. Macromastia: an economic burden? A disease cost analysis based on real-world data in Germany. Arch Gynecol Obstet. 2021;303(2):521-531. doi:10.1007/s00404-020-05841-7

threshold criteria. This was discussed with regards to the issue of deformity, including known syndromes such as Poland Syndrome which can result in breast asymmetry. There was discussion that augmentation has some surgical advantages as a single operation in terms of the extent of scarring, one-off cost and time and post-op morbidity. The wider implications in terms of cost of removal, replacement and any associated longer term morbidity were noted. It was agreed to continue in line with previous policy recommendations that only breast reduction would be funded under this specific policy.

Clinical and Multi-professional Congress review

In their review, CliMPC noted the health benefits outlined above, the system financial position and the importance of harmonising access to address historic inequalities. Balancing these considerations, Congress recommended that breast reduction surgery policies should be harmonised so that services are available via a process of Individual prior approval for the population defined in Section 1.4.

3.1.5. Male sterilisation benefits

Health and other benefits

The main health benefit of contraception is protection against unintended pregnancy, rather than affecting life expectancy, significant disability or acute/long term illness or injury.[1] The risks associated with getting a vasectomy are significantly lower than those associated with female tubal ligation.

Health benefits for female partners/partner capable of pregnancy include the ability to stop hormonal birth control and its associated health risks, and also the opportunity to avoid tubal ligation and associated risks including ectopic pregnancy in the case of failure. The use of health and care resources associated with these risks would also be avoided.

Review of wider socioeconomic impact suggests that unintended pregnancy is one of the most critical challenges facing the public health system and imposes significant financial and social costs on society.[2] Unplanned pregnancies can lead to financial burden on families and inability to progress in careers due to parental commitments. They are also considered as a high-risk pregnancy associated with high rates of negative consequences for mother/birthing parent, partner and the baby such as delayed onset of prenatal care.

[1] Benefits of a Vasectomy | Austin Center for Vasectomy, accessed 31/01/2023
[2] Unintended Pregnancy and Its Adverse Social and Economic Consequences on Health System: A Narrative Review Article – PM, Jan 2015

Clinical and Multi-professional Congress review

In their review, CliMPC noted that vasectomy is the only permanent form of contraception for men and people assigned male at birth. It is clinically effective and can provide health benefits impacting both men / people assigned male at birth and particularly women / people assigned female at birth. There was consensus view that the procedure has a positive effect on gender equality. Congress members therefore aimed to harmonise service policy so that vasectomy under local anaesthetic was routinely funded to maximise access and population benefit, whilst vasectomy under general anaesthetic should be funded via threshold criteria to deliver the best balance between clinical and cost effectiveness, anticipated health benefits and impact on health inequalities.

3.1.6. Female sterilisation benefits

Health and other benefits

The main health benefits of female sterilisation are reduced risk of unwanted pregnancy and reduced risk from alternative contraceptive methods.

Data from the National Survey of Sexual Attitudes and Lifestyles (Natsal-3) showed that 16% of pregnancies are unplanned. 45% of unplanned pregnancies occurred in women aged 16-19, 12.9% occurred in women aged >35. 57% of the unplanned pregnancies results in medical termination, 33.6% ended in miscarriage.[1] Risks of unplanned pregnancies include the psychological burden, and can lead to financial burden on families and inability to progress in careers due to parental commitments. They are also considered as a high-risk pregnancy associated with high rates of negative consequences for mother / birthing parent, partner and the baby such as delayed onset of prenatal care.

Risks associated with alternative contraception methods include failure (i.e. unplanned pregnancy), as well as venous thromboembolism, thrombotic stroke, breast and cervical cancer.[2]

Clinical and Multi-professional Congress review

In their review, CliMPC noted that female sterilisation is clinically effective and is associated with significant health benefits for women and people assigned female at birth – although it remains a higher risk procedure than vasectomy (see clinical / technical case in Section 4.1.6). Congress members therefore wished to harmonise

[1] Wellings K, Jones K, Mercer C, et al. The prevalence of unplanned pregnancy and associated factors in Britain: findings from the third National Survey of Sexual Attitudes and Lifestyles (Natsal-3). Lancet. 2013;382(9907):1907-1816. doi:10.1016/S0140-6736(13)62071-1

[2] Scenario: Combined oral contraceptive | Management | Contraception - combined hormonal methods | CKS | NICE, revised September 2022

policy to maximise access, whilst ensuring quality standardisation of referrals via a process of group prior approval.

4 Clinical / technical case

4.1 Clinical and Multi-Professional Congress

The Clinical and Multi-Professional Congress (CliMPC) is a group of experienced clinical and multi-professional staff, drawing together expertise from across our health and care system. It is chaired by the ICB Medical Director, with members bringing knowledge and experience from community care, mental health, patient engagement, pharmacy, primary care, public health, secondary care, social care and urgent and emergency care. It exists to review and make advisory recommendations upon complex, multi-faceted issues arising within our health and care system.

In February 2022, Congress was asked to review the six service areas explored above. For each service area, information packs were prepared with information on:

- Current funding policies
- Prevalence and service activity
- **Clinical effectiveness**
- **Health benefits**
- **Cost effectiveness**
- **Affordability**
- **Health inequalities**
- **Strategic fit**
- Policy in other systems

The six in bold text above were pre-scored by members. At each Congress meeting, these domains were discussed, before reviewing pre-scores and developing a consensus recommendation on how each procedure should be provided. These are outlined in the sections below and noted elsewhere in this business case where relevant.

4.2 Expert clinical panel

A panel of expert clinicians from across mid and south Essex was convened where CliMPC recommended the use of criteria to define the population for which care should be funded e.g. Group Prior Approval or Individual Prior Approval. Each panel had a briefing pack with:

- Context and Congress recommendations.
- Previous CCG policies.
- Relevant national standards or recommendations (e.g. from NICE).
- Practice from other systems.

The expert clinical panels reviewed these materials, considered any other relevant sources of evidence (e.g. national audits) and made recommendations on the appropriate criteria.

4.3 Outline of clinical cases – service provision policies

4.3.1. Service provision policy for bariatric surgery

Bariatric surgery is part of a four tier weight management service and is considered after individuals have failed to respond to treatment in tiers one to three. Bariatric surgery includes options such as gastric banding, gastric bypass, duodenal switch, sleeve gastrectomy and Roux-en-Y gastric bypass. Clinical criteria are used to guide which option is most appropriate for any individual.

MSE Clinical and Multi-professional Congress (CliMPC) members reviewed the evidence for clinical effectiveness and health benefit, including previous Cochrane review showing evidence of improved weight loss, reduction in co-morbidities and improved quality of life, though long term effects remain unclear due to limited follow-up.[1] CliMPC noted that bariatric surgery is a procedure with a significant evidence base, proven clinical benefits for patients and is deemed cost-effective if offered in-line with NHSE policy criteria. Whilst the average cost of bariatric surgery (£5200) is higher than some other options within the weight management tier system, its indirect impact in reducing progression of co-morbidities, such as diabetes, cardiovascular disease and associated complications, should be noted.

An expert clinical panel recommended that MSE ICS should adopt threshold criteria in line with NICE criteria. There is no clinical justification to add any additional criteria. This panel reviewed this context of the service harmonisation process, along with current NICE criteria and variation within prior CCG criteria, including requirements to be a non-smoker and to have a specific BMI for more than 5 years. There was felt to be no clinical reason to add these criteria to those set out in NICE guidance.

[1] Surgery for obesity, Cochrane, 8 August 2014

Clinical Risk Assessment

There are a number of risks associated with bariatric surgery, including superficial wound infection, the need for revisional surgery for issues such as anastomotic leak or gastric pouch enlargement, wound herniation, eating difficulties and regurgitation, hypoglycaemic episodes. Later potential complications include small bowel obstruction and adhesions. The 30 day mortality rate has been reported as 0.08% in England.[1]

Clinical Engagement

As above, via CliMPC and Expert Clinical Panel.

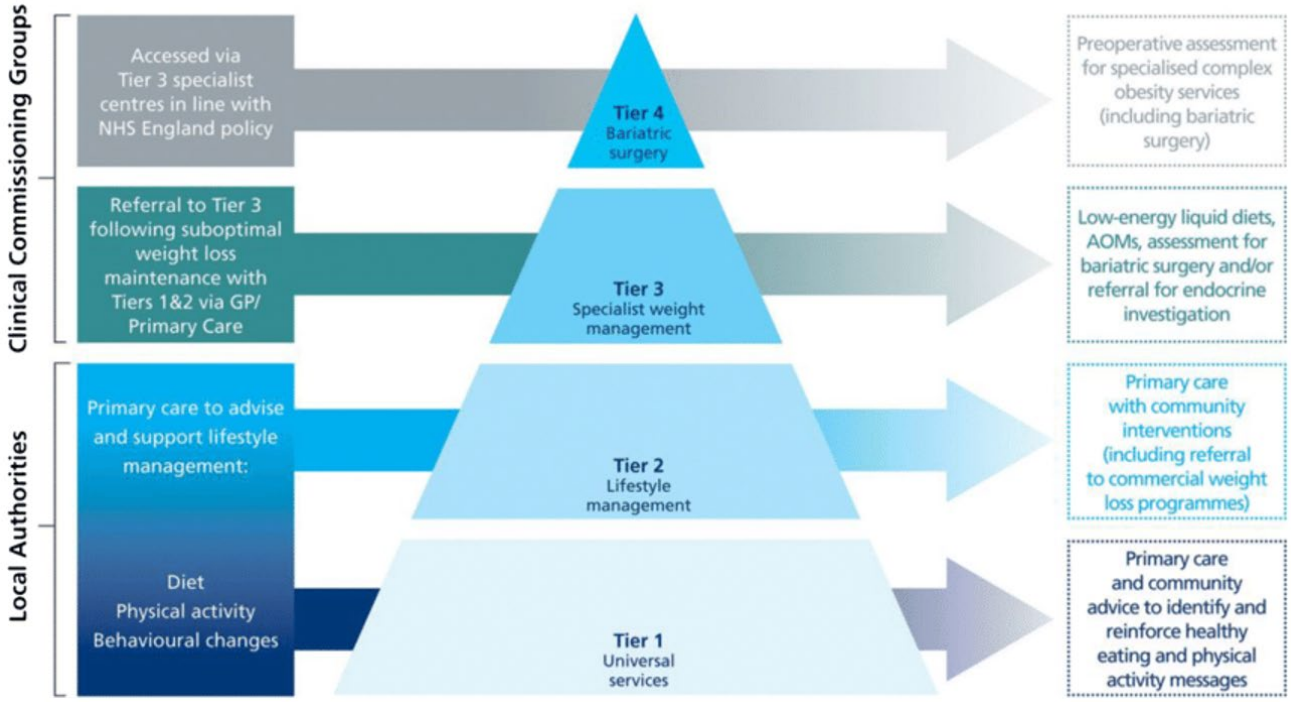


Figure 5 Weight Management Services commissioning model

4.3.2. Service provision policy for tertiary fertility services

Tertiary Fertility Services within the scope of this process include intra-uterine insemination (IUI), in vitro fertilisation (IVF), with or without intra-cytoplasmic sperm injection (ICSI) and sperm and oocyte donation.

- IVF is the fertilisation of an egg by a sperm cell outside of the human body. Embryo transfers are described as ‘fresh’ or ‘frozen’. Fresh transfers occur when the embryo is transferred directly following culture (typically 3-5 days

[1] Mortality related to primary bariatric surgery in England - PMC (nih.gov)

following fertilisation). If multiple embryos are created, the embryos not used in the fresh transfer can be frozen and stored, and subsequently thawed, and transferred to the uterus – this is a 'frozen' transfer. If the fresh transfer does not result in pregnancy the frozen embryos can be used and are considered part of the same IVF cycle. The IVF cycle is complete once all the frozen embryos have been transferred. Different organisations have differing definitions of an IVF cycle i.e. how many embryos may be frozen, or how many can be used overall. In CCGs which funded tertiary fertility services in mid and south Essex, the commonly used definition of one cycle was a maximum of two embryo transfers, one fresh and one frozen.

- Intracytoplasmic sperm injection (ICSI) involves injecting a sperm cell into an egg cell.
- Intrauterine insemination (IUI) involves injecting sperm (donor or partner) into the patient's uterus. This may be done with or without ovarian stimulation.
- Donor insemination (DI) can be used for couples with male infertility and same sex couples. Donated sperm can be used for IUI and IVF.
- Donated eggs (oocyte donation) can be considered for some patients who have ovarian failure, previous ovarian removal or have had previous issues with IVF failure.

CliMPC members reviewed evidence for clinical effectiveness and health benefit associated with these measures. For IVF, this included a 2015 Cochrane review, data from the Human Fertilisation and Embryology Authority (HFEA) and other studies and evidence reviews. The Cochrane review, assessing IVF compared to other options for unexplained subfertility, concluded that IVF is associated with higher live birth rates than expectant management, but there is insufficient evidence to draw firm conclusions.[1] HFEA data shows that estimated live birth rates per IVF treatment for all indications of IVF in the UK vary between 32.2% in women younger than 35 years and 13.4% in women between 40 and 42 years of age.

CliMPC noted evidence showing lower IVF success rates outside a BMI range of 19-30. Evidence on the use of IUI and ICSI was reviewed, including the NICE guidelines and review of evidence, as well as other studies exploring the role of IUI in couples with underlying fertility issues. A majority of CliMPC members agreed that tertiary fertility services are likely to achieve the intended clinical effect, though with limited clinical effectiveness overall.

An expert clinical panel recommended that threshold criteria should include:

[1] In vitro fertilisation for unexplained subfertility - Pandian, Z - 2015 | Cochrane Library

- IVF: A full cycle defined as up to one fresh and one frozen embryo transfer. This will include the cost of freezing and storage. For patients who do not achieve a live birth with the fresh embryo transfer, the transfer of one frozen embryo will be funded. The age of patient at the time that the embryos are frozen is required to be within the age limits set out in the policy. This also applies to the age at transfer.
- Cause of infertility: Couples who have been diagnosed as having a male factor or female factor problems or have had unexplained infertility for at least 2 years, taking into consideration both age and waiting list times. Where the partner receiving IVF is 40-42, the period of unexplained infertility should be at least 1 year.
- Eligible Couples will be offered: a maximum of 2 full cycles of IVF+/-ICSI (local definition of a full cycle) where the partner receiving treatment is between the age of 23 and 39.
  Where the partner is between the age of 40-42, a maximum of 1 full cycle (local definition) will be offered.
- Patients younger than 23 will be considered where investigations have shown conception would be impossible without fertility treatment.
- Any previous IVF cycles, whether self- or NHS-funded, will count towards the total number offered by the ICB.
- The partner receiving IVF should have been registered to an MSE practice for at least 12 months preceding referral to IVF services.
- BMI: Women and people assigned female at birth will only be considered for treatment if their BMI is between 19-30 (Kg/m2). Women and people assigned female at birth with BMI >30 should be referred to the appropriate obesity management pathway.
- Men and people assigned male at birth with a BMI of >35 will not be considered for treatment and should be referred to appropriate obesity management pathway.
- Smoking: Couples must not be non-smoking at the time of treatment.
- Same Sex Couples: If six cycles of privately funded IUI have been unsuccessful, demonstrating infertility, the couple will be eligible for IVF as above.
- Donor gametes: Up to one batch (usually 6) of donor oocytes and one batch of sperm will be funded. Where more than two viable embryos are generated, up to two transfers will be funded in line with the rest of the policy. Any

remaining embryos will be subject to the same criteria as if the oocytes were the couple's own. Fertility products will be stored in line with relevant national guidance.

- Living Children: Fertility treatment will only be offered to couples where the following two criteria are met: a) where there are no living children in the current relationship b) where neither partner has children from previous relationships. This includes any adopted child within their current or previous relationship
- Intrauterine insemination (IUI) will not be funded.

The expert clinical panel recommended that the population for whom access is funded should be defined by specific criteria including weight and smoking status in line with clinical evidence on efficacy and higher risk of spontaneous abortion.[1] They carried through the presence or absence of living children in line with existing policy in some previous CCGs in MSE. In order to demonstrate unexplained infertility, a period of 2 years was agreed (or one year if between 40-42 years due to reduced window of opportunity). In same sex couples, unexplained infertility should be demonstrated via six self-funded cycles of IUI.

The panel wanted to ensure equal IVF access to all ages within the range recommended by NICE, and therefore recommended for 2 cycles for women and people assigned female at birth between the ages of 23-39 years, and 1 cycle for women and people assigned female at birth between the ages of 40-42 years old. The reduced number of cycles in 40-42 years old is consistent with NICE recommendations for reduced number of cycles being made available in this age group. This is based on the lower clinical effectiveness in this age group.

Reciprocal IVF for same-sex couples describes a process where one partner receives ovarian stimulation to produce eggs, and acts as a donor for the other partner, with viable embryos implanted into the other partner so that both contribute to a pregnancy. This process is not recommended by NICE currently, and MSE ICB would review its policy should this situation change.

Given budgetary pressures, the panel recommended that available funding is focused on expanding access to IVF across mid and south Essex given its higher clinical effectiveness. It was therefore recommended not to fund IUI unless additional funding becomes available.

[1] Recommendations | Fertility problems: assessment and treatment | Guidance | NICE

Clinical Risk Assessment

There are risks of IVF including ovarian hyperstimulation (up to a third of patients, 1% moderate or severe symptoms), ectopic pregnancy, multiple births (risk reduced with single embryo transfer) and genetic defects (rare). Evidence of mental health within fertility settings show that both men and women who suffer with infertility are more likely to suffer from mental ill health.[1] IVF itself can cause stress and depression and anxiety symptoms.[2] IVF therefore takes place within the context of tertiary fertility services.

Clinical Engagement

As above, via CliMPC and Expert Clinical Panel.

4.3.3. Service provision policy for breast reduction

Breast reduction (reduction mammoplasty) is a surgical procedure performed on patients with macromastia (commonly referred to as hypermastia), large breasts, for symptom relief. Breast macromastia may cause symptoms such as back ache, skin infections, loss of confidence, anxiety and depression.

CliMPC reviewed available evidence, including that the evidence summary available from the national Evidence Based Interventions work, highlighting one relevant systematic review and three non-randomized studies, showing that surgery is beneficial in patients with specific symptoms. Physical and psychological improvements, such as reduced pain, increased quality of life and less anxiety and depression were found for women with hypermastia following breast reduction surgery. Congress agreed that there was a good clinical evidence base for breast reduction surgery in a specific cohort of patients, and that there should be an Individual prior approval process to ensure that treatment is targeted specifically to that cohort. The aim of surgery is not cosmetic, it is to reduce symptoms (e.g. back ache).

An expert clinical panel recommended that patients should be eligible if all the following are confirmed:

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[1] Karaca N., Karabulut A., Ozkan S., Aktun H., Orengul F., Yilmaz R., Ates S., Batmaz G. Effect of IVF failure on quality of life and emotional status in infertile couples. Eur J Obstet Gynecol Reprod Biol. 2016 Nov;206:158-163. doi: 10.1016/j.ejogrb.2016.09.017. Epub 2016 Sep 20.

[2] Rooney. K., Domar. A. The relationship between stress and infertility. Dialogues Clin Neurosci. 2018 Mar; 20(1): 41–47.

- The patient is suffering from neck ache or backache. Clinical evidence will need to be produced to rule out any other medical/physical problems to cause these symptoms.
- OR The patient has persistent intertrigo for at least one year and confirmed by GP OR another serious functional impairment for at least one year.
- AND Full evidence is provided of all conservative management options that have been attempted, including engaging with weight management services where appropriate, and that the wearing of a professionally fitted brassiere has not relieved the symptoms.
- AND The patient has a BMI <27 and evidence that the weight has been stable for 12 months.
- AND The patient is a non-smoker.
- AND At least 1kg is planned to be removed from each breast.

The panel discussed that previous criteria relating to physical symptoms were appropriate and should continue. The use of a fitted bra could be effective in some cases as a conservative treatment measure and so should continue to have a place within the threshold criteria. The BMI threshold was increased from 25 to 27, to prevent discrimination in terms of proportionality i.e. where a woman or person assigned female at birth has a BMI below 27 but has disproportionately large breasts. Above 27, it was felt that there would need to be greater emphasis on reducing obesity overall before consideration of breast reduction surgery.

The requirement for stable weight has been reduced from 2 years to 1 year, keeping a stability requirement in place to prevent the risks of crash dieting to get under the weight threshold and subsequent rapid weight-gain, negating the effects of breast reduction surgery. However a 1 year period is sufficient to demonstrate stable weight under the BMI threshold. The requirement to be a non-smoker was added due to significant impact on wound healing and surgical outcomes overall. The panel recommended to increase the threshold from 500g to 1kg for the minimum amount planned to be removed from each breast so that surgery is targeted at the most severe clinical presentations.

Clinical Risk Assessment

Breast reduction surgery for hypermastia can cause permanent loss of lactation function of breasts, altered shape and look, as well as decreased areolar sensation, bleeding, bruising, and scarring and often alternative approaches (e.g. weight loss or a professionally fitted bra) work just as well as surgery to reduce symptoms.

Clinical Engagement

Via CliMPC and Expert Clinical Panel.

4.3.4. Service provision policy for breast asymmetry

Breast asymmetry can be due to developmental disorders and acquired conditions secondary to trauma, infection, or surgery. A degree of breast asymmetry is common, however significant difference (e.g. more than 2 cups sizes) is less common. Breast asymmetry corrective surgery reduces the size of, or enlarges, one breast resulting in a similar size of both breasts. Broadly, CCGs in England did not fund breast enlargement for breast asymmetry. Breast surgery to correct for breast asymmetry is widely used and effective at creating symmetric breasts. It has been shown to improve functional capacity and relieve pain in the lower back, shoulders and neck of patients with mammary hypertrophy.[1]

CliMPC reviewed available evidence, which mainly focused on bilateral, rather than unilateral, breast reduction and agreed that it could be clinically effective for a cohort of patients, and should be funded via an Individual prior approval process. The aim of surgery is not cosmetic, but to reduce health symptoms.

An expert clinical panel agreed that the goal of surgery is to correct a significant deformity which is causing an impact on health. Patients will be eligible if all the following are confirmed:

- Clinical evidence rules out any other medical/physical problems to cause these symptoms.
- AND full evidence is provided of all appropriate conservative management options that have been attempted.
- AND there is a difference of at least 2 cup sizes (e.g. C and DD cup size differential) OR evidence of another serious functional impairment for at least one year.
- AND the patient is a non-smoker
- AND patient has had no change in cup size for 1 year, and has reached end of puberty. Referral should be delayed if end of puberty has not been reached.

Only unilateral breast reduction (not unilateral breast augmentation) will be funded.

[1] Functional capacity and postural pain outcomes after reduction mammaplasty - PubMed (nih.gov)

The panel discussed that due to differences in age at completion of puberty, the requirement to be aged 18 or over was replaced with a requirement for stable cup size for 1 year.

In previous CCG policy for breast asymmetry, there were a number of threshold criteria which the panel considered to be more relevant to breast reduction and inappropriate for breast asymmetry. These were removed, including the presence of neck or backache, intertrigo, BMI threshold and stable weight for 2 years.

The issue of mental health as an indication was discussed, though due the apparent difficulty of standardising assessment and attributing poor mental health directly to breast asymmetry meant that the panel agreed not to include this as a criterion at this point.

Previous CCG policies have funded breast reduction in order to improve symmetry, not augmentation. This was discussed with regards to the issue of deformity, including known syndromes such as Poland Syndrome which can result in breast asymmetry. There was discussion that whilst augmentation has some advantages as a single operation in terms of the extent of scarring, initial surgical cost and time, and post-operative morbidity, the wider implications in terms of cost of removal, replacement and any associated longer-term morbidity led to an agreement that reduction only should be funded.

Clinical Risk Assessment

Breast reduction surgery for asymmetry can cause permanent loss of lactation function of the breast operated upon, as well as decreased areolar sensation, bleeding, bruising, and scarring.

Clinical Engagement

As above, via CliMPC and Expert Clinical Panel.

4.3.5. Service provision policy for male sterilisation

Sterilisation is a permanent method of contraception. Vasectomy is an operation to sterilize a man or person assigned male at birth; this can be achieved by the interruption of the vas deferens, preventing sperm from entering the ejaculate. The procedure is usually performed under local anaesthesia normally in primary care. But in exceptional circumstances it is carried out under general anaesthesia in an acute setting.

CliMPC reviewed available evidence including a NICE evidence summary, and were agreed that it shows high clinical effectiveness in preventing pregnancy, and can provide health benefit. Vasectomy is the most effective method of male sterilisation

according to the British Association of Urological Surgeons (BAUS).[1] The main health benefit associated with vasectomy is protection against unintended pregnancy, rather than impact upon life expectancy, disability or acute or long term illness or injury. The lifetime failure rate of vasectomy is approximately 1 in 2000 patients (0.05%) following negative semen testing.[2]

There was a consensus view that the procedure overall has a positive effect on gender equality. It was noted that women spend a disproportionate amount of time, when compared with men, on family planning services including time with their GP. In addition, women and people assigned female at birth suffer side effects of hormonal contraceptives which can increase use of healthcare resources.

An expert clinical panel recommended that threshold criteria should include:

Previous documented adverse reaction to local anaesthesia.

OR

Scarring or deformity distorting the anatomy of the scrotal sac or content making identification and/or control of the spermatic cord through the skin difficult to achieve.

The expert panel reviewed the previous joint policy for Basildon and Brentwood, Castle Point and Rochford, Southend and Thurrock and confirmed that these remained appropriate for use as threshold criteria. Skin infection in the operative sight was considered to be a contraindication to surgery (as it would be for most surgery), but would lead to delay in performing the procedure under local anaesthetic, rather than referral for general anaesthetic.

Clinical Risk Assessment

The risks associated with vasectomy include bleeding and infection, chronic pain and early or late failure, as well as anaesthetic risks where it is performed under local or general anaesthesia. People may regret having had the procedure. It cannot easily be reversed and reversal is not routinely offered on the NHS. Azoospermia must be confirmed at 12 weeks by a post-vasectomy semen analysis.

Clinical Engagement

As above, via CliMPC and Expert Clinical Panel.

[1] Vasectomy | The British Association of Urological Surgeons Limited (baus.org.uk)
[2] Contraception - sterilization | Health topics A to Z | CKS | NICE

4.3.6. Service provision policy for female sterilisation

Sterilisation is a permanent method of contraception. Female sterilisation can involve sealing the fallopian tubes (by clipping, tying or applying rings), or cutting, or even removing them. The procedure usually requires a general anaesthetic.

CliMPC reviewed available evidence, including a Cochrane review, and agreed that it was highly clinically effective and an important form of contraception for some women and people assigned female at birth. The lifetime risk of laparoscopic tubal occlusion failure is estimated to be 1 in 200 patients (0.5%).[1] The main health benefits of female sterilisation are reduced risk of unwanted pregnancy and reduced risk from alternative contraceptive methods.

An expert clinical panel recommended the following threshold criteria:

- Family complete: The patient is certain that their family is complete or that they never want children in the future.
- Contraception: AND there is an absolute clinical contraindication to Long Acting Reversible Contraception (LARC) or has severe side effects to the use of LARC or declines a trial of LARC after counselling from a healthcare professional experienced in fitting these devices.
- Capacity: AND the patient has mental capacity OR all necessary arrangements have been completed to either support them to a position of having capacity or where appropriate advocacy arrangements are in place, in compliance with latest capacity guidance.
- Counselling: AND they are aware that the procedure is permanent but has a failure rate, that reversal is not funded on the NHS (except via Individual Funding Requests), that other forms of LARC have a similar success rate, with lower risk profile. Counselling must also include consideration of vasectomy for their partner where appropriate.
- BMI: AND they must have a BMI less than 35, due to increased clinical risk associated with BMI of 35 and above.
- Exemptions: patients who have a medical condition making pregnancy dangerous or where LARC is contra-indicated or inappropriate will be exempt from these criteria and female sterilisation will be routinely funded.

The expert panel agreed with continuing with existing criteria regarding family being complete. On the use of LARC, they recommended that there would be no clinical benefit from introducing a time requirement for trial of LARC. Following a steer from Congress to review the wording around mental capacity, the panel recommend that

[1] Contraception - sterilization | Health topics A to Z | CKS | NICE

any issues with mental capacity are addressed as part of the process of applying threshold criteria.

The panel reviewed the wording around counselling, indicating that there needed to be clear information given that reversal was not available on the NHS. Also that sterilisation, as a surgical procedure, had a higher risk than other forms of long acting contraception, including vasectomy for partners. Counselling should therefore include discussion of vasectomy where appropriate.

BMI above 35 was considered to be associated with significant clinical risk, outweighing the benefit. The main risk of performing intra-abdominal procedures on obese patients is the additional anaesthetic risk of difficulty ventilating patients, recovery from anaesthesia and the higher risk of wound, chest and more deep-seated body cavity infections. In practice, laparoscopic sterilisation is not lifesaving, and patients with a BMI >35 are currently declined at anaesthetic and surgical pre-operative assessment due to this risk vs benefit consideration. This criterion should therefore be applied uniformly as part of threshold criteria.

Clinical Risk Assessment

The risks associated with female sterilisation include bleeding, infection and damage to other organs. Effective contraception must be continued for a period of time following sterilization, depending on the method used. There is a small risk that the operation will not work. Blocked tubes can re-join immediately or years later. Risks include ectopic pregnancy if the procedure fails (10 year cumulative probability of ectopic pregnancy ranges from 2.4–7.3 per 1000 procedures) and injuries to bowel/bladder/blood vessels requiring laparotomy (2 per 1000 procedures) or leading to death (1 in 12,000 procedures). People may regret having had the procedure. It cannot easily be reversed, and the NHS does not routinely offer reversal procedures.

Clinical Engagement

As above, via CliMPC and Expert Clinical Panel.

5 Financial case

5.1 Overview

Working in partnership with the Clinical and Professional Leadership Directorate, the Resources Directorate have undertaken a level of analysis that helps to identify the potential recurrent cost increases for the ICB should changes to service provision be agreed as part of this process.

Using reasonable assumptions we can expect the harmonisation of service restriction policies as per the preferred option set out in this document to create an annual cost pressure of up to £1.076m. Given the potential for latent demand, there is likely to be a spike in activity in the first few years following policy implementation. This is anticipated to be up to c. 50% of the total annual cost, i.e. up to circa £1.614m.

Non-recurrent transitional costs (i.e. supporting patients currently referred for, or receiving treatment that they would no longer be eligible for under new recommendations), could cost up to c.£150K during year one.

Members should be aware that by implementing these proposed changes, the ICB is pre-committing this recurrent increase in cost from its growth funding for 2023/24, thus the ability to fund any new investments will be limited accordingly. The ICB's initial financial drafts for 2023-24 now make provision for this increased cost.

If approved this business case will enter a mobilisation period leading up to a go-live date of the 1 April 2023.

5.2 Modelling approach

This modelling has been based on an approach of scaling up existing spend across the six clinical treatment areas utilising demographic data as the basis for identifying potential future annual spend.

For fertility services, the incremental cost increase has been broadly based upon the existing south-east Essex criteria. This would see an expansion in services in mid Essex and Basildon and Brentwood, and a shift of criteria in Thurrock.

The other five clinical treatment areas have been modelled illustrating the additional cost of expanding existing service provision to mid Essex to bring it in line with service provision for south Essex.

Whilst simplistic in its nature for the purposes of identifying the potential impact on annual costs this has been considered as sufficient, as both demand and capacity for these services will be impacted by a multitude of variables outside of the ICB's direct control. The outcome of this analysis can be seen in Table 5 below:

SERVICE HARMONISATION - FINANCIAL ANALYSIS

	Baseline Assessment	Estimated Future Costs Per Annum		
Service	Per Annum(£k)	Service Level	Value (£k)	Potential Pressure
Fertility	394	Per SEE Criteria	1,174	(780)
Bariatric Surgery	190	Remove smoker status restriction	202	(12)
Vasectomies	154	Extend to Mid Essex	226	(72)
Female Sterilisation	94	Extend to Mid Essex	138	(44)
Breast Reduction	102	Extend to Mid Essex	149	(47)
Breast Asymetry	102	Extend to Mid Essex and B&B	222	(121)
TOTALS	**1,035**		**2,112**	**(1,076)**

Note we have been unable to disaggregate Breast Asymetry from Breast Reduction, given coding issues - given values though, this is unlikely to have a material impact upon affordability

Table 5 Financial analysis

The key points are:

1. Current cost for the existing level of service provision is circa £1m across the six clinical treatment areas.
2. The scenario illustrated above results in additional annual cost being incurred by the system in the region of £1-1.1m.
3. As a system we are facing significant financial pressure and an ambitious and stretching savings programme over coming years. Any decision to increase service provision over and above existing levels of provision will result in additional costs for the system to manage as part of its overall financial management responsibilities.

Given the potential for latent demand, there is likely to be a spike in activity in the first few years following policy implementation. This is anticipated to be up to c. 50% of the total annual cost i.e. up to circa £1.614m.

The majority of the services under consideration are delivered by a variety of both NHS and non-NHS providers outside and inside the mid and south Essex geography. Our system context includes existing service pressures, and any increased access to services which may occur as a result of this service harmonisation process will take place in this context, with prioritisation according to existing clinical frameworks.

It is clear from the above modelling, the largest increase in demand would relate to fertility services with capacity provided by NHS and non-NHS providers across the pathway. The ICB has ensured that current contractual partners for fertility services have been made aware of the review (see Section 8).

The following analysis is included to support an understanding of the cost relating to the inclusion of particular threshold criteria and transitionary arrangements (further detailed in Section 2.2.3).

- IVF: Analysis of our overall expenditure upon fertility treatment suggests that circa 67% of our annual cost will be incurred upon IVF. Thus, our annual expenditure on IVF amounts to c£787k.

  Making an assumption that approximately 33% of patients undergoing IVF get pregnant during their first cycle, it is therefore reasonable to assume that 33% of our annual cost incurred is on a patient's first cycle.

  Our forecast annual expenditure can, therefore, be expressed in Table 6. Should the ICB, therefore, decide to fund only 1 cycle of IVF, forecast costs would reduce by c£0.5m.

Annual costs	Spend per annum (£k)
Annual 1st cycle costs (33%)	260
Annual 2nd cycle costs (67%)	527
Total expenditure	787

Table 6 IVF spending per cycle

- **IUI:** The agreed tariff rate with all Providers for IUI, is £650 per cycle. Analysis of activity levels in previous years within the Thurrock Alliance (who were the only former CCG to fund IUI activity), suggests that uptake is very low, therefore the ICB's potential exposure should they offer IUI within the revised policy is not expected to be material (although this expectation comes with a margin of uncertainty due to data limitations).

People who smoke:

Should the ICB decide to amend the recommended threshold criteria to exclude smokers from receiving female sterilisation, breast reduction and breast asymmetry

services, our annual expenditure would decrease by an estimated £68k (see table 7).

Service	Estimated future annual value (£k)	Potential reduction re excluding non-smokers (13.3% re national smoking prevalence)
Female sterilization	138	18
Breast reduction	149	20
Breast asymmetry	222	30

Table 7 Value of non-smoking criterion

Transitional arrangements:

There are a number of specific populations for whom transitional arrangements should be funded (see Section 2.2.3). The significant element which could impact cost relates to those in Thurrock who are referred for or are currently receiving IUI.

Should the policies be implemented, as proposed, there will be transitional costs, as a result of patients already being on a pathway, whilst not yet receiving treatment. The assessed transitional costs in year 1 (2023/24) of policy implementation could be up to circa £150k.

6 Management

Governance Process:

- Service Harmonisation Programme Board developed with agreed Terms of Reference and membership.
- Senior Responsible Officer and governance process agreed.
- Programme Milestones with agreed ownership tracked through robust Programme Plan.

Management of Risks:

- RAID log developed and updated at each Programme Board with Risks highlighted and planned mitigation/escalation detail included.

Conflicts of Interest Management:

- Noted in Attendees section of RAID log.

Implementation Plan:

- Four Phases of programme agreed with leadership agreed.
- Development of a Service Harmonisation Working Group to support Phase 3 (Business Case) and Phase 4 (Mobilisation/Implementation).

Project Assurance:

- Regular updates from Working Group to Programme Board to assure Executive programme running to agreed timeline.
- Programme Plan milestones reviewed fortnightly to support programme delivery and meet deadlines.

Post-Implementation and Evaluation arrangements:

- Develop Phase 5 to consider post implementation and evaluation (via Working Group).

Workforce:

- Executive decision required regarding future process development for the ongoing review of existing Service Restriction Policies and potential new documentation (as required) – possible remit extension for existing Service Harmonisation Working Group/Stewardship Directorate.

7 Summary of recommendations

7.1 Options appraisal

7.1.1. Bariatric surgery

Summary of recommendations

- Recommended funding option: Group prior approval
- Recommended threshold criteria:
- They have a BMI of 40 kg/m2 or more, or between 35 kg/m2 and 40 kg/m2 and other significant disease (for example, type 2 diabetes or high blood pressure) that could be improved if they lost weight.
- All appropriate non-surgical measures have been tried but the person has not achieved or maintained adequate, clinically beneficial weight loss.
- The person has been receiving or will receive intensive management in a tier 3 service.
- The person is generally fit for anaesthesia and surgery.
- The person commits to the need for long-term follow-up.

Threshold criteria options appraisal

An expert clinical panel recommended that MSE ICS should adopt threshold criteria in line with NICE criteria.

There is no clinical justification to add any additional criteria. This panel reviewed this context of the service harmonisation process, along with current NICE criteria and variation within prior CCG criteria, including requirements to be a non-smoker and to have a specific BMI for more than 5 years. There was felt to be no clinical reason to add these criteria to those set out in NICE guidance.

Summary of service policy options appraisal

The following options were considered by CliMPC. A summary of their views after deliberation, along with relevant threshold criteria developed through expert panel input and feedback from public consultation are included below.

Option 1 - No Change: continue with current variation in existing CCG policies. This was considered to be unviable as it leads to a situation of effective post code lottery,

widening inequalities, and does not align with NHS constitutional or MSE system values.

Option 2 (**recommended option**) **- Group prior approval**: This option was identified in discussion as the Congress's recommended option, delivering the best balance between clinical and cost-effectiveness, anticipated health benefits, affordability, health inequalities and strategic fit. There was consensus that bariatric surgery should be available with minimum administrative burden for referrers or eligible patient, without compromising standards of quality.

Option 3 - Individual prior approval in line with NICE policy: has the potential benefit of reduced inappropriate referrals due to the stage of commissioner-review of referrals (not present in Option 2 – Threshold). However, CliMPC felt that the additional cost involved, in terms of increased patient and staff time and administrative process, failed to outweigh this benefit. Therefore in the case of bariatric surgery, Individual prior approval process detracted, rather than added value to the pathway.

Option 4 - Individual prior approval as above with additional smoking criteria: would mean adopting an individual prior approval policy with an added criterion of the patient successfully undergoing and maintaining smoking cessation.

CliMPC discussed that successful smoking cessation would reduce the risk associated with bariatric surgery and could indicate a commitment to improving lifestyle. However there is no evidence showing a population-level benefit to this criterion in the context of bariatric surgery.

Indeed, overall CliMPC members agreed that this option's most significant dimension was the potential to widen inequalities through denying access to patients who have not successfully stopped smoking. It was suggested that it is challenging for patients to undergo multiple significant life events and changes all at once (e.g. surgery and smoking cessation). CliMPC agreed that patients who smoke but who are otherwise eligible for bariatric surgery should be offered referral for smoking cessation support. However, successful cessation should not be a part of threshold criteria.

Option 5: Not funded: Whilst this was the most affordable option, it was not the preferred option as it does not deliver against the potential health benefits or upon the societal value placed on this service by those seeking it. It has clear potential to increase inequalities across the population, where more deprived populations are unable to self-fund, whereas less deprived populations may be able to fund private access.

7.1.2. Tertiary fertility services

Summary of recommendations

- Recommended funding option: Individual prior approval, using NICE criteria with additional local criteria
- Recommended threshold criteria:

IVF:

- A full cycle is defined as up to one fresh and one frozen embryo transfer. This will include the cost of freezing and storage. For patients who do not achieve a live birth with the fresh embryo transfer, the transfer of one frozen embryo will be funded. Any previous IVF cycles, whether self- or NHS-funded, will count towards the total number offered by the ICB.
- The age of mother/ birthing parent at the time that the embryos are frozen is required to be within the age limits set out in the policy. This also applies to the age at transfer.
- Patients younger than 23 will be considered where investigations have shown conception would be impossible without fertility treatment.
- Cause of infertility: Couples who have been diagnosed as having a male factor or female factor problems or have had unexplained infertility for at least 2 years, taking into consideration both age and waiting list times. Where the partner receiving IVF is 40-42, the period of unexplained infertility should be at least 1 year.
- Eligible Couples will be offered: a maximum of 2 full cycles of IVF+/-ICSI (local definition of a full cycle) where the partner receiving treatment is between the age of 23 and 39.
  Where the partner is between the age of 40-42, a maximum of 1 full cycle (local definition) will be offered.
- Registration: The partner receiving IVF should have been registered to an MSE practice for at least 12 months preceding referral to IVF services.
- BMI: Women and people assigned female at birth will only be considered for treatment if their BMI is between 19-30 (Kg/m2). Women and people assigned female at birth with BMI >30 should be referred to the appropriate obesity management pathway. Men and people assigned male at birth with a BMI of >35 will not be considered for treatment and should be referred to appropriate obesity management pathway.
- Smoking: Couples must not be non-smoking at the time of treatment.

- Same Sex Couples: If six cycles of privately funded IUI have been unsuccessful, demonstrating infertility, the couple will be eligible for IVF as above.

Donor gametes:

- Up to one batch (usually 6) of donor oocytes and one batch of sperm will be funded. Where more than two viable embryos are generated, up to two transfers will be funded in line with the rest of the policy. Any remaining embryos will be subject to the same criteria as if the oocytes were the couple's own. Fertility products will be stored in line with relevant national guidance.

Living Children:

- Fertility treatment will only be offered to couples where the following two criteria are met: a) where there are no living children in the current relationship b) where neither partner has children from previous relationships. This includes any adopted child within their current or previous relationship.

Intrauterine insemination (IUI) will not be funded.

Threshold criteria options appraisal

The expert clinical panel recommended that the population for whom access is funded should be defined by specific criteria including weight and smoking status in line with clinical evidence on efficacy and higher risk of spontaneous abortion.[1] They carried through the presence or absence of living children in line with existing policy in some previous CCGs in mid and south Essex. In order to demonstrate unexplained infertility, a period of 2 years was agreed (or one year if between 40-42 years due to reduced window of opportunity). In same sex couples, unexplained infertility should be demonstrated via 6 self-funded cycles of IUI.

The panel wanted to ensure equal IVF access to all ages within the range recommended by NICE, and therefore recommended for 2 cycles for women and people assigned female at birth between the ages of 23-39 years, and 1 cycle for women and people assigned female at birth between the ages of 40-42 years old. The reduced number of cycles in 40-42 years old is consistent with NICE recommendations for reduced number of cycles being made available in this age group. This is based on the lower clinical effectiveness in this age group.

Reciprocal IVF for same-sex couples describes a process where one partner receives ovarian stimulation to produce eggs, and acts as a donor for the other partner, with viable embryos implanted into the other partner so that both contribute

to a pregnancy. This process is not recommended by NICE currently, and MSE ICB would review its policy should this situation change.

Given budgetary pressures, the panel recommended that available funding is focused on expanding access to IVF across mid and south Essex given its higher clinical effectiveness. It was therefore recommended not to fund IUI unless additional funding becomes available. We acknowledge guidance within the Women's Health Strategy and note the Government's intention to work with NHS England to implement these commitments. We await further detail from NHS England and will at that stage consider any changes in national approach and the implications for ICB policies. Up to one batch of donor oocytes and sperm will be funded to promote affordability overall.

Threshold criteria cost appraisal

IVF – funding 1 vs 2 cycles:

Analysis of our overall expenditure upon fertility treatment suggests that circa 67% of our annual cost will be incurred upon IVF. Thus, our annual expenditure on IVF amounts to c£787k. Making an assumption that approximately 33% of patients undergoing IVF get pregnant during their first cycle, it is therefore reasonable to assume that 33% of our annual cost incurred is on a patient's first cycle.

Our forecast annual expenditure can, therefore, be expressed in Table 6. Should the ICB, therefore, decide to fund only 1 cycle of IVF, forecast costs would reduce by c£0.5m.

IUI – funding vs not funding:

The agreed tariff rate with all providers for IUI, is £650 per cycle. Analysis of activity levels in previous years within the Thurrock Alliance (who were the only former CCG to fund IUI activity), suggests that uptake is very low, therefore the ICB's potential exposure should they offer IUI within the revised policy is not expected to be material.

IUI may be part of a pathway for two reasons (i) treatment, (ii) diagnosis of 'unexplained infertility'.

(i) As regards use of treatment, our expert panel recommended prioritising available funding on increasing access to IVF, and not funding IUI for treatment, due to is limited clinical effectiveness.

(ii) In order to access funding for IVF, patients must either have a specific diagnosed cause of infertility (see Service Restriction Policy for Tertiary Fertility Services in Appendix 1) or demonstrate 'unexplained infertility'. In male-female couples, this is demonstrated via 1-2 years of being

unable to get pregnant, depending on age (see full wording in Appendix 1). For female same-sex couples, who are unable to demonstrate infertility in the same way, inability to get pregnant despite 6 rounds of IUI is used as the alternative standard. This is also noted in the Equality and Health Inequalities assessment (see Appendix 3). Funding IUI for diagnosis of 'unexplained infertility' for female same-sex couples only would raise the query of whether this unfairly excludes all other populations who might wish to access IUI for treatment purposes. Undertaking to fund IUI for both treatment and diagnosis of 'unexplained infertility' would be a more financially costly option, and therefore has the potential to negatively impact funding, access and outcomes associated with other clinical services. Therefore the recommended option is not to fund IUI.

Summary of service policy options appraisal:

The following options were considered by CliMPC. A summary of their views after deliberation, along with relevant threshold criteria developed through expert panel input and feedback from public consultation are included below.

Option 1: No Change

Continue with current variation in existing CCG policies. This was considered to be unviable as it leads to a situation of effective post code lottery, widening inequalities, and does not align with NHS constitutional or MSE system values.

Option 2: Funded in line with NICE criteria

CliMPC reviewed this complex policy area, noting national NICE recommendations based on cost-effectiveness analysis, along with the high social value placed upon the service by those who are seeking access. They also noted limited clinical effectiveness and health benefits to the couple seeking treatment. Increasing provision of tertiary fertility services across MSE to be in line with NICE criteria would be costly. This low affordability was considered in the local context of a system under significant financial pressures, with any increase in funding for fertility services potentially affecting funding (and therefore residents' access and wider health outcomes) to other services. Providing access in line with NICE recommendations was the costliest option considered by CliMPC, and therefore had the greatest potential impact to negatively impact access to other clinical services. Due to the significant affordability issue with this option, and the implications for other clinical services and population outcomes, this is not the preferred option.

Option 3 (recommended option): Funded via individual prior approval in line with NICE criteria with additional local MSE ICS criteria

This is the preferred option, which is based upon NICE threshold criteria, but includes additional local threshold criteria, which have previously been in operation in certain CCGs within mid and south Essex and across the country, including for example the local definition of an IVF cycle, and smoking and living children threshold criteria.

The purpose of including additional threshold criteria beyond those included within NICE guidance is to reduce the likely cost to the ICS, improving affordability and reducing potentially negative population health impact through necessitating funding reduction in other services. The threshold criteria aim to maximise clinical effectiveness overall for the eligible population, whilst optimising equity. The policy should be implemented via an individual prior approval process to ensure rigorous application of threshold criteria.

Option 4: Not funded

Whilst this was the most affordable option, it was not the preferred option as it does not deliver against the potential health benefits or upon the societal value placed on this service by those seeking it. It has clear potential to increase inequalities across the population, where more deprived populations are unable to self-fund, whereas less deprived populations may be able to fund private access.

7.1.3. Breast reduction

Summary of recommendations

- Recommended funding option: Individual prior approval
- Recommended threshold criteria

Patients will be eligible if all the following are confirmed:

- The patient is suffering from neck ache or backache. Clinical evidence will need to be produced to rule out any other medical/physical problems to cause these symptoms.
- OR The patient has persistent intertrigo for at least one year and confirmed by GP OR another serious functional impairment for at least one year.
- AND Full evidence is provided of all conservative management options that have been attempted, including engaging with weight management services where appropriate, and that the wearing of a professionally fitted brassiere has not relieved the symptoms.
- AND The patient has a BMI <27 and evidence that the weight has been stable for 12 months.

- AND The patient is a non-smoker.
- AND At least 1kg is planned to be removed from each breast.

Patients who have predictable breast changes due to pregnancy are excluded.

Initial assessment should be done the by referrer prior to appointment with consultant plastic surgeon to ensure criteria are met. Assessment of the thorax should be carried out, including any indicated diagnostics. Written information on risks and benefits should be provided to enable informed decision-making. Patients should be informed that smoking increases post-op complications, and patient must be a non-smoker. Women should be informed that breast surgery for macromastia can cause permanent loss of lactation.

Threshold criteria options appraisal:

The panel discussed that previous criteria relating to physical symptoms were appropriate and should continue. The use of a fitted bra could be effective in some cases as a conservative treatment measure and so should continue to have a place within the threshold criteria.

The BMI threshold was increased from 25 to 27, to prevent discrimination in terms of proportionality i.e. where a woman or person assigned female at birth has a BMI below 27, but has disproportionately large breasts. Above 27, it was felt that there would need to be greater emphasis on reducing obesity overall before consideration of breast reduction surgery.

The requirement for stable weight has been reduced from 2 years to 1 year, keeping a stability requirement in place to prevent the risks of crash dieting to get under the weight threshold and subsequent rapid weight-gain, negating the effects of breast reduction surgery. However a 1 year period is sufficient to demonstrate stable weight under the BMI threshold.

The requirement to be a non-smoker was added due to significant impact on wound healing and surgical outcomes overall. The panel recommended to increase the threshold from 500g to 1kg for the minimum amount planned to be removed from each breast so that surgery is targeted at the most severe clinical presentations.

Summary of service policy options appraisal:

The following options were considered by CliMPC. A summary of their views after deliberation, along with relevant threshold criteria developed through expert panel input and feedback from public consultation are included below.

Option 1 – No Change: continue with current variation in existing CCG policies. This was considered to be unviable as it leads to a situation of effective post code

lottery, widening inequalities, and does not align with NHS constitutional or MSE system values.

Option 2 – Routinely Funded: health benefits at a population level associated with breast reduction are not sufficient to outweigh affordability concerns (and consequent funding impact on other services) associated with making this routinely funded.

Option 3 – Group prior approval: CliMPC agreed that breast reduction surgery is cost effective and brings significant health benefits to a specific population. However, there was a consensus that affordability concerns dictate that closer review of referrals than is applied under a policy of group prior approval would be needed, to ensure that referrals adhere to threshold criteria. This was the reason that individual prior approval was preferred over group prior approval.

Option 4 (recommended option) – Individual prior approval: This option was preferred as best balancing the delivery of health benefits for the population in whom this intervention would be most cost effective, with an Individual prior approval process ensuring use of threshold criteria to promote affordability.

Option 5 – Not Funded: Whilst this was the most affordable option, it was not the preferred option as it does not deliver against the potential health benefits and has clear potential to increase inequalities across the population, where more deprived populations are unable to self-fund, whereas less deprived populations may be able to fund private access.

7.1.4. Breast asymmetry

Summary of recommendations

- Recommended funding option: Individual prior approval
- Recommended threshold criteria:

The goal of surgery is to correct a significant deformity which is causing an impact on health. Patients will be eligible if all the following are confirmed:

- Clinical evidence rules out any other medical/physical problems to cause these symptoms.
- AND full evidence is provided of all appropriate conservative management options that have been attempted.
- AND there is a difference of at least 2 cup sizes (e.g. C and DD cup size differential) OR evidence of another serious functional impairment for at least one year.

- AND the patient is a non-smoker.
- AND patient has had no change in cup size for 1 year, and has reached end of puberty. Referral should be delayed if end of puberty has not been reached.

Only unilateral breast reduction (not unilateral breast augmentation) will be funded. This policy does not cover gynaecomastia.

Procedures for cosmetic purposes only will not be funded. Contour irregularities and moderate asymmetry (including dog-ears, nipple direction or position, breast size and shape disparity) are predictable following surgery. Any post-surgical cosmetic irregularities will not be funded by the ICB in revision surgery.

Threshold criteria options appraisal

The panel discussed that due to differences in age at completion of puberty, the requirement to be aged 18 or over was replaced with a requirement for stable cup size for 1 year.

The issue of mental health as an indication was discussed, though due the apparent difficulty of standardising assessment and attributing poor mental health directly to breast asymmetry meant that the panel agreed not to include this as a criterion at this point.

Previous CCG policies have funded breast reduction in order to improve symmetry, not augmentation. This was discussed with regards to the issue of deformity, including known syndromes such as Poland Syndrome which can result in breast asymmetry. There was discussion that whilst augmentation has some advantages as a single operation in terms of the extent of scarring, initial surgical cost and time, and post-operative morbidity, the wider implications in terms of cost of removal, replacement and any associated longer-term morbidity led to an agreement that reduction only should be funded.

Summary of service policy options appraisal:

The following options were considered by CliMPC. A summary of their views after deliberation, along with relevant threshold criteria developed through expert panel input and feedback from public consultation are included below.

Option 1 – No Change: continue with current variation in existing CCG policies. This was considered to be unviable as it leads to a situation of effective post code lottery, widening inequalities, and does not align with NHS constitutional or MSE system values.

Option 2 – Routinely Funded: health benefits at a population level associated with breast asymmetry surgery are not sufficient to outweigh affordability concerns (and consequent funding impact on other services) associated with making this routinely funded.

Option 3 – Group prior approval: CliMPC agreed that breast reduction surgery is cost effective and brings significant health benefits to a specific population. However, there was a consensus that affordability concerns dictate that closer review of referrals than is applied under a policy of group prior approval would be needed, to ensure that referrals adhere to threshold criteria. This was the reason that individual prior approval was preferred over group prior approval.

Option 4 (recommended option) – Individual prior approval: This option was preferred as best balancing the delivery of health benefits for the population in whom this intervention would be most cost effective, with an individual prior approval process ensuring use of threshold criteria to promote affordability.

Option 5 – Not funded: Whilst this was the most affordable option, it was not the preferred option as it does not deliver against the potential health benefits and has clear potential to increase inequalities across the population, where more deprived populations are unable to self-fund, whereas less deprived populations may be able to fund private access.

Threshold criteria cost appraisal

People who smoke

Non-smoking is a recommended threshold criterion within female sterilisation, breast reduction and breast asymmetry policies. The inclusion of this criterion could be related to £68k difference in annual value (see Table 7).

7.1.5. Male sterilisation

Summary of recommendations

- Recommended funding option: routinely funded (for sterilisation under local anaesthetic)
- Recommended funding option: Group prior approval (for sterilisation under general anaesthetic)

Recommended threshold criteria

Previous documented adverse reaction to local anaesthesia.

OR

Scarring or deformity distorting the anatomy of the scrotal sac or content making identification and/or control of the spermatic cord through the skin difficult to achieve.

Threshold criteria options appraisal

The expert panel reviewed the previous joint policy for Basildon and Brentwood, Castle Point and Rochford, Southend and Thurrock, and confirmed that these remained appropriate for use as threshold criteria. Skin infection in the operative sight was considered to be a contraindication to surgery (as it would be for most surgery), but would lead to delay in performing the procedure under local anaesthetic, rather than referral for general anaesthetic.

Summary of service policy options appraisal

The following options were considered by CliMPC. A summary of their views after deliberation, along with relevant threshold criteria developed through expert panel input and feedback from public consultation are included below.

Vasectomy under LA

Option 1 (preferred option) – Routinely Funded: Vasectomy under local anaesthetic is highly clinically effective and has clear health benefits which include a positive impact on gender equality. The potential to reduce requirement for women and people assigned female at birth to use Long Acting Reversible Contraceptives (LARC) or undergo female sterilisation surgery, with the attendant risks of each option was viewed as significant. Affordability was not considered to be a substantial barrier to routinely funding this treatment. Overall, there was consensus that should be vasectomy under local anaesthetic should be available with minimum administrative burden for referrers or eligible patients.

Option 2- Not funded: Whilst this was a more affordable option, it was not the preferred option as it does not deliver against the potential health benefits and has clear potential to increase inequalities across the population, where more deprived populations are unable to self-fund, whereas less deprived populations may be able to fund private access.

Vasectomy under GA

Option 1 – No change: Continue with current variation in existing CCG policies. This was considered to be unviable as it leads to a situation of effective post code lottery, widening inequalities, and does not align with NHS constitutional or MSE system values

Option 2 – Routinely Funded: vasectomy under general anaesthetic is significantly more costly than under local anaesthetic, and carries a higher clinical risk. Therefore, rather than having routinely funded access, it is more appropriate to have clear

threshold criteria in place to support standardisation of clinical decision-making on the need for vasectomy under general anaesthetic.

Option 3 (recommended option) – Group prior approval: Congress recommended this option overall, noting significant clinical and cost-effectiveness, and judging that access via a process of group prior approval may best balance the realisation of potential health benefits with affordability requirements.

Option 4 – Individual prior approval: The additional scrutiny of referrals via a process of individual prior approval, with additional investment of patient and administrative time, was not felt to add significant value in terms of affordability. Therefore this was not the preferred option.

Option 5 – Not funded: Whilst this was the most affordable option, it was not the preferred option as it does not deliver against the potential health benefits and has clear potential to increase inequalities across the population, where more deprived populations are unable to self-fund, whereas less deprived populations may be able to fund private access.

7.1.6. Female sterilisation

Summary of recommendations

- Recommended funding option: Group prior approval
- Recommended threshold criteria:

Family complete: The patient is certain that their family is complete or that they never want children in the future.

Contraception: AND there is an absolute clinical contraindication to Long Acting Reversible Contraception (LARC) or has severe side effects to the use of LARC or declines a trial of LARC after counselling from a healthcare professional experienced in fitting these devices.

Capacity: AND the patient has mental capacity OR all necessary arrangements have been completed to either support them to a position of having capacity or where appropriate advocacy arrangements are in place, in compliance with latest capacity guidance.

Counselling: AND they are aware that the procedure is permanent but has a failure rate, that reversal is not funded on the NHS (except via Individual Funding Requests), that other forms of LARC have a similar success rate, with lower risk profile. Counselling must also include consideration of vasectomy for their partner where appropriate.

Exemptions: patients who have a medical condition making pregnancy dangerous or where LARC is contra-indicated or inappropriate will be exempt from these criteria and female sterilisation will be routinely funded.

Guidance note on – BMI: there is an increased clinical risk associated with BMI of 35 and above, and patients are likely to be advised regarding weight management support services at surgical assessment.

Threshold criteria options appraisal:

The expert panel agreed with continuing with existing criteria regarding family being complete. On the use of LARC, they recommended that there would be no clinical benefit from introducing a time requirement for trial of LARC. Following a steer from Congress to review the wording around mental capacity, the panel recommend that any issues with mental capacity are addressed as part of the process of applying threshold criteria.

The panel reviewed the wording around counselling, indicating that there needed to be clear information given that reversal was not available on the NHS. Also that sterilisation, as a surgical procedure, had a higher risk than other forms of long acting contraception, including vasectomy for partners. Counselling should therefore include discussion of vasectomy where appropriate.

BMI above 35 was considered to be associated with significant clinical risk, outweighing the benefit. The main risk of performing intra-abdominal procedures on obese patients is the additional anaesthetic risk of difficulty ventilating patients, recovery from anaesthesia and the higher risk of wound, chest and more deep-seated body cavity infections. In practice, laparoscopic sterilisation is not lifesaving, and patients with a BMI >35 are currently declined at anaesthetic and surgical pre-operative assessment due to this risk vs benefit consideration. This criterion should therefore be applied uniformly as part of threshold criteria.

Summary of service policy options appraisal:

The following options were considered by CliMPC. A summary of their views after deliberation, along with relevant threshold criteria developed through expert panel input and feedback from public consultation are included below.

Option 1 – No change: continue with current variation in existing CCG policies. This was considered to be unviable as it leads to a situation of effective post code lottery, widening inequalities, and does not align with NHS constitutional or MSE system values.

Option 2 – Routinely funded: Health benefits at a population level associated with breast asymmetry surgery are not sufficient to outweigh affordability concerns (and

consequent funding impact on other services) associated with making this routinely funded. The other main reason why this was not viewed as the preferred option by CliMPC was the lack of standardisation of referrals without the guidance of threshold criteria.

Option 3 (recommended option) – Group prior approval: this was the preferred options as CliMPC considered that the use of threshold criteria under a process of Group prior approval was unlikely to act as a significant barrier to access, but would add beneficial standardisation of referrals to ensure equity of access across the system.

Option 4 – Individual prior approval: The additional scrutiny of referrals via a process of Individual prior approval, with additional investment of patient and administrative time, was not felt to add significant value in terms of affordability. Therefore this was not the preferred option.

Option 5 – Not funded: Whilst this was the most affordable option, it was not the preferred option as it does not deliver against the potential health benefits and has clear potential to increase inequalities across the population, where more deprived populations are unable to self-fund, whereas less deprived populations may be able to fund private access.

7.1.7. Transitional arrangements

Summary of recommendations

The ICB should implement transitional arrangements for those who are already on, or have been referred to, a treatment pathway.

From April 2023, the six new policies will replace the relevant legacy policies across mid and south Essex. However, where an individual is undergoing or has already been referred for NHS-funded treatment on any of the relevant pathways prior to that date, transitional arrangements will be applied.

In either of these cases, the individual should experience no disadvantage as a result of the new MSE policies. Therefore:

- Where a new policy disadvantages the patient, the legacy policy will apply (see below); and
- Where a new policy is advantageous to the patient, the new MSE policy will apply.

These transitional arrangements will apply to relevant patients until the course of treatment specified in the relevant policy is complete, or until the patient is no longer eligible for NHS funded treatment.

Policy	Populations who should be covered under transitional arrangements
Tertiary fertility services	Thurrock: female-male couples eligible for IVF, who could access 3 rounds of IUI under Thurrock CCG policy.
Breast reduction	Basildon and Brentwood, Castle Point and Rochford, Southend, Thurrock: people who would have been eligible to have between 500-999g removed per breast under CCG policies. And people who smoke.
Breast asymmetry	Castle Point and Rochford, Southend, Thurrock: people who smoke.
Female sterilisation	Castle Point and Rochford, Southend, Thurrock: access may be slightly reduced due to shift from routinely funded to Group prior approval (likely minimal impact).

Transitional arrangements cost appraisal: up to circa £150K

There are a number of specific populations for whom transitional arrangements should be funded. The significant element which could impact cost relates to those in Thurrock who are referred for or are currently receiving IUI.

Should the policies be implemented, as proposed, there will be transitional costs, as a result of patients already being on a pathway, whilst not yet receiving treatment. The assessed transitional costs in year 1 (2023/24) of policy implementation could be up to circa £150k.

Policy	Populations who should be covered under transitional arrangements
Bariatric surgery	None identified
Tertiary fertility services	Thurrock: reduction in access for female-male couples eligible for IVF who might previously have accessed IUI, from 3 funded cycles to none. Cost appraisal above.
Breast reduction	Basildon and Brentwood, Castle Point and Rochford, Southend, Thurrock: people who could have 500-999g removed per breast (proposed minimum tissue weight for removal rising from 500g to 1kg), and for people who smoke (likely minimal impact expected as smokers normally declined at surgical assessment).
Breast asymmetry	Castle Point and Rochford, Southend, Thurrock: people who smoke (minimal impact expected as smokers normally declined at surgical assessment).
Vasectomy	None identified
Female sterilisation	Castle Point and Rochford, Southend, Thurrock: access may be slightly reduced due to shift from routinely funded to Group prior approval (likely minimal impact as per guidance from CliMPC).

7.2 Benefits realisation

What are the critical success factors?

- Standardised policies that balance the needs and views of patients with resources available to the ICS.
- Effective communication of the new policies.
- Effective implementation of the new policy arrangements.

What are the intended (measurable) benefits:

1. The primary benefit of the business case is the standardisation of access to care for the six clinical areas across the ICS from five legacy positions by April 2023. This will help reduce health inequalities (particularly geographic inequalities) which is one of the core functions of the ICS.
2. A number of additional benefits can be expected. These include:
    1. Patient choice: many patients will have a wider range of options available to them.
    2. Patient experience: greater clarity and simplicity of referral pathways across MSE will support better patient experience.
    3. Patient outcomes: treatment such as bariatric surgery can provide better outcomes for certain people with obesity, for instance.
    4. Improved health and wellbeing: better or more consistent access to services will support people to feel in greater control of decisions about their health.
    5. Reduced administrative burden: one standardised policy will be simpler and easier to administrate than five which will free up ICB staff time to focus on other priority tasks.
    6. Clarity for professionals: clinicians across mid and south Essex will find policies easier to navigate across mid and south Essex due to the reduction in variation.

7.3 Timeline for review

ICB funding team to review service policy activity and referral equity every three years (April 2026). We will monitor complaints, patient experience data and Individual prior approval referrals received by the central ICB funding team to inform such policy reviews.

7.4 Engagement and communications plan

Duty to Engage – plan for public and stakeholder engagement

Project ownership: Claire Hankey – Director of Communications and Engagement

Stakeholders: Healthwatch, Essex, Thurrock and Southend, LGBT Mummies, virtual view (citizen's panel) members and other community groups that link with our health inequality groups, plus our integrated care system partners. Staff and providers of the current/new services.

Governance groups: Essex HOSC, Thurrock HOSC and Southend People Scrutiny Committee.

Engagement Requirements: Patient representatives will required to be part of the six different work streams (services) as part of the mobilisation exercise.

8 Procurement route

Existing contracts for the six services are already in place. See further information below.

8.1 Contract type, length or extension to existing contract

Bariatric, Breast reduction/ asymmetry, female sterilisation: it is accepted that NHS General & Acute Service Providers do not follow a formal competitive procurement processes on an annual basis. Contracts are awarded on an annual basis. MSE ICB are the Co-ordinating Commissioner for Mid & South Essex NHS Foundation Trust (MSEFT), and also Barking Havering & Redbridge NHS Trust (BHRT), and are Associate Commissioners to the other Trusts where there are existing patient flows for surgery.

Fertility: Following a competitive procurement process, seven providers (Bourne Biosciences, Cambridge University Hospital, Care Fertility, Create Fertility, Guys & St Thomas, Herts & Essex Fertility Centre, IVI London Wimpole) were awarded contracts from 1 April 2022 for a term of 4 years.

Male sterilisation: via Primary Care Contracts.

8.2 Contract management arrangements

NHS General & Acute Providers (providers of bariatric, breast reduction / asymmetry, female sterilisation): The revised Prior Approval Policy would need to be updated within the MSEFT and BHRT Contracts by Contract Variation. (The Co-

ordinating Commissioner may at any time during a contract year give the provider not less than one month's notice in writing of any new or replacement Prior Approval Scheme, or of any amendment to an existing Prior Approval Scheme. That new, replacement or amended Prior Approval Scheme must be implemented by the Provider on the date set out in the notice, and will only be applicable to decisions to offer treatment made after that date).

Where MSE ICB is an Associate to an NHS Provider contract, generally only the Co-ordinating Commissioner policy would be included within the contract, in a bid to reduce the administrative burden on providers of managing separate Commissioner-specific Prior Approval schemes. For NHS providers there will be a move away from fixed block contracts to variable cost and volume baselines at National Unit Prices for elective services from April 2023.

Fertility – As part of the procurement all bidders were advised that there would likely be some form of harmonisation of policy during the contract term and this was accepted as part of the bidding process. Consideration will need to be given however as to whether the revised / harmonised policy is so different from those that went out under the procurement that it is deemed "unrecognisable" and would likely constitute a material change to the contract, this would need to be discussed accordingly with the providers. The revised Prior Approval Policy would then need to be reflected within the contracts by Contract Variation, as described above. Contracts were secured on a cost and volume basis at local prices.

9 Project timetable

	SERVICE HARMONISATION - Project Work Plan					
Last refreshed 09/01/23	**Task**	**Lead(s)**	**Start Date**	**Finish Date**	**RAG**	**Comment/Update and mitigation if off track**
1. Infrastructure						
1.1	**System Structure and Leadership**					
	Business Case Signed off	RF/JC	05.09.22	01-Feb-23		
	SH Governance and leadership agreed	MT	05.09.22	27.09.22		Completed via Program Board
	Communication and engagement agreed across ICB	CH	01.09.22	30.09.22		Awaiting draft consultation plan
	Agreement on Communications & Engagement support provision for SH	CH	01.09.22	30.09.22		Awaiting draft consultation plan
	Stakeholder Mgt Plan in place	CH	01.09.22	30.09.22		Awaiting draft consultation plan
	SH Strategy refreshed and aligned with revised ICS Strategy	JC/PR	01.09.22	December		Awaiting final ICS Strategy
2. Quality Assurance						
2.1	**SRP Quality Assurance**					
	Completion and sign off of impact assessments (EQIA/PIA etc.)	RF/PS	01.09.22	30.09.22		NA to follow up with Information Governance to determine need for PIA
	Present outcomes of impact assessments to Quality Committee to ensure they are completed, appropriate and have followed due process - completed	PS	30.09.23	November		NA to double check need to publish EHIA's and draft initial PIA for assessment by Information Governance
3. Communications & Engagement						
3.1	**Phase 1 - Consultation Preparation**	CH/TS	27.09.22	Sept/Oct		
	pre-consultation engagement			20.10.22		
	independent analysis report			20.10.22		
	Draft consultation plan			20.10.22		
	Draft consultation document			20.10.22		
	Draft main survey questions			20.10.22		
3.2	**Phase 2**	CH/TS	27.09.22	13.10.22		
	Board approval for consultation launch - 20th October	RF		13.10.22		
	Liason with MSEFT Governors			07.12.22		
	Liason with x3 HOSC's - **additional representation required**			November		03/11 - Thurrock & Essex HOSC 29/11 - Southend HOSC
	Draft Stakeholder briefing			31.10.22		
	Prepare for discussions sessions			31.10.22		
	Prepare press and media updates			31.10.22		
	Briefing and prepartion with key spokespeople			31.10.22		
3.3	**Phase 3 - Consultation**	CH/TS	20.10.22	15.12.22		
	Publish consultation materials via website and distribution			31.10.22		
	Formal launch and media programme			31.10.22		
	Ongoing stakeholder briefings and updates			Ongoing		
	Programme of workshops - Alliance & Clinical Directors required plus Public Health and Quality Team member representatives to attend.			November		09/11 - The Beehive, Grays 10/11 - Witham Public Hall 22/11 - Pitsea Leisure Centre 24/11 - The Forum, Southend 29/11 - Online Forum
	Sessions with targeted groups			15.12.22		Mens Group (10 attendees) IVF (1 female) Bariatric booked for 15/12 LGBT Mummies (15/12) No requirement from LD community at this point
	Feedback via survey, letters, notes from meetings and workshops		31.10.22	19.12.22		Post 19/12 consultation end
3.4	**Phase 4 - Consultation outcome and decisions**	CH/TS	Jan-23	Feb-23		
	Feedback collated and prepared for analysis	External Co.		13.01.23		
	Independent analysis and outcome report	External Co.		13.01.23		
	Outcome report for consideration	CH		19.01.23		SH Programme Board Agenda item Return agenda item for HOSC (TS to advise dates)

4. Business Case (Phase 3)						
4.1	**Preparation & Submission**					
	Preparation of full Business Case	EC/PS	03.01.23	30.01.23		To be taken forward through SH Working Group
	Identify SRO lead for business case (phase 3)	EC/PS	15.09.22	30.09.22		Confirmed as RF/PS
	Development of Working Group to take forward Phase 3 & Phase 4	EC/PS	12.10.22	17.10.22		SB to circulate recurring invite w/c 17/10
	Develop centralised Complaints procedure and process	WG/PS	12.10.22	09.02.23		
	ICB Board decision making business case submitted	JC/RF	09.02.23	09.02.23		Papers Due 30.01.23
5. Primary Care Engagement						
	Initial meeting to discuss Primary Care deliverables (i.e. Consultation with PCN's)	WG/AB	15.09.22	29.09.22		Included within Comms section
	Commission Vasectomy service for Mid-Essex	WG/AB	12.10.22	01-May-23		Engage with incumbent providers to agree a contract variation dependant on Board Decision
6. Service Implementation (Phase 4)						
6.1	**Provider Mobilisation/Contracting**					PR email to Janette Joshi
	Prepare mobilisation and implementation of new service offer	RF/PS? EH/LO	Jan-23	01-Apr-23		Via Working Group
	Identify lead for service delivery/mobilisation	JC/RF/PS	15.09.23	28.10.22		Via Working Group
	Engage with existing Providers re: possible changes in service provision	PS/EC/EH/LO	Jan-23	01.04.23		
	Engage with Procurement/Contract Management team to prepare for contract variation etc.	PS/KW/EH/LO	12.10.22	19.01.23		Janette Joshi to complete narrative for procurement route slide within Business Case
6.2	**Go Live'**					
	New ICB Policy invoked	PS/EH/LO	01.04.23	01.04.23		
7. ICB Governance						
7.1	**System Awareness**					
	PCCC - advise on potential impact on Primary Care & outline recommendations from Congress	WG/PS	Nov-22	16.11.22		
	F&IC - explain financial impact of proposed SRP's (feedback recommendations to Board on financial affordability & associated risks)	JK/AK/LB	11.01.23	11.01.23		Papers Due 02.01.23
	Congress - Re-assessment and further advice to the Board if result of consultation requires changes to the original proposals from congress	RF/PS	26.01.23	26.01.23		Papers Due 17.01.23
	F&IC - Feedback on consultation results and possible changes to proposal (recommendation to Board on final outcome)	JK/AK/LB	01.02.23	01.02.23		Papers Due 23.01.23
	Quality - (virtual) - mobilisation planning and associated quality risks	MG/JB	Feb-23	24.02.23		
	Alliances - advise on outcomes of consultation process and potential differences at 'place'		Feb-23	Feb-23		Dates TBC
	SLEG/SFLG - mobilisation	RF/JC	Feb-23	Mar-23		Dates TBC
	SLEG - capacity to deliver	RF/JC	Feb-23	Mar-23		Dates TBC
	SFLG - budget pressures on system	RF/JC	Feb-23	Mar-23		Dates TBC
8. Ongoing Reporting						
8.1	**Review Process for Service Restriction Policies**					
	Develop process to clinically review SRP's in line with National Policy and align/communicate where necessary	EC/PS	27.09.22	30.01.23		Narrative for ongoing process to be embedded within Full Business Case (draft to Board on 19.01.23)

10 Checklist and sign-off

Check	Sign off
SLT Support?	Via participation through programme board
Engagement complete?	Yes
Co-produced?	Public consultation
Meets strategic objectives?	Yes (e.g. tackle inequalities)
Equality Impact Assessment complete?	Yes
Budget available / approved?	Yes – via Finance and Investment Committee - 1 Feb (funding through growth funding)
Committee Support?	FIC 1 Feb, ICB 9 Feb
Contributes to Social Value?	Yes
Advice obtained from Estates?	NA
Advice obtained from Digital/IT/IG?	NA
MSE Partners / Stewardship consulted?	NA
Service specification included as appendix?	Full policies included – Appendix 1
Procurement Route approved?	NA
Compliant with procurement policy?	NA
Entered on procurement register?	NA
Meets duty to reduce inequalities?	Yes
Privacy Impact Assessment Complete?	NA
Meets Regulator requirements?	Yes
Contributes to Net Zero sustainability requirements?	NA
Benefits clearly set out (SMART)?	Yes
Advice obtained from Finance?	Yes
Advice obtained from HR?	NA
Exec/SFLG Endorse?	Input via Execs on programme board

11 Declaration and approval

I confirm that all elements (as necessary) of the business case have been completed and all items have been completed on the checklist.	Yes
I confirm users have been fully involved in co-production and the sponsoring workstream support the proposal.	Yes
I confirm that arrangements are in place to manage uncertainties and risks associated with the proposal and ensure that the proposal/project to supported to ensure delivery.	Yes

SRO Signature:	Ronan Fenton
Date:	02/02/23
Implementation Start Date:	01/04/23

DOR / Finance Signature:	Jen Kearton
Date:	02/02/23
Committee / Date of Approval:	Finance and Investment Committee – 01/02/23
Comments/Notes:	

12 Appendices

12.1 Appendix 1 Service Restriction Policies (SRP)

12.2 Appendix 2 Glossary

12.3 Appendix 3 Equalities and Health Inequalities Impact Assessments (EHIIA)

12.4 Appendix 4 Consultation engagement analysis report

Appendix 1

Service Restriction Policy

Contents

SERVICE RESTRICTION POLICY: BARIATRIC SURGERY

Policy statement: Bariatric Surgery

Status: Group Prior Approval

Mid and South Essex ICB commissions specialist obesity services on a restricted basis, including Bariatric Surgery.

Patients may be referred for assessment and subsequent treatment by Specialist Obesity Services in line with service specification, which include assessment for bariatric surgery, if they meet **ALL** the following criteria

- Patient is 18 year or older.

- The person has a body mass index (BMI) of 40 kg/m^2 or more without co-morbidities, OR between 35 kg/m^2 and 40 kg/m^2 and other significant diseases (for example type 2 diabetes, hypertension, cardiovascular disease, osteoarthritis, dyslipidaemia, and sleep apnoea) that could be improved if they lost weight.

- The person has completed Tier Three weight management service including the maintenance period, and the person has not achieved or maintained adequate, clinically beneficial weight loss. (A tier three service is a weight management programme that supports adults with severe and complex obesity to lose weight through a range of interventions including psychological approaches and dietary changes).
- GP has addressed and optimised management of any underlying social circumstances or clinical conditions which may be affecting weight management in the patient

  - hormone problems such as underactive thyroid, Cushing's syndrome, polycystic ovarian syndrome (PCOS):
  - substance misuse
  - lack of sleep- excluding obstructive sleep apnoea - Epworth score of 10 or less
  - depression- patients with a score of more than 17 on PHQ9 screening tool must be referred to IAPT and condition managed before referral
  - alcohol consumption-refer to Openroad or other appropriate service and condition managed before referral
  - social circumstances- refer to appropriate service through Essex Connects (social prescribing project) or other appropriate service **Nice Guidance PH53**

Obesity surgery for children and adolescents is commissioned by NHSE.

Patients not meeting the above criteria will not be funded unless there are **clinically exceptional circumstances.**

Individual funding requests should only be made where the patient demonstrates clinical exceptionality.

Further information on applying for funding in exceptional clinical circumstances can be found on the ICS' website.

SERVICE RESTRICTION POLICY: Tertiary Fertility Services

Policy statement: Tertiary Fertility Services

Status: Individual Prior Approval

Mid and south Essex ICB commission Assisted Conception Using IVF/ICSI/IUI for Infertility in accordance with the criteria defined in this policy.

In creating this policy, the ICB has reviewed this clinical condition and the options for its treatment. It has considered the place of this treatment in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources.

Assisted conception is the name given to treatments that can help a woman or person assigned female at birth get pregnant without the need for sexual intercourse. There are a variety of treatments, and what is suitable for each individual will depend on their particular circumstances.

The options included in this policy are:

- intrauterine insemination (IUI)
- in vitro fertilisation (IVF)
- IVF with intracytoplasmic sperm injection (ICSI)
- the use of donor sperm (donor insemination) or eggs (egg donation).

Certain forms of assisted reproduction (IUI, IVF, ICSI, donor insemination and egg donation) are regulated by law and their use is controlled by the Human Fertilisation and Embryology Authority (HFEA).

This policy document defines the arrangements for funding of this treatment for the people ordinarily resident in the UK and registered with a GP with Mid and south Essex ICB.

Treatments excluded from this policy:

- Pre-implantation Genetic Diagnosis and associated IVF/ICSI. This service is commissioned by NHS England
- Specialist Fertility Services for members of the Armed Forces are commissioned separately by NHS England

For Egg and Sperm storage associated with fertility preservation- see Sperm, Embryo or Oocyte Cryopreservation policy

Referrals

- Referrals to fertility specialist services must be made by the secondary care provider following prerequisite investigations or treatments required, which may be undertaken at either the primary level or secondary level as appropriate.
- The agreed referral forms will need to be completed and include information such as any investigations, information on patients and clearly state whether the patient is eligible for specialist treatment.

All referrals must be individually approved for funding prior to referral.

SERVICE RESTRICTION POLICY: Tertiary Fertility Services 2

Policy statement: Tertiary Fertility Services

Status: Individual Prior Approval

Eligibility for Fertility Treatment

Couples must have experienced unexplained infertility for two (2) or more years (if between ages of 23-39 years old) or one or more (1) year (if between ages of 40-42 years old) of regular unprotected sexual intercourse or they are using artificial insemination to conceive and have not become pregnant after 6 cycles.
For couples with a diagnosed cause of infertility as listed below there is no time criterion and should be referred for assessment for assisted conception.

1. Tubal damage, which includes:
    a. Bilateral salpingectomy
    b. Moderate or severe distortion not amenable to tubal surgery

2. Premature Menopause (defined as amenorrhoea for a period more than 6 months together with a raised FSH (follicle stimulating hormones) >25 and occurring before age 40 years)

3. Male factor infertility. Results of semen analysis conducted as part of an initial assessment should be compared with the following World Health Organization reference values*:
    a. semen volume: 1.5 ml or more
    b. pH: 7.2 or more
    c. sperm concentration: 15 million spermatozoa per ml or more
    d. total sperm number: 39 million spermatozoa per ejaculate or more
    e. total motility (percentage of progressive motility and non-progressive motility): 40% or more motile or 32% or more with progressive motility
    f. vitality: 58% or more live spermatozoa
    g. sperm morphology (percentage of normal forms): 4% or more.

4. Ovulation problems adequately treated but not successfully treated i.e. no successful pregnancy achieved

5. Endometriosis where Specialist opinion is that IVF is the correct treatment

6. Patients meeting the criteria defined in the Sperm, Embryo or Oocyte Cryopreservation Policy.

Additional Criteria

In addition to the above eligibility criteria, ALL the following criteria must also be met:

- Both individuals in the couple must be ordinarily resident in the UK and have been registered with a GP within Mid and south Essex ICB for a minimum of 12 months
- The woman or person assigned female at birth must be between their 23rd and 42nd birthday, with a BMI of more than 19kg/m2 and less than 30kg/m2
- The man or person assigned male at birth must have a BMI of less than 35kg/m2.
- There should be no surviving children from this relationship including adopted children but excluding fostered children. There should be no children from previous relationships. There is an explicit and recorded assessment that the social circumstances of the family unit have been considered within the context of the assessment of the welfare of the child.
- The welfare of any resulting children is paramount. In order to take into account, the welfare of the child, the clinician should consider factors which are likely to cause serious physical, psychological or medical harm, either to the child to be born or to any existing children of the family. This is a requirement of the licencing body, Human Fertilisation and Embryology Authority (HFEA).

SERVICE RESTRICTION POLICY: Tertiary Fertility Services 3

Policy statement: Tertiary Fertility Services

Status: Individual Prior Approval

Additional Criteria continued

- If any fertility treatment results in a surviving child, then the couple will no longer be considered childless and will not be eligible for further NHS funded fertility treatments, including the implantation of any stored embryos. Any costs relating to the continued storage of the embryos beyond the first calendar year of the retrieval date is the responsibility of the couple.
- Both partners must be confirmed non-smokers
- Written consent to treatment is required from both partners
- Neither partner has been sterilised.

Intrauterine Insemination (IUI) and Donor Insemination (DI)

IUI and DI are separate from IVF treatment; however, the couple may then access IVF treatment if appropriate. For the purposes of this policy:

Donor insemination is defined as the placement of donor sperm into the vagina or cervix and is not funded.

Intrauterine insemination is defined as the clinical delivery of sperm into the uterine cavity.

IUI in same-sex relationships: Up to 6 cycles of IUI must be self- funded for people in same-sex relationships, prior to seeking access to other forms of assisted conception if required.

People with unexplained infertility, mild endometriosis or mild male factor infertility, who are having regular unprotected vaginal sexual intercourse: IUI either with or without ovarian stimulation will not be funded routinely; instead, couples should try to conceive for a total of 2 years (this can include up to 1 year before their fertility investigations) before IVF will be considered (or a total of 1 year between the ages of 40-42 years old). Couples must meet all criteria as defined in this policy.

Donor Sperm

The availability of donor sperm is currently limited in the UK. The patient may be able to provide a sperm donor, alternatively patients who require donor sperm will be placed on the waiting list for an initial period of 3 years, after which they will be

reviewed to assess whether the fertility policy eligibility criteria are still met. The ICB will fund the use of up to a maximum of one batch of donor sperm.

If either of the couple exceeds the age criteria prior to donor sperm becoming available, they will no longer be eligible for treatment.

SERVICE RESTRICTION POLICY: Tertiary Fertility Services 4

Policy statement: Tertiary Fertility Services

Status: Individual Prior Approval

Intrauterine Insemination (IUI) and Donor Insemination (DI) continued

Donor Eggs

Patients are eligible for donor eggs if they have undergone premature ovarian failure (amenorrhoea >6 months and a raised FSH >25) due to an identifiable pathological or iatrogenic cause before the age of 40 years.

Donor eggs are also used to avoid transmission of inherited disorders to a child where the couple meet the other eligibility criteria. This service is commissioned by NHS England- Pre-implantation Genetic Diagnosis and associated IVF/ICSI.

Unfortunately, the availability of donor eggs remains severely limited in the UK. The patient may be able to provide an egg donor; alternatively, the patient will be placed on the waiting list for an initial period of 3 years, after which they will be reviewed to assess whether the fertility policy eligibility criteria are still met. The ICB will fund the use of up to a maximum of six donor eggs. If either of the couple exceeds the age criteria prior to a donor egg becoming available, they will no longer be eligible for treatment.

Intracytoplasmic sperm injection (ICSI)

For some patients, their sperm are not capable of fertilising eggs in the usual way. If this is the case, they and their partner may be offered a procedure called intracytoplasmic sperm injection (ICSI), in which a single sperm is injected directly into an egg. Patients should only be offered ICSI if:

- there are few sperm in their semen, or they are of poor quality, or;
- there are no sperm in their semen (either because of a blockage or another cause) but there are sperm in their testes which can be recovered surgically, or;
- they have already tried IVF but there was poor or no fertilisation of the eggs.

In these situations, ICSI increases the chance of fertilising eggs compared with IVF used on its own. However, it does not make any difference as to whether this will lead to a successful pregnancy. If a man/ person assigned male at birth is unable to ejaculate, it is possible to obtain their sperm using surgical sperm recovery (this procedure is not covered by this policy). They should be offered the chance to freeze some of their sperm for possible use at a later date.

Gametes and Embryo Storage

The cost of egg and sperm storage will be included in the funding of treatment for which it is required, to be commissioned in accordance with this policy and the funding policy of the ICB Storage will be funded by the ICB for a maximum of 3 years or until four embryo transfers have been undertaken or until 6 months post successful live birth, whichever is the shorter. Following this period continued storage may be self-funded.

Patients should be advised at the start of treatment that this is the level of service available on the NHS and following this period continued storage will need to be funded by themselves or allowed to perish. Any embryo storage funded privately prior to the implementation of this policy will remain privately funded.

SERVICE RESTRICTION POLICY: Tertiary Fertility Services 5

Policy statement: Tertiary Fertility Services

Status: Individual Prior Approval

In-Vitro Fertilisation (IVF)

Women and people assigned female at birth before their 40th birthday

A woman or person assigned female at birth from their 23rd birthday but before their 40th birthday will be funded for a maximum of 4 embryo transfers (fresh and frozen) obtained from a maximum of 2 cycles of IVF, with or without ICSI, which includes any abandoned/cancelled cycles (as defined) if:

- they have a diagnosed cause of infertility

OR

- they have been trying to get pregnant through regular unprotected sexual intercourse for a total of two (2) years

OR

- they are using artificial insemination to conceive and have not become pregnant after six (6) cycles of intrauterine insemination

AND

- there is no evidence of low ovarian reserve (defined as FSH 9 IU/l or more (using Leeds assay); OR antral follicle count of 4 or less; OR AMH of 5 pmol/l or less

Women and people assigned female at birth before their 43rd birthday.

A woman or person assigned female at birth from their 40th birthday but before their 42nd birthday will be funded a maximum of two (2) embryo transfers (fresh and frozen) obtained from a maximum of one (1) cycle of IVF, with or without ICSI, which includes any abandoned/cancelled cycles (as defined) if all of the following apply:

- they have a diagnosed cause of infertility

OR

- they have been trying to get pregnant through regular unprotected sexual intercourse for a total of one (1) years

OR

- for same sex couples they have not become pregnant after six (6) cycles of intrauterine insemination;

AND

- there is no evidence of low ovarian reserve (defined as FSH 9 IU/l or more (using Leeds assay); OR antral follicle count of 4 or less; OR AMH of 5 pmol/l or less
- there has been a discussion of the additional implications of IVF and pregnancy at this age

SERVICE RESTRICTION POLICY: Tertiary Fertility Services 6

Policy statement: Tertiary Fertility Services

Status: Individual Prior Approval

Outline of IVF cycle

IVF involves four basic steps: ovarian stimulation, egg collection, insemination and finally embryo transfer.

Under this policy, all stored and viable embryos from an IVF treatment cycle up to the maximum number of embryos according to age as defined must be used before a new IVF treatment cycle (stimulation/egg collection/insemination) will be funded. This includes embryos resulting from previously self-funded cycles. Where maximum number of embryos according to age have been transferred, no further IVF treatment cycles will be funded.

Frozen Embryo

Embryos that are not used during the fresh transfer should be quality graded using the UK NEQAS embryo morphology scheme and may be frozen for subsequent use.

Abandoned/Cancelled Cycles

An abandoned/cancelled IVF/ICSI cycle is defined as the failure of egg retrieval, usually due to lack of response (where less than three mature follicles are present) or excessive response to gonadotrophins; failure of fertilisation and failure of cleavage of embryos. Beyond this stage, a cycle will be counted as complete whether or not a transfer is attempted.

If a cycle is commenced and ovarian response is poor, a clinical decision would need to be taken as to whether a further cycle should be attempted, or if the use of a donor egg may be considered for further IVF cycles

Age of person intending to become pregnant

Age as a criterion for access to fertility treatments is applied in line with the NICE Clinical Guideline on Fertility which is based on a comprehensive review of the relationship between age and the clinical effectiveness of fertility treatment. The patient intending to become pregnant must be between the ages of 23 – 42 years (as defined in this policy) to be eligible for NHS funding. No embryo transfers (fresh or frozen) will be funded on or after the patient's 43rd birthday. Referrers should be mindful of the patient's age at the point of referral and the age limit for new cycle.

Number of cycles and embryo transfers funded

Women and people assigned female at birth from their 23rd birthday and before their 40th birthday will be funded for a maximum of 4 embryo transfers (fresh and frozen) obtained from a maximum of 2 cycles of IVF, with or without ICSI, which includes any abandoned/cancelled cycles. All viable embryos from each cycle must be used before a further cycle will be funded, and then only if the maximum of 4 embryo (fresh and frozen) transfers has not been exceeded.

Women and people assigned female at birth aged from their 40th birthday and before their 43rd birthday will be funded a maximum of two (2) embryo transfers (fresh and frozen) obtained from a maximum of one (1) cycle of IVF, with or without ICSI, which includes any abandoned/cancelled cycles.

Where couples have previously self-funded a cycle then the couples must utilise any previously frozen embryos as part of the NHS funded embryo transfers, rather than undergo ovarian stimulation, egg retrieval and fertilisation again. Previous IVF cycles, whether self- or NHS-funded, will count towards the total cycles of IVF. No new cycle or embryo transfers will be funded after the patient's 43rd birthday.

SERVICE RESTRICTION POLICY: Tertiary Fertility Services 7

Policy statement: Tertiary Fertility Services

Status: Individual Prior Approval

Single Embryo Transfer

Fresh embryo(s) transfer to the uterus constitutes one transfer and each subsequent transfer to the uterus of frozen embryos would constitute another transfer.

Multiple births are associated with greater risk to mothers/ birthing partners and children and the HFEA therefore recommends that steps are taken by providers to minimize them. This is currently achieved by only transferring a single embryo for couples who are at high risk.

We support the HFEA guidance on single embryo transfer. All providers are required to have a multiple births minimisation strategy.

We commission ultrasound guided embryo transfer in line with NICE Fertility Guideline.

Embryo transfer strategies:

- For women and people assigned female at birth before their 37th birthday only one embryo or blastocyst to be transferred in the first cycle of IVF and for subsequent cycles only one embryo/blastocyst to be transferred unless no top-quality embryo/blastocyst available then no more than 2 embryos to be transferred
- For women and people assigned female at birth from their 37th birthday and up to but not including their 39th birthday only one embryo/blastocyst to be transferred unless no top-quality embryo/blastocyst available then no more than 2 embryos to be transferred.
- For women and people assigned female at birth from their 40th birthday and up to but not including their 43rd birthday consider double embryo transfer.
- No embryo transfers will be funded from their 43rd birthday.

SERVICE RESTRICTION POLICY: Breast Reduction Surgery

Policy statement: Breast Reduction

Status: Individual Prior Approval

Mid and South Essex ICB commissions surgery for breast reduction on a restricted basis.

Procedures for cosmetic purposes only will not be funded.

Women and people capable of pregnancy should be informed that breast surgery for hypermastia can cause permanent loss of lactation. They must be provided with written information to allow them to balance the risks and benefits of breast surgery.

Breast reduction will be funded if **ALL** the following criteria are met

a) Woman/ person assigned female at birth are aged at least 18 years.

b) The patient has received a full package of supportive care from their GP such as advice on weight loss and managing pain

c) In cases of thoracic/ shoulder girdle discomfort, a physiotherapy assessment has been provided

d) Breast size results in functional symptoms over at least 12 months that require other treatments/interventions (e.g. intractable candidal intertrigo; thoracic backache/kyphosis where a professionally fitted bra has not helped with backache, soft tissue indentations at site of bra straps). Clinical evidence will need to be produced to rule out any other medical/physical problems to cause these symptoms.

e) Body mass index (BMI) is <27kg/m^2 and stable for at least twelve months

f) Breast reduction planned to be 1kg or more per breast

g) The patient is a non-smoker at the time of referral (confirmed by CO reading).

Initial assessment must be done by the GP prior to referral to ensure criteria a) to g) are met.

Contour irregularities and moderate asymmetry (including dog-ears, nipple direction or position, breast size and shape disparity) are predictable following surgery. Any post-surgical cosmetic irregularities will not be funded by the ICB in revision surgery.

Patients not meeting the above criteria will not be funded unless there are **clinically exceptional circumstances.**

Individual funding requests should only be made where the patient demonstrates clinical exceptionality.

Further information on applying for funding in exceptional clinical circumstances can be found on the ICS' website.

Add in review date as all policies will have individual dates

SERVICE RESTRICTION POLICY: Breast Asymmetry Surgery

Policy statement: Breast Asymmetry

Status: Individual Prior Approval

Mid and south Essex ICB commissions unilateral breast reduction surgery for breast asymmetry on a restricted basis.

Procedures for cosmetic purposes only will not be funded. Funding will only be considered if there is gross disparity of breast cup sizes i.e. asymmetry where there is at least 2 cup size difference in breast size on initial consultation with the patient's GP.

Patients are eligible for surgery to correct breast asymmetry if **ALL** the following criteria are met and confirmed by a consultant plastic or breast surgeon:

- Clinical evidence rules out any other medical problems to cause this presentation;
- There is no ability to maintain a normal breast shape using non-surgical methods (e.g. padded bra), **and**
- There is a difference of at least 2 cup sizes (e.g. C and DD cup size differential), **and**
- The patient has had no change in cup size for 1 year as documented in patient's clinical record, **and**
- Where relevant, treatment of the underlying cause of the problem has been undertaken, **and**
- The patient is a non-smoker at the time of referral (confirmed by CO reading).

Only unilateral breast **reduction** (not unilateral breast augmentation) will be funded.

Contour irregularities and moderate asymmetry (including dog-ears, nipple direction or position, breast size and shape disparity) are predictable following surgery. Any post-surgical cosmetic irregularities will not be funded by the ICB in revision surgery.

Patients not meeting the above criteria will not be funded unless there are **clinically exceptional circumstances.**

Individual funding requests should only be made where the patient demonstrates clinical exceptionality.

Further information on applying for funding in exceptional clinical circumstances can be found on the ICS' website.

Add in review date as all policies will have individual dates

SERVICE RESTRICTION POLICY: Male Sterilisation

Policy statement: Male sterilisation (Vasectomy) under Local Anaesthetic

Status: Routinely funded

Policy statement: Male sterilisation (Vasectomy) under General Anaesthetic

Status: Individual Prior Approval

Mid and south Essex ICB commissions male sterilisation (Vasectomy) under General Anaesthetic on a restricted basis.

Sterilisation is an irreversible method of contraception. The surgery involves cutting the tubes that carry sperm from a patient's testicles so that when they ejaculate, the semen has no sperm in it and cannot fertilise another person's egg. As this procedure is invasive and requires anaesthetic it comes with associated health risks.

Counselling: the patient is aware that the procedure is permanent but has a failure rate, and that reversal is not funded on the NHS (except via Exceptional Clinical Circumstances).

Vasectomy, tubal occlusion, and other methods of contraception should be discussed with all patients requesting sterilisation irrespective of their gender. They should be advised that vasectomy is safer, quicker to perform and is associated with less morbidity than laparoscopic sterilisation for women/ people assigned female at birth.

Vasectomy under general anaesthetic will only be funded in the following circumstances:

1. Previous documented adverse reaction to local anaesthesia **OR**
2. Scarring or deformity distorting the anatomy of the scrotal sac or content making identification and/or control of the spermatic cord through the skin difficult to achieve.

Unless the criteria above are met, the referral should be made to a Primary Care Provider.

Patients not meeting the above criteria will not be funded unless there are **clinically exceptional circumstances.**

Individual funding requests should only be made where the patient demonstrates clinical exceptionality.

Further information on applying for funding in exceptional clinical circumstances can be found on the ICS' website.

SERVICE RESTRICTION POLICY: Female Sterilisation

Policy statement: Female Sterilisation

Status: Group Prior Approval

Mid and South Essex ICB commission Female Sterilisation on a restricted basis.

Sterilisation is an irreversible method of contraception. The surgery involves blocking or sealing the fallopian tubes, which link the ovaries to the uterus, thus preventing the eggs from reaching the sperm and becoming fertilised. As this procedure is invasive and usually requires general anaesthetic it comes with associated health risks. There are many methods of contraception accessible in the ICB, some of which may be as or more clinically effective, and that are associated with lower acute health risks.

Counselling: patient is aware that the procedure is permanent but has a failure rate, that reversal is not funded on the NHS (unless Exceptional Clinical Circumstances), that other forms of LARC have a similar success rate, with lower risk profile.

Vasectomy, tubal occlusion and other methods of contraception should be discussed with all patients requesting sterilisation irrespective of their gender. Individuals should be made aware that some LARC methods are as effective as sterilisation and may confer non-contraceptive benefits. They should be advised that vasectomy is safer, quicker to perform and is associated with less morbidity than laparoscopic sterilisation.

Where an individual patient's BMI is above 35, this will be reviewed carefully at surgical assessment, and options for appropriate weight management may be considered prior to a decision on surgery.

Patients will be eligible if **ALL** the following are confirmed:

1. The patient is certain that their family is complete, or they have a medical condition making pregnancy dangerous, and that they never want children in the future, **AND**
2. Contraception: there is an absolute clinical contraindication to Long-Acting Reversible Contraception (LARC) or has severe side effects to the use of LARC or declines a trial of LARC after counselling from a healthcare professional experienced in fitting these devices.

Patients not meeting the above criteria will not be funded unless there are **clinically exceptional circumstances.**

Individual funding requests should only be made where the patient demonstrates clinical exceptionality.

Further information on applying for funding in exceptional clinical circumstances can be found on the ICS' website

12.2 Appendix 2 Glossary

- **Group Prior Approvals** (previously known as threshold approval) – these procedures are commissioned by the ICB for a specific population cohort only, defined through a set of threshold criteria within the commissioning policy, which can be applied at the point of referral, without a process of individual prior approval (for example, cataract surgery).
- **Individual Prior Approvals** - procedures are commissioned by the ICB for a specific population cohort only defined through a set of threshold criteria within the commissioning policy and which require individual funding approval on a patient-by-patient and, in some circumstances, on a treatment-by-treatment basis, before the treatment can be provided.
- **Not Funded** – these procedures have been assessed as Procedures of Limited Clinical Value in line with national guidance and will not be funded unless there are **exceptional clinical circumstances.** This requires an application to be made using the Individual Funding Request process, but funding will only be considered where the patient demonstrates clinical exceptionality. Individual Funding Requests are considered by a panel.
- **Individual Funding Requests (IFR)** – the ICB will enable clinicians, on behalf of their patient, the opportunity to make specific funding requests via the IFR process. Requests may include patients with conditions for which there is no commissioning policy, including patients with rare conditions, and patients whose proposed treatment is outside agreed commissioning policies (exceptional clinical circumstances) or service agreements.

Acronym	Full title
CCG	Clinical Commissioning Group
CliMPC	Clinical and Multi-professional Congress
ECHR	European Convention of Human Rights
EHIIA	Equality and Health Inequality Impact Assessment
FSRH	Faculty of Sexual and Reproductive Healthcare
GA	general anaesthesia
HOSC	Health Overview and Scrutiny Committee
HRA	Human Rights Act 1998
ICB	Integrated Care Board
ICS	Integrated Care System
ICSI	Intra-cytoplasmic sperm injection
IUI	Intra-uterine insemination
IVF	In vitro fertilisation
LA	Local anaesthetic
LARC	Long Acting Reversible Contraception

Acronym	Full title
MSEFT	Mid and South Essex NHS Foundation Trust
NHSE	NHS England
NICE	The National Institute for Health and Care Excellence
PCN	Primary Care Network

Equalities and Health Inequalities Impact Assessment (EHIIA): Bariatric surgery

Appendix 3

A	**DETAILS OF WORK BEING UNDERTAKEN**					
A1	**Title of Project/Activity/Programme/Policy being assessed?**	**Bariatric Surgery**				
A2	**Policy Ref (if applicable):**					
A3	**Please indicate the commissioning status:**	**Re-commissioning existing service**				
A4	**What are the intended outcomes of this work? (why the work is being undertaken and objectives)**	**Harmonisation of former MSE CCG policies to develop system-wide policy for MSE ICB.**				
A5	**Project/Policy Lead Officer:**	**Peter Scolding**				
A6	**Head of Service responsible for this work:**	**Ronan Fenton**				
A7	**Committee responsible for this work:**			**Service Harmonisation Programme Board**		
A8	**Who will primarily be affected by this work?**	**Patients/Service Users**	**Other Outside Organisation**	**Please state name of 'other organisation'**	**Homerton Hospital and other centres where bariatric surgery is carried out for MSE population**	
B	**EQUALITY ACT 2010 - PUBLIC SECTOR EQUALITY DUTY**					
	Public Sector Equality Duties	**Response**	**Please give succinct / brief reason(s) for your response and which protected characteristics are affected, either positively or negatively (i.e. Age, Disability, Gender Reassignment, Marriage/Civil Partnership, Pregnancy/Maternity, Race/Ethnicity, Religion or Belief, Sex/Gender, Sexual Orientation) .**				
B1	**Could the work help to eliminate unlawful discrimination, harassment, victimisation or prevent any other conduct prohibited by the Act?**	**No**	**Protected characteristics are not considered when making clinical decision on being eligible for bariatric surgery, all patients are considered equally**			
B2	**Could the work help to advance equality of opportunity between people who share a protected characteristic and those who do not?**	**No**	**Protected characteristics are not considered when making clinical decision on being eligible for bariatric surgery, all patients are considered equally**			
B3	**Could the initiative help to foster good relations between people who share a protected characteristic and those who don't?**	**No**	**Protected characteristics are not considered when making clinical decision on being eligible for bariatric surgery, all patients are considered equally**			

C	PROTECTED CHARACTERISTICS UNDER THE EQUALITY ACT 2010	ACCESS TO SERVICES			HEALTH OUTCOMES		
		Will the work impact, either directly or indirectly, on the ability of protected groups to ACCESS services?	Please provide an explanation for your response, including details of any stakeholder engagement.	Please provide details of action you will take to remove/mitigate any negative impact.	Will the work impact, either directly or indirectly on HEALTH OUTCOMES for protected groups?	Please provide an explanation for your response, including details of any stakeholder engagement.	Please provide details of action you will take to remove/mitigate any negative impact.
C1	Age	No Impact	This policy is for adults, 18 and over. Access to bariatric surgery is not age dependant as per this work and a cut off to surgery would be based on clinical decision.		No Impact		
C2	Disability	No Impact			No Impact		
C2a	Physical Disability	No Impact	Tier 3 is focussed on diet and nutrition but if the patient is unable to exercise, this is taken into consideration and is not a barrier for patient to access to tier 4 services		No Impact		
C2b	Mental Health/Learning Disability	No impact	Access to bariatric surgery is made on physical parameters e.g. BMI...patients ability to deal with the psychological impact will be considered and tier 3 could be waivered to consider tier 4 services		No impact		
C3	Gender Reassignment	No Impact			No Impact		
C4	Marriage/Civil Partnership	No Impact			No Impact		

Equalities and Health Inequalities Impact Assessment (EHIIA): Bariatric surgery

C	PROTECTED CHARACTERISTICS UNDER THE EQUALITY ACT 2010	ACCESS TO SERVICES			HEALTH OUTCOMES		
		Will the work impact, either directly or indirectly, on the ability of protected groups to ACCESS services?	Please provide an explanation for your response, including details of any stakeholder engagement.	Please provide details of action you will take to remove/mitigate any negative impact.	Will the work impact, either directly or indirectly on HEALTH OUTCOMES for protected groups?	Please provide an explanation for your response, including details of any stakeholder engagement.	Please provide details of action you will take to remove/mitigate any negative impact.
C5	Pregnancy/Maternity (inc. Breastfeeding Mothers)	No Impact	Surgery will be offered considering clinical suitability as with all surgery		No Impact		
C6	Race/Ethnicity	Not sure yet	BMI threshold used, with acknowledgement that values may vary across different ethnic groups. Values in recommended policy in line with national Evidence Based Interventions.	Update in line with any changes to national guidance	No Impact		
C7	Religion of Belief	No Impact			No Impact		
C8	Sex (Gender)	No Impact			No Impact		
C9	Sexual Orientation	No Impact			No Impact		
C10	If not already referred to in your responses, have you carried out any engagement with relevant groups where a negative impact has been identified?	Yes	See Consultation report – and slides 13 onwards				

D	HARD TO REACH / SELDOM HEARD GROUPS	ACCESS TO SERVICES			HEALTH OUTCOMES		
	For guidance, hold your cursor in cells with a red triangle in the top right hand corner and refer to the EHIIA Guidance document	Will the work impact, either directly or indirectly, on the ability of people within these groups to ACCESS services?	Please provide an explanation for your response, including details of any stakeholder engagement.	Please provide details of action you will take to remove/mitigate any negative impact.	Will the work impact, either directly or indirectly on HEALTH OUTCOMES for people within these groups?	Please provide an explanation for your response, including details of any stakeholder engagement.	Please provide details of action you will take to remove/mitigate any negative impact.
D1	Carers	No Impact					
D2	Homeless/Rough Sleepers	No Impact					
D3	Migrant Workers	No Impact	The service will be accessible and free to those who are ordinarily resident and those with indefinite leave to remain.				
D4	Vulnerable Migrants (Refugees/Asylum Seekers)	No Impact	Asylum seekers and refugees are able to access this service. Refused asylum can access primary care, emergency care and care for infectious diseases free of charge. Some primary care services will be chargeable. They may be able to access these services and secondary care services if they have support from the home office. For more information see: https://www.gov.uk/guidance/nhs-entitlements-migrant-health-guide				
D5	Sex Workers	No Impact					

Equalities and Health Inequalities Impact Assessment (EHIIA): Bariatric surgery

D	HARD TO REACH / SELDOM HEARD GROUPS	ACCESS TO SERVICES			HEALTH OUTCOMES		
	For guidance, hold your cursor in cells with a red triangle in the top right hand corner and refer to the EHIIA Guidance document	Will the work impact, either directly or indirectly, on the ability of people within these groups to ACCESS services?	Please provide an explanation for your response, including details of any stakeholder engagement.	Please provide details of action you will take to remove/mitigate any negative impact.	Will the work impact, either directly or indirectly on HEALTH OUTCOMES for people within these groups?	Please provide an explanation for your response, including details of any stakeholder engagement.	Please provide details of action you will take to remove/mitigate any negative impact.
D6	Traveller Community (inc. Gypsies & Roma)	No Impact					
D7	Those who have experienced Female Genital Mutilation	No Impact					
D8	Those who have experienced Human Trafficking / Modern Slavery	No Impact					
D9	Those experiencing/recovering from Substance/Alcohol Abuse	Not Sure Yet	Patients/Service Users need to demonstrate they are fit for surgery and can comply with the requirements that need to be met at tier 3 and 4, but individual circumstances will be considered				
D10	Those living in economically deprived communities	No Impact					
D11	Those living within geographically isolated communities	No Impact					
D12	Prisoners / Ex-offenders	No Impact					
D13	Commuters	No Impact					
D14	Vulnerable Adults, e.g. Victims of Domestic Abuse	No Impact					
D15	Looked After Children	Not Applicable					

D16	Ex-service personnel / veterans	No Impact					
D17	Other groups that you have identified (please detail)	No Impact					
D18	If not already referred to in your responses, have you carried out any engagement with relevant groups?	Yes	See Consultation report – and slides 13 onwards				
E	PUBLIC SERVICES (SOCIAL VALUE) ACT 2012						
	Social, Economic and Environmental Benefits	Response	If Yes, please provide a brief summary of the relevant benefits. If No, and you will be conducting a procurement process, consider and detail below how you might be able to secure an improvement in each benefit.				
E1	Could this initiative secure wider social benefits?	Yes					
E2	Could this initiative secure wider economic benefits?	Yes					
E3	Could this initiative secure wider environmental benefits?	No					
E4	Public Involvement						
	Will you be undertaking a public involvement exercise (consultation/engagement) on the above matters?	Yes	See Consultation report – and slides 13 onwards				

EHIIA: Tertiary Fertility Services

A	**DETAILS OF WORK BEING UNDERTAKEN**					
A1	**Title of Project/Activity/Programme/Policy being assessed?**		**Tertiary Fertility Services (including intrauterine insemination (IUI),in vitro fertilisation (IVF) with or without intra-cytoplasmic sperm injection (ICSI), egg donation, sperm donation, and donor insemination (DI))**			
A2	**Policy Ref (if applicable):**					
A3	**Please indicate the commissioning status:**		**Re-commissioning existing service**			
A4	**What are the intended outcomes of this work? (why the work is being undertaken and objectives)**		**Harmonisation of former MSE CCG policies to develop system-wide policy for MSE ICB.**			
A5	**Project/Policy Lead Officer:**		**Ronan Fenton**			
A6	**Head of Service responsible for this work:**		**Peter Scolding**			
A7	**Committee responsible for this work:**					**Service Harmonisation Programme Board**
A8	**Who will <u>primarily</u> be affected by this work?**		**Patients/Service Users**			
B	**EQUALITY ACT 2010 - PUBLIC SECTOR EQUALITY DUTY**					
	Public Sector Equality Duties	**Response**	**Please give succinct / brief reason(s) for your response <u>and</u> which protected characteristics are affected, either positively or negatively (i.e. Age, Disability, Gender Reassignment, Marriage/Civil Partnership, Pregnancy/Maternity, Race/Ethnicity, Religion or Belief, Sex/Gender, Sexual Orientation) .**			
B1	**Could the work help to eliminate unlawful discrimination, harassment, victimisation or prevent any other conduct prohibited by the Act?**	**No**				
B2	**Could the work help to advance equality of opportunity between people who share a protected characteristic and those who do not?**	**No**				
B3	**Could the initiative help to foster good relations between people who share a protected characteristic and those who don't?**	**No**				

C	PROTECTED CHARACTERISTICS UNDER THE EQUALITY ACT 2010	ACCESS TO SERVICES			HEALTH OUTCOMES		
	For guidance, hold your cursor in cells with a red triangle in the top right hand corner and refer to the EHIIA Guidance document	Will the work impact, either directly or indirectly, on the ability of protected groups to ACCESS services?	Please provide an explanation for your response, including details of any stakeholder engagement.	Please provide details of action you will take to remove/mitigate any negative impact.	Will the work impact, either directly or indirectly on HEALTH OUTCOMES for protected groups?	Please provide an explanation for your response, including details of any stakeholder engagement.	Please provide details of action you will take to remove/mitigate any negative impact.
C1	Age	Negative Impact	There are age restrictions on this service. This is in line with the principles within NICE guidance of having more cycles available in the younger age group (23-39yrs) than older group (40-42yrs).		No Impact		
C2	Disability	No Impact			No Impact		
C2a	Physical Disability	No Impact			No Impact		

EHIIA: Tertiary Fertility Services

C	PROTECTED CHARACTERISTICS UNDER THE EQUALITY ACT 2010	ACCESS TO SERVICES			HEALTH OUTCOMES		
	For guidance, hold your cursor in cells with a red triangle in the top right hand corner and refer to the EHIIA Guidance document	Will the work impact, either directly or indirectly, on the ability of protected groups to ACCESS services?	Please provide an explanation for your response, including details of any stakeholder engagement.	Please provide details of action you will take to remove/mitigate any negative impact.	Will the work impact, either directly or indirectly on HEALTH OUTCOMES for protected groups?	Please provide an explanation for your response, including details of any stakeholder engagement.	Please provide details of action you will take to remove/mitigate any negative impact.
C2b	Mental Health/Learning Disability	No Impact	Patients accessing this service must be able to consent to treatment.		No Impact		
C3	Gender Reassignment	No Impact	People who are transgender and/or non-binary who have not undergone, or are undergoing, medical transition can access this service if they meet the IPA criteria. Certain treatments related to medical transition may affect whether a person meets the IPA criteria. This service does not include surrogacy which is covered under another policy.		No Impact		
C4	Marriage/Civil Partnership	No Impact	Couples can access this service irrespective of their marital status. Singletons are unable to access this service.		No Impact		

C5	Pregnancy/Maternity (inc. Breastfeeding Mothers)	No Impact			No Impact		
C6	Race/Ethnicity	Not Sure Yet	BMI threshold may need to be updated for different ethnic groups in line with any national guidance showing different BMI levels for different ethnic groups.	Update in line with any changes to national guidance	No Impact		
C7	Religion of Belief	No Impact			No Impact		
C8	Sex (Gender)	No Impact			No Impact		
C9	Sexual Orientation	Not sure yet	This policy change would increase the number of cycles women in same-sex relationships may be able to access. Women in a same-sex relationship will have to self-fund IUI prior to being able to access IVF - in order to prove unexplained infertility, which is a criteria for all accessing this service. Men in a same sex-relationship are unable to access this service. This service does not cover surrogacy, which is within another policy.	This policy will be kept under review, in line with any national changes to implement the Government's commitments in the Women's Health Strategy, including moves towards recommending reciprocal IVF.	No Impact		
C10	If not already referred to in your responses, have you carried out any engagement with relevant groups where a negative impact has been identified?	Yes	See Consultation report – and slides 13 onwards				

EHIIA: Tertiary Fertility Services

D	HARD TO REACH / SELDOM HEARD GROUPS	ACCESS TO SERVICES			HEALTH OUTCOMES		
	For guidance, hold your cursor in cells with a red triangle in the top right hand corner and refer to the EHIIA Guidance document	Will the work impact, either directly or indirectly, on the ability of people within these groups to ACCESS services?	Please provide an explanation for your response, including details of any stakeholder engagement.	Please provide details of action you will take to remove/mitigate any negative impact.	Will the work impact, either directly or indirectly on HEALTH OUTCOMES for people within these groups?	Please provide an explanation for your response, including details of any stakeholder engagement.	Please provide details of action you will take to remove/mitigate any negative impact.
D1	Carers	No Impact			No Impact		
D2	Homeless/Rough Sleepers	No Impact			No Impact		
D3	Migrant Workers	No Impact	The service will be accessible and free to those who are ordinarily resident and those with indefinite leave to remain. Otherwise migrant workers may need to pay for this service.		No Impact		
D4	Vulnerable Migrants (Refugees/Asylum Seekers)	No Impact	Asylum seekers and refugees are able to access this service. Refused asylum can access primary care, emergency care and care for infectious diseases free of charge. Some primary care services will be chargeable. They may be able to access these services and secondary care services if they have support from the home office. For more information see: https://www.gov.uk/guidance/nhs-entitlements-migrant-health-guide.		No Impact		

D5	Sex Workers	No Impact			No Impact		
D6	Traveller Community (inc. Gypsies & Roma)	Not Sure Yet	Requirement to be registered with GP within MSE for 1 yr may impact on this community.		No Impact		
D7	Those who have experienced Female Genital Mutilation	No Impact			No Impact		
D8	Those who have experienced Human Trafficking / Modern Slavery	No Impact			No Impact		

EHIIA: Tertiary Fertility Services

D	HARD TO REACH / SELDOM HEARD GROUPS	ACCESS TO SERVICES			HEALTH OUTCOMES		
	For guidance, hold your cursor in cells with a red triangle in the top right hand corner and refer to the EHIIA Guidance document	Will the work impact, either directly or indirectly, on the ability of people within these groups to ACCESS services?	Please provide an explanation for your response, including details of any stakeholder engagement.	Please provide details of action you will take to remove/mitigate any negative impact.	Will the work impact, either directly or indirectly on HEALTH OUTCOMES for people within these groups?	Please provide an explanation for your response, including details of any stakeholder engagement.	Please provide details of action you will take to remove/mitigate any negative impact.
D9	Those experiencing/recovering from Substance/Alcohol Abuse	No Impact			No Impact	Patients who are currently using recreational drugs or exceeding the recommended amounts of alcohol can access this service. However would not receive treatment because of the possible detrimental effects of drugs and alcohol on the foetus if successful.	
D10	Those living in economically deprived communities	No Impact			No Impact		
D11	Those living within geographically isolated communities	No Impact			No Impact		
D12	Prisoners / Ex-offenders	No Impact	Some prisoners have accessed tertiary fertility services, although uncommon. Prisoners will need permission from the relevant authorities.		No Impact		
D13	Commuters	No Impact			No Impact		
D14	Vulnerable Adults, e.g. Victims of Domestic Abuse	No Impact			No Impact		

D15	Looked After Children	No Impact			No Impact		
D16	Ex-service personnel / veterans	No Impact			No Impact		
D17	Other groups that you have identified (please detail)	No Impact			No Impact		
D18	If not already referred to in your responses, have you carried out any engagement with relevant groups?	Yes	See Consultation report – and slides 13 onwards				

E	PUBLIC SERVICES (SOCIAL VALUE) ACT 2012		
	Social, Economic and Environmental Benefits	Response	If Yes, please provide a brief summary of the relevant benefits. If No, and you will be conducting a procurement process, consider and detail below how you might be able to secure an improvement in each benefit.
E1	Could this initiative secure wider social benefits?	Not Sure Yet	Despite increased access across the system this service is unlikely to have social benefits.
E2	Could this initiative secure wider economic benefits?	Not Sure Yet	Increased access across the system may reduce the private spending by couples and could increase their spend in the local economy.
E3	Could this initiative secure wider environmental benefits?	Not Sure Yet	Increased access may result in more pregnancies and a resultant small increase in environmental costs.
E4	Public Involvement		
	Will you be undertaking a public involvement exercise (consultation/engagement) on the above matters?	Yes	See Consultation report – and slides 13 onwards

EHIIA: BREAST REDUCTION

A	**DETAILS OF WORK BEING UNDERTAKEN**					
A1	**Title of Project/Activity/Programme/Policy being assessed?**		**Breast Reduction Surgery (Reduction Mammoplasty)**			
A2	**Policy Ref (if applicable):**					
A3	**Please indicate the commissioning status:**		**Re-commissioning existing service**			
A4	**What are the intended outcomes of this work? (why the work is being undertaken and objectives)**		**Harmonisation of former MSE CCG policies to develop system-wide policy for MSE ICB.**			
A5	**Project/Policy Lead Officer:**		**Ronan Fenton**			
A6	**Head of Service responsible for this work:**		**Peter Scolding**			
A7	**Committee responsible for this work:**		**Service Harmonisation Programme Board**			
A8	**Who will <u>primarily</u> be affected by this work?**		**Patients/Service Users**			
B	**EQUALITY ACT 2010 - PUBLIC SECTOR EQUALITY DUTY**					
	Public Sector Equality Duties	**Response**	**Please give succinct / brief reason(s) for your response <u>and</u> which protected characteristics are affected, either positively or negatively (i.e. Age, Disability, Gender Reassignment, Marriage/Civil Partnership, Pregnancy/Maternity, Race/Ethnicity, Religion or Belief, Sex/Gender, Sexual Orientation) .**			
B1	**Could the work help to eliminate unlawful discrimination, harassment, victimisation or prevent any other conduct prohibited by the Act?**	**No**				
B2	**Could the work help to advance equality of opportunity between people who share a protected characteristic and those who do not?**	**No**				
B3	**Could the initiative help to foster good relations between people who share a protected characteristic and those who don't?**	**No**				

C	PROTECTED CHARACTERISTICS UNDER THE EQUALITY ACT 2010	ACCESS TO SERVICES			HEALTH OUTCOMES		
		Will the work impact, either directly or indirectly, on the ability of protected groups to ACCESS services?	Please provide an explanation for your response, including details of any stakeholder engagement.	Please provide details of action you will take to remove/mitigate any negative impact.	Will the work impact, either directly or indirectly on HEALTH OUTCOMES for protected groups?	Please provide an explanation for your response, including details of any stakeholder engagement.	Please provide details of action you will take to remove/mitigate any negative impact.
C1	Age	Not Sure Yet	Only patients aged over 18 and who have reached the end of puberty can access this service.		No Impact		
C2	Disability	No Impact			No Impact		
C2a	Physical Disability	No Impact			No Impact		
C2b	Mental Health/Learning Disability	No Impact			No Impact		
C3	Gender Reassignment	No Impact	Patients assigned female sex at birth can access this service if they meet the criteria irrespective of their gender identity.		No Impact		

EHIIA: BREAST REDUCTION

C4	Marriage/Civil Partnership	No Impact			No Impact		
C5	Pregnancy/Maternity (inc. Breastfeeding Mothers)	No Impact			No Impact		
C6	Race/Ethnicity	No Impact			No Impact		
C7	Religion of Belief	No Impact			No Impact		
C8	Sex (Gender)	Positive Impact	The service was previously not commissioned in Mid Essex, and Basildon and Brentwood. It will now be commissioned on an IPA policy and therefore more patients will have access. This service is only available to those assigned female sex at birth.		Positive Impact	Some patients in MSE are likely to have a health benefit from this funding policy by receiving surgery and reducing the morbidity associated with macromastia, including but not limited to improved mental health and wellbeing, and improved mobility and overall physical wellbeing. This service is only available to those assigned female sex at birth.	
C9	Sexual Orientation	No Impact	The criteria will be applied irrespective of the patient's sexual orientation.		No Impact		
C10	If not already referred to in your responses, have you carried out any engagement with relevant groups where a negative impact has been identified?	Yes	See Consultation report – and slides 13 onwards				

EHIIA: BREAST REDUCTION

D	HARD TO REACH / SELDOM HEARD GROUPS	ACCESS TO SERVICES			HEALTH OUTCOMES		
		Will the work impact, either directly or indirectly, on the ability of people within these groups to ACCESS services?	Please provide an explanation for your response, including details of any stakeholder engagement.	Please provide details of action you will take to remove/mitigate any negative impact.	Will the work impact, either directly or indirectly on HEALTH OUTCOMES for people within these groups?	Please provide an explanation for your response, including details of any stakeholder engagement.	Please provide details of action you will take to remove/mitigate any negative impact.
D1	Carers	No Impact			No Impact		
D2	Homeless/Rough Sleepers	No Impact			No Impact		
D3	Migrant Workers	No Impact	The service will be accessible and free to those who are ordinarily resident and those with indefinite leave to remain. Otherwise migrant workers may need to pay for this service.		No Impact		
D4	Vulnerable Migrants (Refugees/Asylum Seekers)	No Impact	Asylum seekers and refugees are able to access this service. Refused asylum can access primary care, emergency care and care for infectious diseases free of charge. Some primary care services will be chargeable. They may be able to access these services and secondary care services if they have support from the home office. For more information see: https://www.gov.uk/guidance/nhs-entitlements-migrant-health-guide.		No Impact		
D5	Sex Workers	No Impact			No Impact		
D6	Traveller Community (inc. Gypsies & Roma)	No Impact			No Impact		
D7	Those who have experienced Female Genital Mutilation	No Impact			No Impact		

D8	Those who have experienced Human Trafficking / Modern Slavery	No Impact			No Impact		
D9	Those experiencing/recovering from Substance/Alcohol Abuse	No Impact			No Impact		
D10	Those living in economically deprived communities	No Impact			No Impact		
D11	Those living within geographically isolated communities	No Impact			No Impact		
D12	Prisoners / Ex-offenders	No Impact			No Impact		
D13	Commuters	No Impact			No Impact		
D14	Vulnerable Adults, e.g. Victims of Domestic Abuse	No Impact			No Impact		
D15	Looked After Children	No Impact			No Impact		
D16	Ex-service personnel / veterans	No Impact			No Impact		
D17	Other groups that you have identified (please detail)	No Impact			No Impact		

EHIIA: BREAST REDUCTION

D	HARD TO REACH / SELDOM HEARD GROUPS	ACCESS TO SERVICES			HEALTH OUTCOMES		
		Will the work impact, either directly or indirectly, on the ability of people within these groups to ACCESS services?	Please provide an explanation for your response, including details of any stakeholder engagement.	Please provide details of action you will take to remove/mitigate any negative impact.	Will the work impact, either directly or indirectly on HEALTH OUTCOMES for people within these groups?	Please provide an explanation for your response, including details of any stakeholder engagement.	Please provide details of action you will take to remove/mitigate any negative impact.
D18	If not already referred to in your responses, have you carried out any engagement with relevant groups?	Yes	See Consultation report – and slides 13 onwards				

E	PUBLIC SERVICES (SOCIAL VALUE) ACT 2012		
	Social, Economic and Environmental Benefits	Response	If Yes, please provide a brief summary of the relevant benefits. If No, and you will be conducting a procurement process, consider and detail below how you might be able to secure an improvement in each benefit.
E1	Could this initiative secure wider social benefits?	Not Sure Yet	Increased access across the system may result in more women having surgery and a reduction in the psychological effects of macromastia (which can cause social anxiety).
E2	Could this initiative secure wider economic benefits?	Not Sure Yet	Increased access across the system may result in more women having surgery and a possible reduced requirement for psychological support and less sick days.
E3	Could this initiative secure wider environmental benefits?	Not Sure Yet	Increased access may result in more women having surgery and therefore a small increase in environmental costs associated.
E4	Public Involvement		
	Will you be undertaking a public involvement exercise (consultation/engagement) on the above matters?	Yes	See Consultation report – and slides 13 onwards

EHIIA: BREAST ASYMMETRY

C	PROTECTED CHARACTERISTICS UNDER THE EQUALITY ACT 2010	ACCESS TO SERVICES			HEALTH OUTCOMES		
		Will the work impact, either directly or indirectly, on the ability of protected groups to ACCESS services?	Please provide an explanation for your response, including details of any stakeholder engagement.	Please provide details of action you will take to remove/mitigate any negative impact.	Will the work impact, either directly or indirectly on HEALTH OUTCOMES for protected groups?	Please provide an explanation for your response, including details of any stakeholder engagement.	Please provide details of action you will take to remove/mitigate any negative impact.
C2a	Physical Disability	No Impact			No Impact		
C2b	Mental Health/Learning Disability	No Impact			No Impact		
C3	Gender Reassignment	No Impact	Patients assigned female sex at birth can access this service if they meet the IPA criteria.		No Impact		
C4	Marriage/Civil Partnership	No Impact			No Impact		

C5	Pregnancy/Maternity (inc. Breastfeeding Mothers)	No Impact			No Impact		
C6	Race/Ethnicity	No Impact			No Impact		
C7	Religion of Belief	No Impact			No Impact		
C8	Sex (Gender)	Positive Impact	The service was previously not commissioned in Mid Essex, and Basildon and Brentwood. It will now be commissioned on an IPA policy and therefore more patients will have access. This service is only available to those assigned female sex at birth.		Positive Impact	Some patients in MSE are likely to have a health benefit from this funding policy by receiving surgery and reducing the morbidity associated with breast asymmetry, including but not limited to improved mental health and wellbeing. This service is only available to those assigned female sex at birth.	
C9	Sexual Orientation	No Impact	The criteria will be applied irrespective of the patient's sexual orientation.		No Impact		
C10	If not already referred to in your responses, have you carried out any engagement with relevant groups where a negative impact has been identified?	Yes	See Consultation report – and slides 13 onwards				

EHIIA: BREAST ASYMMETRY

D+A31:H45	HARD TO REACH / SELDOM HEARD GROUPS	ACCESS TO SERVICES			HEALTH OUTCOMES		
		Will the work impact, either directly or indirectly, on the ability of people within these groups to ACCESS services?	Please provide an explanation for your response, including details of any stakeholder engagement.	Please provide details of action you will take to remove/mitigate any negative impact.	Will the work impact, either directly or indirectly on HEALTH OUTCOMES for people within these groups?	Please provide an explanation for your response, including details of any stakeholder engagement.	Please provide details of action you will take to remove/mitigate any negative impact.
D1	Carers	No Impact			No Impact		
D2	Homeless/Rough Sleepers	No Impact			No Impact		
D3	Migrant Workers	No Impact	The service will be accessible and free to those who are ordinarily resident and those with indefinite leave to remain. Otherwise migrant workers may need to pay for this service.		No Impact		
D4	Vulnerable Migrants (Refugees/Asylum Seekers)	No Impact	Asylum seekers and refugees are able to access this service. Refused asylum can access primary care, emergency care and care for infectious diseases free of charge. Some primary care services will be chargeable. They may be able to access these services and secondary care services if they have support from the home office. For more information see: https://www.gov.uk/guidance/nhs-entitlements-migrant-health-guide		No Impact		
D5	Sex Workers	No Impact			No Impact		
D6	Traveller Community (inc. Gypsies & Roma)	No Impact			No Impact		

D7	**Those who have experienced Female Genital Mutilation**	**No Impact**			**No Impact**		
D8	**Those who have experienced Human Trafficking / Modern Slavery**	**No Impact**			**No Impact**		
D9	**Those experiencing/recovering from Substance/Alcohol Abuse**	**No Impact**			**No Impact**		
D10	**Those living in economically deprived communities**	**No Impact**			**No Impact**		
D11	**Those living within geographically isolated communities**	**No Impact**			**No Impact**		
D12	**Prisoners / Ex-offenders**	**No Impact**			**No Impact**		
D13	**Commuters**	**No Impact**			**No Impact**		

EHIIA: BREAST ASYMMETRY

	HARD TO REACH / SELDOM HEARD GROUPS	ACCESS TO SERVICES			HEALTH OUTCOMES		
		Will the work impact, either directly or indirectly, on the ability of people within these groups to ACCESS services?	Please provide an explanation for your response, including details of any stakeholder engagement.	Please provide details of action you will take to remove/mitigate any negative impact.	Will the work impact, either directly or indirectly on HEALTH OUTCOMES for people within these groups?	Please provide an explanation for your response, including details of any stakeholder engagement.	Please provide details of action you will take to remove/mitigate any negative impact.
D13	Commuters	No Impact			No Impact		
D14	Vulnerable Adults, e.g. Victims of Domestic Abuse	No Impact			No Impact		
D15	Looked After Children	No Impact			No Impact		
D16	Ex-service personnel / veterans	No Impact			No Impact		
D17	Other groups that you have identified (please detail)	No Impact			No Impact		
D18	If not already referred to in your responses, have you carried out any engagement with relevant groups?	Yes	See Consultation report – and slides 13 onwards				
E	PUBLIC SERVICES (SOCIAL VALUE) ACT 2012						
	Social, Economic and Environmental Benefits	Response	If Yes, please provide a brief summary of the relevant benefits. If No, and you will be conducting a procurement process, consider and detail below how you might be able to secure an improvement in each benefit.				
E1	Could this initiative secure wider social benefits?	Not Sure Yet	Increased access across the system may result in more women having surgery and a reduction in the psychological effects of breast asymmetry (which can cause social anxiety).				
E2	Could this initiative secure wider economic benefits?	Not Sure Yet	Increased access across the system may result in more women having surgery and a possible reduced requirement for psychological support and less sick days.				

E3	**Could this initiative secure wider environmental benefits?**	**Not Sure Yet**	**Increased access may result in more women having surgery and therefore a small increase in environmental costs associated.**
E4	**Public Involvement**		
	Will you be undertaking a public involvement exercise (consultation/engagement) on the above matters?	**Yes**	**See Consultation report – and slides 13 onwards**

EHIIA: MALE STERILISATION

A	**DETAILS OF WORK BEING UNDERTAKEN**					
A1	**Title of Project/Activity/Programme/Policy being assessed?**		**Vasectomy**			
A2	**Policy Ref (if applicable):**					
A3	**Please indicate the commissioning status:**		**Re-commissioning existing service**			
A4	**What are the intended outcomes of this work? (why the work is being undertaken and objectives)**		**Harmonisation of former MSE CCG policies to develop system-wide policy for MSE ICB.**			
A5	**Project/Policy Lead Officer:**		**Peter Scolding**			
A6	**Head of Service responsible for this work:**		**Ronan Fenton**			
A7	**Committee responsible for this work:**		**Service Harmonisation Programme Board**			
A8	**Who will <u>primarily</u> be affected by this work?**		**Patients/Service Users**			
B	**EQUALITY ACT 2010 - PUBLIC SECTOR EQUALITY DUTY**					
	Public Sector Equality Duties	**Response**	**Please give succinct / brief reason(s) for your response <u>and</u> which protected characteristics are affected, either positively or negatively (i.e. Age, Disability, Gender Reassignment, Marriage/Civil Partnership, Pregnancy/Maternity, Race/Ethnicity, Religion or Belief, Sex/Gender, Sexual Orientation) .**			
B1	**Could the work help to eliminate unlawful discrimination, harassment, victimisation or prevent any other conduct prohibited by the Act?**	**No**				
B2	**Could the work help to advance equality of opportunity between people who share a protected characteristic and those who do not?**	**Yes**	**Increase gender equality, reducing burden on females**			
B3	**Could the initiative help to foster good relations between people who share a protected characteristic and those who don't?**	**No**				

C	PROTECTED CHARACTERISTICS UNDER THE EQUALITY ACT 2010	ACCESS TO SERVICES			HEALTH OUTCOMES		
		Will the work impact, either directly or indirectly, on the ability of protected groups to ACCESS services?	Please provide an explanation for your response, including details of any stakeholder engagement.	Please provide details of action you will take to remove/mitigate any negative impact.	Will the work impact, either directly or indirectly on HEALTH OUTCOMES for protected groups?	Please provide an explanation for your response, including details of any stakeholder engagement.	Please provide details of action you will take to remove/mitigate any negative impact.
C1	Age	No Impact	This policy is for adult patients 18 and over		No Impact		
C2	Disability	No Impact			No Impact		

EHIIA: MALE STERILISATION

C	PROTECTED CHARACTERISTICS UNDER THE EQUALITY ACT 2010	ACCESS TO SERVICES			HEALTH OUTCOMES		
		Will the work impact, either directly or indirectly, on the ability of protected groups to ACCESS services?	Please provide an explanation for your response, including details of any stakeholder engagement.	Please provide details of action you will take to remove/mitigate any negative impact.	Will the work impact, either directly or indirectly on HEALTH OUTCOMES for protected groups?	Please provide an explanation for your response, including details of any stakeholder engagement.	Please provide details of action you will take to remove/mitigate any negative impact.
c	Physical Disability	No Impact	This policy does not breach the Equality Act 2010 if the patient has a physical or mental impairment that has a 'substantial' and 'long-term' negative effect on their ability to do normal daily activities.		No Impact		
C2b	Mental Health/Learning Disability	Not Sure Yet	The policy is effective under the Independent Mental Capacity Advocate (IMCA) service came into effect with the Mental Capacity Act (MCA) in April 2007. The IMCA service provides advocates to speak for a person who lacks capacity and has no one else to support them.		Not Sure Yet		
C3	Gender Reassignment	No Impact	This policy does not discriminate against a transgender and/or non-binary people. Patients assigned male at birth can access this service if they meet the IPA criteria		No Impact		

C4	Marriage/Civil Partnership	No Impact	This policy protects patient's individual choice and protects them from having to discuss with their partner		No Impact		
C5	Pregnancy/Maternity (inc. Breastfeeding Mothers)	No Impact			No Impact		
C6	Race/Ethnicity	No Impact			No Impact		
C7	Religion of Belief	Not Sure Yet	In some cases patients may not wish to disclose their wish for sterilisation with their partner. In those cases access to the service is not restricted. Access to other contraception methods will not be negatively affected by this policy.	Appropriate counselling	No Impact		

EHIIA: MALE STERILISATION

C	PROTECTED CHARACTERISTICS UNDER THE EQUALITY ACT 2010	ACCESS TO SERVICES			HEALTH OUTCOMES		
		Will the work impact, either directly or indirectly, on the ability of protected groups to ACCESS services?	Please provide an explanation for your response, including details of any stakeholder engagement.	Please provide details of action you will take to remove/mitigate any negative impact.	Will the work impact, either directly or indirectly on HEALTH OUTCOMES for protected groups?	Please provide an explanation for your response, including details of any stakeholder engagement.	Please provide details of action you will take to remove/mitigate any negative impact.
C8	Sex (Gender)	Not Sure Yet	The service was previously not commissioned in Mid Essex, patients in Mid Essex will have greater access. We do not expect a negative impact in those areas where it was previously fully commissioned. This service is only available to those assigned male sex at birth.		Positive Impact	Female partners or partners assigned female at birth then may not have to go through more invasive procedure like female sterilisation, reduce chance of abortion and unwanted pregnancies	
C9	Sexual Orientation	No Impact	The procedure is available irrespective of sexual orientation		No Impact		
C10	If not already referred to in your responses, have you carried out any engagement with relevant groups where a negative impact has been identified?	Yes	See Consultation report – and slides 13 onwards				

	HARD TO REACH / SELDOM HEARD GROUPS	ACCESS TO SERVICES			HEALTH OUTCOMES		
		Will the work impact, either directly or indirectly, on the ability of people within these groups to ACCESS services?	Please provide an explanation for your response, including details of any stakeholder engagement.	Please provide details of action you will take to remove/mitigate any negative impact.	Will the work impact, either directly or indirectly on HEALTH OUTCOMES for people within these groups?	Please provide an explanation for your response, including details of any stakeholder engagement.	Please provide details of action you will take to remove/mitigate any negative impact.
D1	Carers	No Impact			No Impact		
D2	Homeless/Rough Sleepers	No Impact			No Impact		
D3	Migrant Workers	No Impact	The service will be accessible and free to those who are ordinarily resident and those with indefinite leave to remain.		No Impact	Other contraceptives are available to migrant workers free of charge. We do not anticipate having a negative impact on this population group. There may be a small number of patients who are unable to tolerate a LARC but would be able to receive barrier methods free of charge.	

EHIIA: MALE STERILISATION

	HARD TO REACH / SELDOM HEARD GROUPS	ACCESS TO SERVICES			HEALTH OUTCOMES		
		Will the work impact, either directly or indirectly, on the ability of people within these groups to ACCESS services?	Please provide an explanation for your response, including details of any stakeholder engagement.	Please provide details of action you will take to remove/mitigate any negative impact.	Will the work impact, either directly or indirectly on HEALTH OUTCOMES for people within these groups?	Please provide an explanation for your response, including details of any stakeholder engagement.	Please provide details of action you will take to remove/mitigate any negative impact.
D4	Vulnerable Migrants (Refugees/Asylum Seekers)	No Impact	Asylum seekers and refugees are able to access this service. Refused asylum can access primary care, emergency care and care for infectious diseases free of charge. They may be able to access secondary care services if they have support from the home office. For more information see: https://www.gov.uk/guidance/nhs-entitlements-migrant-health-guide		No Impact	Other contraceptives are available to failed asylum seekers free of charge. We do not anticipate having a negative impact on this population group. There may be a small number of patients who are unable to tolerate a LARC but would be able to receive barrier methods free of charge.	
D5	Sex Workers	No Impact			Not Sure Yet	Reduce the chances of abortion and possible negative effect on patient mental health as a result	
D6	Traveller Community (inc. Gypsies & Roma)	No Impact			No Impact		
D7	Those who have experienced Female Genital Mutilation	No Impact			No Impact		
D8	Those who have experienced Human Trafficking / Modern Slavery	No Impact			No Impact		
D9	Those experiencing/recovering from Substance/Alcohol Abuse	Not Sure Yet			No Impact		

D10	Those living in economically deprived communities	Positive Impact	Access to permanent contraception		Positive Impact	Reduce the chances of abortion and possible negative effect on patient mental health as a result	
D11	Those living within geographically isolated communities	No Impact			No Impact		
D12	Prisoners / Ex-offenders	No Impact			No Impact		
D13	Commuters	No Impact			No Impact		
D14	Vulnerable Adults, e.g. Victims of Domestic Abuse	No Impact			No Impact		

EHIIA: MALE STERILISATION

	HARD TO REACH / SELDOM HEARD GROUPS	ACCESS TO SERVICES			HEALTH OUTCOMES		
		Will the work impact, either directly or indirectly, on the ability of people within these groups to ACCESS services?	Please provide an explanation for your response, including details of any stakeholder engagement.	Please provide details of action you will take to remove/mitigate any negative impact.	Will the work impact, either directly or indirectly on HEALTH OUTCOMES for people within these groups?	Please provide an explanation for your response, including details of any stakeholder engagement.	Please provide details of action you will take to remove/mitigate any negative impact.
D15	Looked After Children	Not Applicable			No Impact		
D16	Ex-service personnel / veterans	No Impact			No Impact		
D17	Other groups that you have identified (please detail)	No Impact			No Impact		
D18	If not already referred to in your responses, have you carried out any engagement with relevant groups?	Yes	See Consultation report – and slides 13 onwards				

EHIIA: FEMALE STERILISATION

A	**DETAILS OF WORK BEING UNDERTAKEN**					
A1	**Title of Project/Activity/Programme/Policy being assessed?**		**Female sterilisation**			
A2	**Policy Ref (if applicable):**					
A3	**Please indicate the commissioning status:**		**Re-commissioning existing service**			
A4	**What are the intended outcomes of this work? (why the work is being undertaken and objectives)**		**Harmonisation of former MSE CCG policies to develop system-wide policy for MSE ICB.**			
A5	**Project/Policy Lead Officer:**		**Peter Scolding**			
A6	**Head of Service responsible for this work:**		**Ronan Fenton**			
A7	**Committee responsible for this work:**		**Service Harmonisation Programme Board**			
A8	**Who will <u>primarily</u> be affected by this work?**		**Patients/Service Users**			
B	**EQUALITY ACT 2010 - PUBLIC SECTOR EQUALITY DUTY**					
	Public Sector Equality Duties	**Response**	**Please give succinct / brief reason(s) for your response <u>and</u> which protected characteristics are affected, either positively or negatively (i.e. Age, Disability, Gender Reassignment, Marriage/Civil Partnership, Pregnancy/Maternity, Race/Ethnicity, Religion or Belief, Sex/Gender, Sexual Orientation) .**			
B1	**Could the work help to eliminate unlawful discrimination, harassment, victimisation or prevent any other conduct prohibited by the Act?**	**No**				
B2	**Could the work help to advance equality of opportunity between people who share a protected characteristic and those who do not?**	**No**				
B3	**Could the initiative help to foster good relations between people who share a protected characteristic and those who don't?**	**No**				

C	PROTECTED CHARACTERISTICS UNDER THE EQUALITY ACT 2010	ACCESS TO SERVICES			HEALTH OUTCOMES		
		Will the work impact, either directly or indirectly, on the ability of protected groups to ACCESS services?	Please provide an explanation for your response, including details of any stakeholder engagement.	Please provide details of action you will take to remove/mitigate any negative impact.	Will the work impact, either directly or indirectly on HEALTH OUTCOMES for protected groups?	Please provide an explanation for your response, including details of any stakeholder engagement.	Please provide details of action you will take to remove/mitigate any negative impact.
C1	Age	No Impact	Patients must be over the age of 18 and be pre-menopause.		No Impact		
C2	Disability	No Impact			No Impact		

EHIIA: FEMALE STERILISATION

C	PROTECTED CHARACTERISTICS UNDER THE EQUALITY ACT 2010	ACCESS TO SERVICES			HEALTH OUTCOMES		
		Will the work impact, either directly or indirectly, on the ability of protected groups to ACCESS services?	Please provide an explanation for your response, including details of any stakeholder engagement.	Please provide details of action you will take to remove/mitigate any negative impact.	Will the work impact, either directly or indirectly on HEALTH OUTCOMES for protected groups?	Please provide an explanation for your response, including details of any stakeholder engagement.	Please provide details of action you will take to remove/mitigate any negative impact.
C2a	Physical Disability	No Impact	Women or people assigned female at birth with a disability will have the same access to female sterilisation as those without - the threshold criteria will have to be met.		No Impact		
C2b	Mental Health/Learning Disability	Not Sure Yet	We have included information in the threshold criteria regarding consent - previously patients had to be able to give consent and we have removed this to ensure those patients who are unable can have a best		Not Sure Yet	Potential positive impact as patients who lack capacity to consent are now able to access the service as described in column E. This may prevent unwanted	

			interest decision as outlined in the Mental Capacity Act.			**pregnancy in this group of patients.**	
C3	**Gender Reassignment**	**No Impact**	**Transgender men and non-binary people assigned female at birth who have not undergone hysterectomy or bilateral oophorectomy (i.e. Are considered fertile) can access this service.**		**No Impact**		
C4	**Marriage/Civil Partnership**	**No Impact**	**There is no legal requirement for a patient to inform their partner prior to sterilisation. Ideally partners would be present in the discussion with a clinician however in some situations a patient may not wish to disclose this to their partner. This would not restrict their access to the service.**	**Appropriate counselling.**	**No Impact**		

C5	**Pregnancy/Maternity (inc. Breastfeeding Mothers)**	**No Impact**			**No Impact**	**Some studies have reported higher rates of dissatisfaction and regret in patients who have sterilisation performed at the time of caesarean section.**	**Appropriate counselling and consent.**

EHIIA: FEMALE STERILISATION

C	PROTECTED CHARACTERISTICS UNDER THE EQUALITY ACT 2010	ACCESS TO SERVICES			HEALTH OUTCOMES		
		Will the work impact, either directly or indirectly, on the ability of protected groups to ACCESS services?	Please provide an explanation for your response, including details of any stakeholder engagement.	Please provide details of action you will take to remove/mitigate any negative impact.	Will the work impact, either directly or indirectly on HEALTH OUTCOMES for protected groups?	Please provide an explanation for your response, including details of any stakeholder engagement.	Please provide details of action you will take to remove/mitigate any negative impact.
C6	Race/Ethnicity	No Impact	In some cases patients may not wish to disclose their wish for sterilisation with their partner. In those cases access to the service is not restricted. Access to other contraception methods will not be negatively affected by this policy.	Appropriate counselling.	No Impact		
C7	Religion of Belief	No Impact	In some cases patients may not wish to disclose their wish for sterilisation with their partner. In those cases access to the service is not restricted. Access to other contraception methods will not be negatively affected by this policy.	Appropriate counselling.	No Impact		

C8	Sex (Gender)	Not Sure Yet	The service was previously not commissioned in Mid Essex and was fully commissioned in Southend, Castle Point and Rochford and Thurrock. Patients in Mid Essex will have greater access. We do not expect a negative impact in those areas where it was previously fully commissioned as the threshold criteria we have placed is likely to reflect the clinical decision making previously used in those areas. This service is only available to those assigned female sex at birth		Not Sure Yet		
C9	Sexual Orientation	No Impact	The criteria will be applied irrespective of the patient's sexual orientation.				
C10	If not already referred to in your responses, have you carried out any engagement with relevant groups where a negative impact has been identified?	Yes	See Consultation report – and slides 13 onwards				

EHIIA: FEMALE STERILISATION

	HARD TO REACH / SELDOM HEARD GROUPS	ACCESS TO SERVICES			HEALTH OUTCOMES		
		Will the work impact, either directly or indirectly, on the ability of people within these groups to ACCESS services?	Please provide an explanation for your response, including details of any stakeholder engagement.	Please provide details of action you will take to remove/mitigate any negative impact.	Will the work impact, either directly or indirectly on HEALTH OUTCOMES for people within these groups?	Please provide an explanation for your response, including details of any stakeholder engagement.	Please provide details of action you will take to remove/mitigate any negative impact.
D1	Carers	No Impact			No Impact		
D2	Homeless/Rough Sleepers	No Impact			No Impact		
D3	Migrant Workers	No Impact	The service will be accessible and free to those who are ordinarily resident and those with indefinite leave to remain. Otherwise migrant workers may be charged for this service.		No Impact	Other contraceptives are available to migrant workers free of charge. We do not anticipate having a negative impact on this population group. There may be a small number of patients who are unable to tolerate a LARC but would be able to receive barrier methods free of charge.	

D4	Vulnerable Migrants (Refugees/Asylum Seekers)	Not Sure Yet	Asylum seekers and refugees are able to access this service. Refused asylum can access primary care, emergency care and care for infectious diseases free of charge. Some primary care services will be chargeable. They may be able to access these services and secondary care services if they have support from the home office. For more information see: https://www.gov.uk/guidance/nhs-entitlements-migrant-health-guide		No Impact	Other contraceptives are available to failed asylum seekers free of charge. We do not anticipate having a negative impact on this population group. There may be a small number of patients who are unable to tolerate a LARC but would be able to receive barrier methods free of charge.	
D5	Sex Workers	No Impact			No Impact		
D6	Traveller Community (inc. Gypsies & Roma)	No Impact			No Impact		
D7	Those who have experienced Female Genital Mutilation	No Impact			No Impact		

EHIIA: FEMALE STERILISATION

	HARD TO REACH / SELDOM HEARD GROUPS	ACCESS TO SERVICES			HEALTH OUTCOMES		
		Will the work impact, either directly or indirectly, on the ability of people within these groups to ACCESS services?	Please provide an explanation for your response, including details of any stakeholder engagement.	Please provide details of action you will take to remove/mitigate any negative impact.	Will the work impact, either directly or indirectly on HEALTH OUTCOMES for people within these groups?	Please provide an explanation for your response, including details of any stakeholder engagement.	Please provide details of action you will take to remove/mitigate any negative impact.
D8	Those who have experienced Human Trafficking / Modern Slavery	No Impact			No Impact		
D9	Those experiencing/recovering from Substance/Alcohol Abuse	No Impact			No Impact		
D10	Those living in economically deprived communities	Not Sure Yet	Fewer people from economically deprived areas may be able to access the service compared with areas of relative affluency. Economically deprived areas have higher rates of obesity. The threshold criteria includes a BMI cut off of <35 (therefore patients over a BMI of 35 will not be able to access the service).		No Impact		
D11	Those living within geographically isolated communities	No Impact			No Impact		
D12	Prisoners / Ex-offenders	No Impact			No Impact		
D13	Commuters	No Impact			No Impact		
D14	Vulnerable Adults, e.g. Victims of Domestic Abuse	No Impact			No Impact		

D15	Looked After Children	No Impact			No Impact		
D16	Ex-service personnel / veterans	No Impact			No Impact		
D17	Other groups that you have identified (please detail)	No Impact			No Impact		
D18	If not already referred to in your responses, have you carried out any engagement with relevant groups?	Yes	See Consultation report – and slides 13 onwards				
E	PUBLIC SERVICES (SOCIAL VALUE) ACT 2012						
	Social, Economic and Environmental Benefits	Response	If Yes, please provide a brief summary of the relevant benefits. If No, and you will be conducting a procurement process, consider and detail below how you might be able to secure an improvement in each benefit.				
E1	Could this initiative secure wider social benefits?	Not Sure Yet	Greater autonomy for women in Mid Essex. May prevent a small number of unwanted pregnancies.				
E2	Could this initiative secure wider economic benefits?	Not Sure Yet	May prevent a small number of unwanted pregnancies.				
E3	Could this initiative secure wider environmental benefits?	Not Sure Yet	May prevent a small number of unwanted pregnancies.				
E4	Public Involvement						
	Will you be undertaking a public involvement exercise (consultation/engagement) on the above matters?	Yes	See Consultation report – and slides 13 onwards				

Appendix 4

stand.

NHS
Mid and South Essex
Integrated Care Board

Report on Mid and South Essex Integrated Care Board (ICB) public consultation

Service harmonisation: Bringing equity to services across mid and south Essex

31 October – 19 December 2022

A report by Stand

for Mid and South Essex ICB

January 2023

Contents

1 Executive summary

1.1 Introduction

Mid and South Essex Integrated Care Board want to change the policies for six services that are currently only funded by the NHS in this area under certain circumstances, so that there is one single policy for all the services.

These services are:

- Weight loss surgery (bariatric surgery)
- Correction for uneven breasts (breast asymmetry)
- Breast reduction
- Female sterilisation
- Vasectomy (male sterilisation)
- Special fertility services including: Intra-uterine insemination (IUI); In vitro fertilisation (IVF), with or without intra-cytoplasmic sperm injection (ICSI): Sperm and egg donation (sperm and oocyte donation)

The ICB ran a public consultation about this from 31 October to 19 December 2022. This report analyses the responses from the public consultation.

The public consultation included a survey and a number of engagement events and focus groups. It was publicised widely among stakeholders, websites, in the media and on social media.

The ICB assessed potential health inequalities for different groups within society and approached those likely to be impacted. The consultation document (Appendix 1) and survey (Appendix 2) were available on request in other languages and an easy read version of the document (Appendix 3) was developed.

1.2 Summary of feedback

A total of 210 people responded to the online survey, with one additional paper response being received once the consultation had closed. As the analysis of the online survey had already been completed when this was received, the views of this individual were considered separately.

The people who responded to the online survey were mainly people who:

- are currently affected by this policy as a patient or service user (33%);
- have a close relationship with someone who is affected by this policy or has been affected in the past (18%);
- feel they might be affected in the future (25%); and
- 15% have a professional interest in this policy.

Survey respondents were given the option to select the clinical service areas that they wished to provide their views for or comment on the proposed policy update generally.

Twenty people participated in public events or focus groups. One person in a focus group shared with own views and the views of other people from their organisation.

Most online survey respondents supported the proposed policy updates. The highest levels of support were for special fertility services (78%), bariatric surgery (74%) and vasectomy (72%). For the other clinical service areas – breast asymmetry, breast reduction and female sterilisation - approximately two thirds expressed support for the changes.

Objections to the proposed policy updates were raised by some respondents, including the feeling that further consideration is needed before making the updates, and around the proposed threshold criteria for the services, in particular with regards to special fertility services.

Participants in the focus groups and public events were generally supportive of the changes. That support was tempered with several queries and points for further consideration that were raised about the policy update in general, as well as specifically for the different clinical services.

Online survey findings

Service	No. of respondents who completed the survey section	Percentage support for policy update*
Bariatric surgery	49	74%
Breast asymmetry	30	67%
Breast reduction	42	69%
Female sterilisation	32	63%
Vasectomy	32	72%
Special fertility services	154	78%
Proposed policy update (general)	12	50%

**Proportion of respondents who strongly support or support the proposed policy update.*

Overall, it was felt that the policy changes would enable equitable access for all residents in Mid and South Essex and remove the 'postcode lottery' that currently exists. Further, for some clinical areas i.e., bariatric surgery, breast asymmetry, breast reduction, it was thought that the changes would result in improved quality of life for patients, whilst reducing associated costs for the NHS.

Additional specific benefits were identified through improved access to the other clinical service areas such as vasectomy – allowing men to take greater responsibility of their reproductive choices, female sterilisation – giving women the right to choose this as a form of contraception, and special fertility services – giving childless couples the opportunity to have children.

For those that oppose the updates or feel that further consideration is needed, this mostly related to the proposed threshold criteria for the services – for example, it being too high, concerns around the use and accuracy of BMI as an indicator, and potential discrimination of patients dependent on their age or BMI.

The greatest challenge was made with regards to special fertility services where it was felt that there is opportunity for the threshold criteria to be more inclusive and provide more equitable access for same sex couples, single parents, blended families, and those who have in the past accessed treatment privately. It was thought that the proposed policy update as it stands would result in potential areas of inequalities and discrimination which need to be considered to help avoid further implications, including legal challenge.

It must be noted that there was a small cohort of survey respondents who felt strongly that these clinical services should not be funded by the NHS; it was thought that the money should be better spent on improving basic and/or essential services such as improving access to primary care and cancer services.

When reviewing these clinical services, it was felt important that consideration of the financial implications is made to ensure best use of resources as well as the impact that these changes will have on patients' mental and physical health, as well as that of their partners and families. Additionally, it was felt important to consider patients' input, choice, and communication, as well as the time it will take to implement these changes.

1.3 Health Overview and Scrutiny

The ICB presented information about the public consultation to three health scrutiny committees, Essex, Thurrock and Southend. Essex committee noted the report and asked for a further update in February. Thurrock and Southend committees noted the information and asked for an analysis of the consultation at future meetings.

1.4 Miscellaneous responses

In addition to the survey responses 27 emails were received about the consultation. Most were about practical details. One asked whether discussions had been held with the other ICSs in Essex and one expressed a lack of confidence in the consultation process. Replies were sent to all the emails.

1.5 Next steps

The report will be presented to the ICB decision making board on 19 February 2023 in order to make a final decision about the future policies.

2 Introduction

2.1 Context

Mid and South Essex Integrated Care Board (the ICB) was formed on 01 July 2022. It is responsible for planning, organising, and buying NHS funded healthcare for the 1.2 million people living across mid and south Essex.

The ICB wants to change the policies for six clinical services that are currently only funded by the NHS in this area under certain circumstances.

These services are:

- Weight loss surgery (bariatric surgery)
- Correction for uneven breasts (breast asymmetry)
- Breast reduction
- Female sterilisation
- Vasectomy (male sterilisation)
- Special fertility services including: Intra-uterine insemination (IUI); In vitro fertilisation (IVF), with or without intra-cytoplasmic sperm injection (ICSI): Sperm and egg donation (sperm and oocyte donation)

At the moment the policies for these six services differ depending on where people live. For example, people living in the commissioning areas of Basildon, Brentwood and Mid Essex can't access IVF services on the NHS, when people living in other areas of mid and south Essex can. The ICB wants to change these policies, so everyone living in mid and south Essex has the same opportunities.

The ICB therefore ran a public consultation from 31 October to 19 December 2022 setting out their proposals to help bring the old policies into a new single policy for each of the six service areas, in order to understand the views of patients, the public, staff and stakeholders.

This report analyses the responses from the public consultation.

This report was prepared by Stand, an independent expert community of engagement practitioners with a long history of informing policy, strategy, service design and transformational change programmes.

Together Stand's experienced specialist team holds a range of relevant professional accreditations.

3 Methodology

3.1 Engagement activity

The consultation included the following activity

- A survey to gather feedback from the public, those who have and who may use the services
- Engagement events, in person and online
- Focus groups
- Briefing key stakeholders, including Health Overview and Scrutiny Committees

3.1.1 Survey

The survey was available online and in printed format. Printed surveys (Appendix 2) along with the consultation document (Appendix 1) were distributed to all libraries in mid and south Essex and were available on request from the ICB. An easy read version of the consultation document was also available (Appendix 3).

3.1.2 Engagement events

Five public engagement events were arranged in geographic locations across mid and south Essex. Four were held in person and one was held online via Zoom, as follows:

Date	Place	Attendance
9 November 2022	Greys	0 attendees
10 November 2022	Witham	1 attendee
22 November 2022	Basildon	1 attendee
24 November 2022	Southend	0 attendees
30 November 2022	Online	5 attendees

3.1.3 Focus groups

Focus groups were held as follows:

Date	Group	Attendance
15 December	LGBT Mummies	1
21 November 2022	Microsoft Teams conversation	1
22 November	Online Men's Focus Group (including reps from Blind Veterans, Agewell, Community 360, Gambling Education Network)	10
15 December	Bariatric focus group	1

3.2 Data protection

All those who participated were informed of the ICB's and Stand's data protection policies. Participants' data has only been used for the engagement activity and held in line with the latest data protection regulations. Every effort has been taken to ensure that these individuals cannot be identified.

3.3 Delivery team

The engagement activity was delivered by the ICB's communications and engagement team, supported by Stand (see above).

3.4 Equalities and health inequalities

The ICB assessed potential health inequalities for different groups within society and approached those likely to be impacted, who included the LGBT community, Travellers, people with mental health conditions, people with learning disabilities and people from deprived communities. They also made sure that groups representing all the nine protected characteristics received information including the link to the online survey and information about how to access printed copies of the survey and consultation document to take part in the consultation.

The consultation document (Appendix 1) and survey (Appendix 2) were available on request in other languages and an easy read version of the document (Appendix 3) was developed.

Among the wide range of people contacted with information about the consultation were:

- Eight organisations working with Travellers
- LGBTQI + groups.
- Thirty four mental health groups
- Eighty organisations who work with people with learning disabilities. The easy read version of the consultation document was made widely available and approaches were made to run focus groups for this cohort
- Sex workers
- People from minority ethnic groups.
- Faith groups
- Twenty two organisations working with homeless people

The feedback indicated that sometimes people were not willing to talk in groups about the services in the public consultation and were much happier talking on a one-to-one basis because of the nature of the services being offered or because of cultural preferences. Where focus groups could be organised the reports from them have been analysed.

With regard to deprivation, the monitoring data captures the household incomes of people who responded to the questionnaire and shows that 24% had just enough money for basic necessities and little else and 5% don't have enough money for basic necessities and sometimes or often run out of money. This illustrates that people from a wide range of socio-economic groups completed the survey.

3.5 Publicity and promotion

Information about the public consultation was sent to 37 media outlets. It was also promoted on social media and through communication by email. More than 5,500 people have signed up with the ICB for general news and updates and approximately 800 people have signed up to receive the engagement newsletter, and they were all targeted with information about the public consultation.

The organisations who received information included those listed above in the equalities section, together with public sector partners and neighbours in the NHS and local authorities and 368 mid and south Essex patient and public representatives.

The consultation received widespread coverage in local newspapers, particularly the Basildon Echo and Essex Chronicle, and was picked up by organisations with a special interest, such as Bourn Hall Fertility UK, who promoted it on their Instagram feed.

Information about the consultation together with links to the consultation document and survey was available on the ICB's website, generating 1,096 page views of which 915 were unique. The average time spent on the page was two minutes 11 seconds.

The ICB's Instagram account put out films to encourage people to take part as the consultation progressed.

There were 58 social media posts with a total of 160 clicks. The reach was 7,200, and with 13,000 impressions. There was a good engagement rate of 2.40%.

3.6 Next steps

The report will be presented to the ICB decision making board on 9 February 2023 in order to make a final decision about the future policies.

This will support their ambition to end the variation that has existed up to now in accessing these services for those who would clinically benefit in mid and south Essex.

4 Analysis

4.1 Analysis of survey responses

4.1.1 Respondent profile

A total of 210 people responded to the online survey, with one additional paper response being received once the consultation had closed, which brought the total sample size to 211.

As the analysis of the responses to the online survey had already been completed prior to the paper response being received, the response from this individual is presented separately (See Section Additional paper response received). The following therefore presents the findings of the online survey only.

Slightly higher proportions were from Basildon Borough Council (23%), Chelmsford City Council (16%), Southend-on-Sea City Council (14%) and Braintree District Council (12%).

Other areas (5%) included Babergh, Colchester, Epping, Tendring, South Cambs, Uttersford and Cambridge.

Q Please tell us which council area you live in? (N=210)

Area	No.	%
Basildon Borough Council	48	23%
Chelmsford City Council	33	16%
Southend-on-Sea City Council	30	14%
Braintree District Council	25	12%
Brentwood Borough Council	19	9%
Thurrock Council	14	7%
Castle Point Borough Council	13	6%
Maldon District Council	11	5%
Other	10	5%
Rochford District Council	7	3%

A third of respondents (33%) are currently affected by this policy as a patient / service user, whilst 18% have a close relationship with someone who is affected by this policy or has been affected in the past and a quarter (25%) feel they might be affected by this policy in the future.

Furthermore, 15% have a professional interest in this policy, whilst 18% are not affected by this policy in any way.

The majority of those who selected other (7%) indicated that they have been affected by this policy in the past.

Q. Which of the following statements apply to you? (N=210)*

Response	No.	%
I am currently affected by this policy - patient or service user	70	33%
I might be affected by this policy in the future	52	25%
I have a close relationship with someone who is affected or has been affected by this policy in the past e.g., carer	37	18%
I am not affected by this policy in any way	38	18%
I have a professional interest in this policy - staff / clinician	31	15%
Other	14	7%

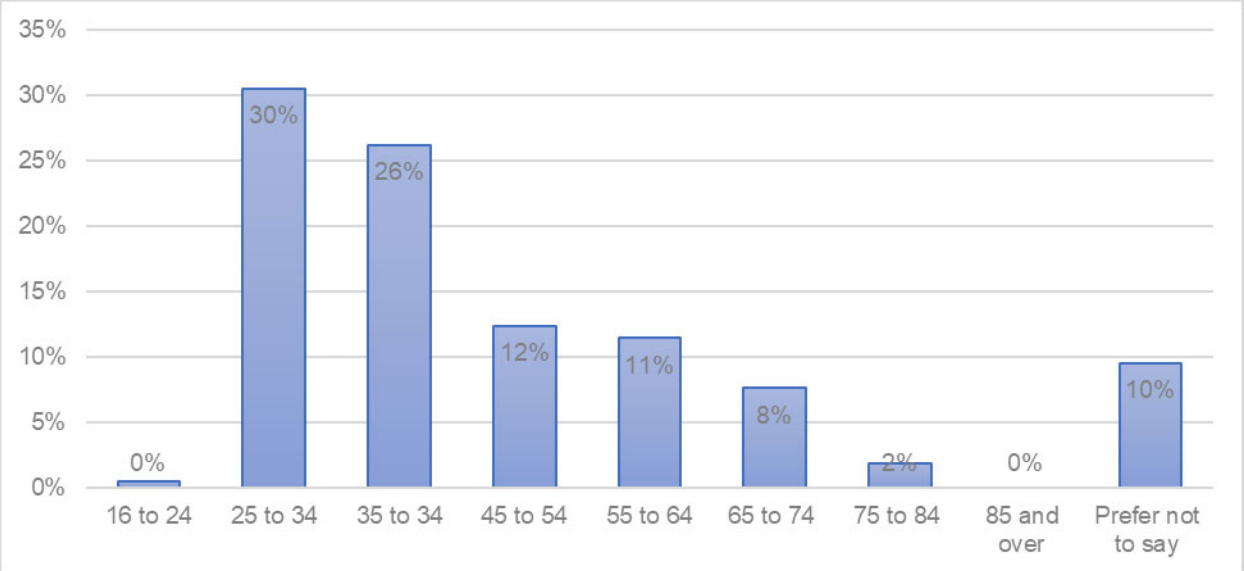
**Due to the multiple response nature of this question, percentages do not add up to 100%.*

A summary of the demographic profile of the online survey respondents is provided here:

- The highest proportions were aged 25 to 34 years (30%) and 35 to 44 years (26%) (see Figure below).
- 14% were currently pregnant or had been in the last year.
- 82% were White – English, Welsh, Scottish, Northern Irish, or British, with much smaller proportions White Irish (1%), Asian or British Asian – Indian (1%), Black, Black British Caribbean or African – Caribbean (1%) or other (2%) (10% preferred not to say).
- The majority were heterosexual or straight (83%) with much smaller proportions' bisexual (4%) or gay / lesbian (1%) (12% preferred not to say).
- The majority (87%) stated that their gender identity matches their gender assigned at birth, whilst 1% said it didn't and 12% preferred not to say.
- 79% identify as a woman (including a trans woman), whilst 10% identify as a man (including a trans man) (11% preferred not to say).
- 90% stated their first language was English, whilst 10% preferred not to say.
- 25% stated having a physical or mental health condition(s) or illness(es) which has lasted or is expected to last 12 months or more. Two thirds of these (68%) indicated that this reduces their ability to carry out day-to-day activities to some extent.
- In terms of their current financial situation:
    - 46% have more than enough money for basic necessities, and a little spare that they can save / spend on extras or leisure.

- 24% have just enough money for basic necessities and little else.
- 6% have more than enough money for basic necessities, and a lot spare that they can save / spend on extras or leisure.
- 5% don't have enough money for basic necessities and sometimes or often run out of money.
- 19% preferred not to respond to this question.

Figure 1 Age profile of online survey respondents (N=210)



The full demographic breakdown of survey respondents, which includes the additional paper response received, is available in Section 4.3. Due to this addition, there is slight variation in the percentages to those presented above.

4.1.2 Clinical service - bariatric surgery

This section of the survey was completed by 49 individuals. Overall, there was strong support for the proposed policy update with regards to bariatric surgery with 33% strongly supporting and 41% supporting this. In contrast, 16% oppose the changes to some extent. This included individuals from:

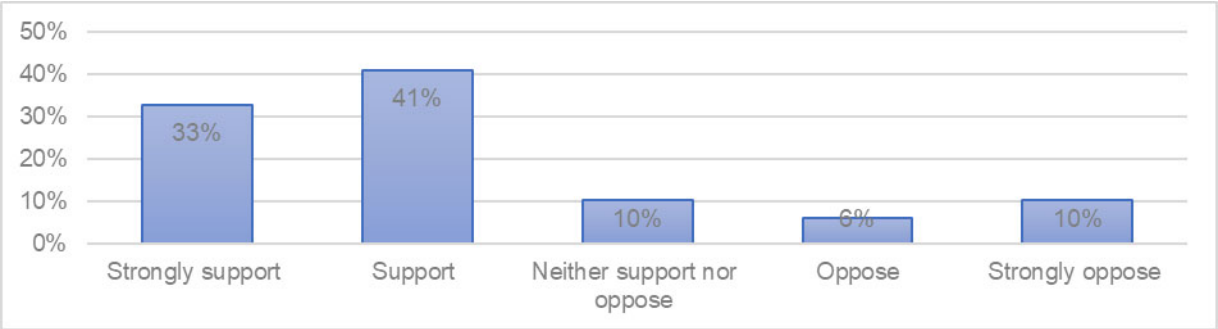
- Chelmsford City Council (N=2; 6%*)
- Thurrock Council (N=2; 14%*)
- Brentwood Borough Council (N=1; 5%*)
- Basildon Borough Council (N=1; 2%*)
- Braintree District Council (N=1; 4%*)
- Southend-on-Sea City Council (N=1; 3%*)

**Percentages shown as a proportion of respondents from this area.*

Q. To what extent do you support or oppose the proposed policy update? (N=49)

Support or oppose	No.	%
Strongly support	16	33%
Support	20	41%
Neither support/oppose	5	10%
Oppose	3	6%
Strongly oppose	5	10%

Figure 2 To what extent do you support or oppose the proposed policy update? (N=49)



In terms of support for the proposed policy update, there was agreement that access to this treatment should be fair and available for all. Furthermore, it was thought that providing access will result in improvements to the quality of life of patients as well as being cost-effective for the NHS, reducing longer-term medical costs.

> *"Important to have unified policy and bariatric surgery is becoming more commonly recommended"*

> *"Can save costs for diabetes - also help improve individuals lives for health and mental health"*

Respondents also expressed their support for the threshold criteria in terms of patients needing to demonstrate their own effort to reduce their weight and/or show commitment to long-term follow up.

> *"Needs to be available to all areas to support weight loss but important it's not rushed into, and other options tried first as not an easy option. Fully agree there needs to be long-term follow up and support"*

For those that opposed the update or felt that further thought was needed, comment was made about the need to consider the counselling / support that must be provided both pre- and post-operatively to help patients address the root causes of their problem, as well as educate them around dietary needs and body image.

> *"Psychological support for this issue is one of the most important aspects that need to be looked at"*

Comment was additionally made about the threshold criteria in terms of it being 'too high' with 'too many obstacles for patients to overcome', this included the use and accuracy of BMI as an indicator, as well as a feeling that NHS funding should not be used in this way.

> *"The use of BMI is a very crude and generally ineffective means of determining need - an athlete (especially those who undertake weight training) will almost certainly achieve a high BMI but have very little actual fat. Fat density and distribution scans would be far more effective."*

> *"It depends on there being sufficient funding in the system without affecting provision for major life-threatening conditions such as cancer, heart problems etc"*

Q Please explain your response (N=45)*

Support / positive comments	**No.**	**%**
Accessibility needed for all / fairer	9	20%
Will result in improvements to patients' quality of life	9	20%
Support that patients need to have demonstrated own effort / exhausted all other avenues	4	9%
Cost effective / will reduce the need for longer-term medial costs	4	9%
Support commitment to long-term follow up	3	7%
Objections / further considerations	**No.**	**%**
Importance of counselling / support pre- and post-operatively	7	16%
Disagreement with threshold criteria	7	16%
Disagreement that NHS funding should be allocated to this / feeling that patients need to try other things to lose weight	6	13%
Other comments	**No.**	**%**
Other, including: Support if medical reasons	4	9%

Should be considered on case-by-case basis Comment about personal experience		
Not sure	1	2%

**Due to the free text nature of this question, percentages do not equate to 100%.*

4.1.3 Clinical service - breast asymmetry

This section of the survey was completed by 30 individuals. Overall, 50% strongly support and 17% support the proposed policy update for breast asymmetry. In contrast, 26% oppose these changes to some extent. These respondents were from:

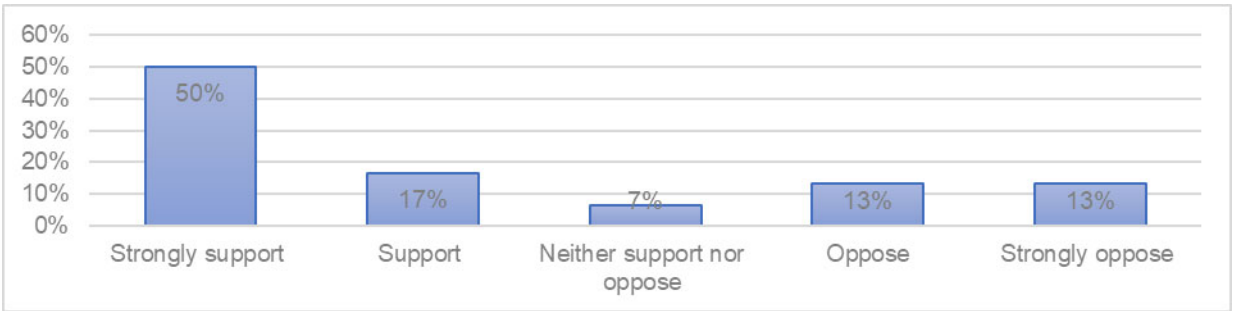
- Brentwood Borough Council (N=2; 11%*)
- Chelmsford City Council (N=2; 6%*)
- Castle Point Borough Council (N=2; 15%*),
- Basildon Borough Council (N=1; 2%*)
- Southend-on-Sea City Council (N=1; 3%*).

**Percentages shown as a proportion of respondents from this area.*

Q To what extent do you support or oppose the proposed policy update? (N=30)

Support or oppose	No.	%
Strongly support	15	50%
Support	5	17%
Neither support/oppose	2	7%
Oppose	4	13%
Strongly oppose	4	13%

Figure 3 To what extent do you support or oppose the proposed policy update? (N=30)



In support of the proposed policy update, respondents noted how this will help to improve the physical and mental health of patients that require this type of surgery and ensure fairness / equitable access for all residents across the region.

> *"All residents should access to the same service. It should not be a postcode lottery"*

> *"Treatment to prevent preventable anxiety is justified"*

In contrast, for those that opposed the update or felt that further thought was needed, concern was raised about the threshold criteria, in terms of:

- It being too high.
- The difficulty of providing evidence of serious functional impairment for at least one year.
- The omission of gynecomastia (enlarged male breasts).
- Care being denied to smokers, with no mention of drug / alcohol use.
- Two cup sizes of difference not being significant enough to have huge impact on physical health.

> *"I would like to know why the patient must be a non-smoker, but no alcohol and no drugs are not mentioned? Also, why gynecomastia is not covered?"*

It was additionally felt by a few, that in some cases, augmentation of the smaller breast must also be made.

> *"I do think in some cases augmentation of the smaller breast should be considered, depending on the person's body and other factors."*

Other comments were made around the surgery being seen as cosmetic, with feeling that this should not be funded by the NHS.

> *"This surgery should not be NHS funded unless there is a SERIOUS risk to health and the patient has been means-tested to rule out the possibility of private treatment"*

Q: Please explain your response (N=28)*

Support / positive comments	**No.**	**%**
Will result in improvement to patients' physical and mental health	9	43%
Fair and accessible for all	2	7%
Objections / further considerations	**No.**	**%**
Disagreement with the threshold criteria	6	21%

Seen as cosmetic / disagreement with NHS funding being used this way	5	18%
Breast augmentation must also be considered	3	11%
Other comments	**No.**	**%**
Other, including: Should be limited access for this Should be decided on case-by-case basis and only undertaken if other measures have been attempted first	2	7%

**Due to the free text nature of this question, percentages do not equate to 100%.*

4.1.4 Clinical service - breast reduction

This section of the survey was completed by 42 individuals. Overall, 38% strongly support and 31% support the proposed policy update for breast reduction. In contrast, 24% oppose this change to some extent. The latter included individuals from:

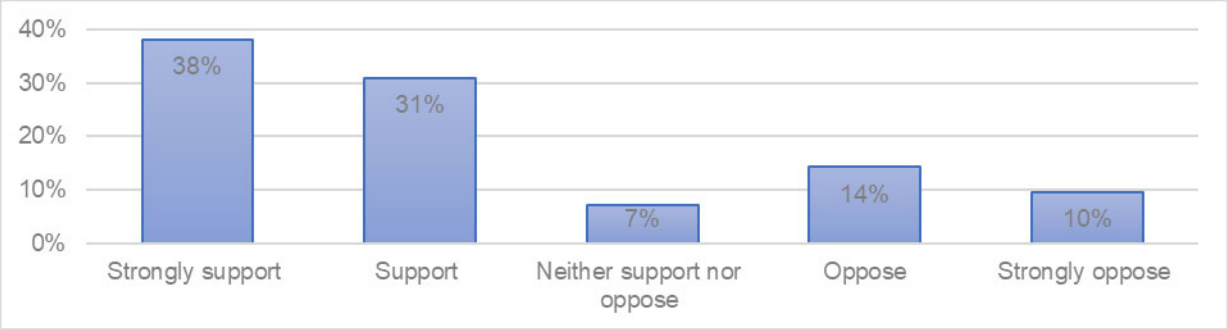
- Chelmsford City Council (N=3; 9%*)
- Brentwood Borough Council (N=2; 11%*)
- Basildon Borough Council (N=2; 4%*)
- Maldon District Councill (N=1; 9%*)
- Southend-on-Sea City Council (N=1; 3%*)
- Castle Point Borough Council (N=1; 8%*)

**Percentages shown as a proportion of respondents from this area.*

Q To what extent do you support or oppose the proposed policy update? (N=42)

Support or oppose	**No.**	**%**
Strongly support	16	38%
Support	13	31%
Neither support/oppose	3	7%
Oppose	6	14%
Strongly oppose	4	10%

Figure 4 To what extent do you support or oppose the proposed policy update? (N=42)



In support of the proposed policy update, respondents indicated their agreement with the criteria and how it provides fairness and accessibility for all. Furthermore, others talked of the physical and mental health benefits that this would bring to patients, as well as the reduction in associated costs for the NHS.

> *"Quality of life for those who have larger breasts and constant pain and rubbing"*

> *"As something that can cause both physical severe back pain, and affect mental health, it would benefit many people for care to be provided on the NHS"*

Others felt the proposed policy changes would be acceptable if a clinical need is proven and/or if other interventions such as diet and exercise, haven't worked.

> *"I would support if the clinical evidence of significant pain could be provided, and that pain was impacting on day-to-day life. If not, as with the previous service area, this falls under the banner of cosmetic surgery and should not be funded by the NHS"*

> *"This procedure should not be NHS funded unless a SERIOUS risk to health and the patient has been means-tested to rule out the possibility of private procedure"*

For those that opposed the update or felt that further consideration was needed, concern was raised about the use of BMI as an indicator. More specifically, BMI was described as being 'irrelevant' and 'old-fashioned', failing to consider muscle mass and the weight of the breasts.

> *"I support that this is offered however I think considerations need to be made, especially with regards to BMI. Someone with very large breasts will show up as a higher BMI due to their weight, which may skew results."*

Further disagreement / comment was made about the threshold criteria in terms of:

- It being too high e.g., a patient needs to suffer from persistent intertrigo (a rash caused by skin-to-skin rubbing) for at least a year (or other serious functional impairment) before they are allowed surgery.

- BMI level should be increased / decreased.
- Suggested alternative criterion around the lifestyle the patient wishes to live.
- Omission of non-smokers but no consideration of alcohol / drug use.
- Current 500g considered a better criterion.

"There needs to be an alternative criterion around the lifestyle the patient wishes to live. For example: a) the patient is struggling to exercise due to breast pain despite using a supportive sports bra and boob buddy. b) the patient used to partake in certain activities/sports but due to breast growth (either following puberty or pregnancy) has found this more difficult."

Additionally, breast reduction was viewed by others as a type of cosmetic surgery, and/or not something that should be funded by the NHS.

Q Please explain your response (N=40)*

Support / positive comments	**No.**	**%**
Agree with criteria and fairness / accessibility for all	12	30%
Physical / mental health benefits (and associated costs for NHS)	6	15%
Acceptable if clinical need proven	3	8%
Acceptable if other interventions haven't worked	1	3%
Objections / further considerations	**No.**	**%**
Concern of accuracy of BMI as an indicator	11	28%
Disagreement with threshold criteria	8	20%
Seen as cosmetic / do not agree with NHS funding being used in this way	6	15%
Other comments	**No.**	**%**
Comment about personal experience	1	3%

**Due to the free text nature of this question, percentages do not equate to 100%.*

4.1.5 Clinical service - female sterilisation

This section of the survey was completed by 32 individuals. Overall, 44% strongly support and 19% support the proposed policy update for female sterilisation. In contrast, 25% oppose this change to some extent. This included individuals from:

- Castle Point Borough Council (N=2; 15%*)
- Brentwood Borough Council (N=2; 11%*)
- Basildon Borough Council (N=1; 2%*)
- Maldon District Council (N=1; 9%*)

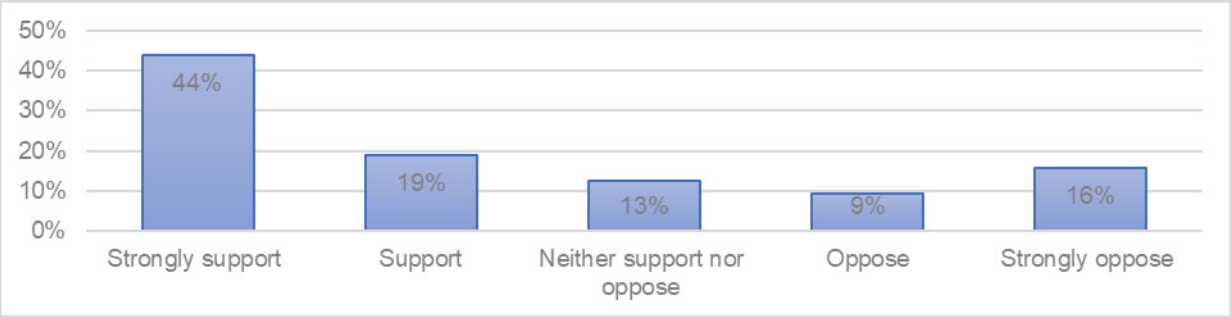
- Rochford District Council (N=1; 14%*)
- Chelmsford City Council (N=1; 3%*)

**Percentages shown as a proportion of respondents from this area.*

Q To what extent do you support or oppose the proposed policy update? (N=32)

Support or oppose	No.	%
Strongly support	14	44%
Support	6	19%
Neither support/oppose	4	13%
Oppose	3	9%
Strongly oppose	5	16%

Figure 5 To what extent do you support or oppose the proposed policy update? (N=32)



In support of the proposed policy update, respondents indicated their agreement with the criteria and how it enables fair access for all. Furthermore, others agreed with women's rights to choose this as a form of contraception.

"These policy updates will bring equality"

"Everyone should have a choice on their body."

In contrast, for those that opposed the update or felt that further thought was needed, concern was raised about the threshold criteria, in terms of:

- The BMI level being too high / patients being penalised for being overweight.
- BMI not being an accurate indicator of weight.
- Approval should be individual (not group).
- Disagreement with the criterion around Long-Acting Reversible Contraception (LARC) and patients having to have 'severe side effects'.
- Issue with criterion around capacity of patients.

- Feeling that there should be no caveats to a woman making decisions regarding her own body (i.e., counselling, consideration of vasectomy) / inequality with threshold criteria for vasectomy.
- Feeling that an additional exemption is required for women who are having to do this surgery without consultation with their partners (i.e., due to religious / cultural issues).

"I disagree about BMI limit, there are many reasons for increased BMI and in fact surely getting pregnant makes it a high risk one by default of mum is bigger. I also disagree that you aren't putting the same restrictions on male vasectomy."

"I oppose this due to the restrictions around LARC. What is considered 'severe side effects'? LARC, whilst reliable, are not found to be suitable by many women. Also, what is being put in place for women with a BMI of over 35?"

Furthermore, others felt that NHS funding should not be used in this way and/or female sterilisation is not a medical matter.

"There are alternative, less permanent measures that can be utilised. I have a real issue with this for patients who lack capacity. This should not be funded by the NHS although note likely to effect very small numbers of patients."

Q Please explain your response (N=30)*

Support / positive comments	**No.**	**%**
Agree with criteria and accessibility for all / fairer	8	27%
Agree with women's rights to choose this as a form of contraception	7	23%
Support for statement around capacity	2	7%
Objections / further considerations	**No.**	**%**
Disagreement with threshold criteria	8	27%
Do not agree with funding being used in this way / not a medical matter	5	17%
Objection: Relationships can fail with unfortunate consequences for future relationships for the other partner Oppose when used as a personal / lifestyle choice	2	7%
Other comments	**No.**	**%**
Other comment, including: Concern as to whether doctors will have the correct	3	10%

conversations with patients More information needed		

**Due to the free text nature of this question, percentages do not equate to 100%.*

4.1.6 Clinical service - vasectomy

This section of the survey was completed by 32 individuals. Overall, 56% strongly support and 16% support the proposed policy update for vasectomy. In contrast, 15% oppose this change to some extent. The latter included individuals from:

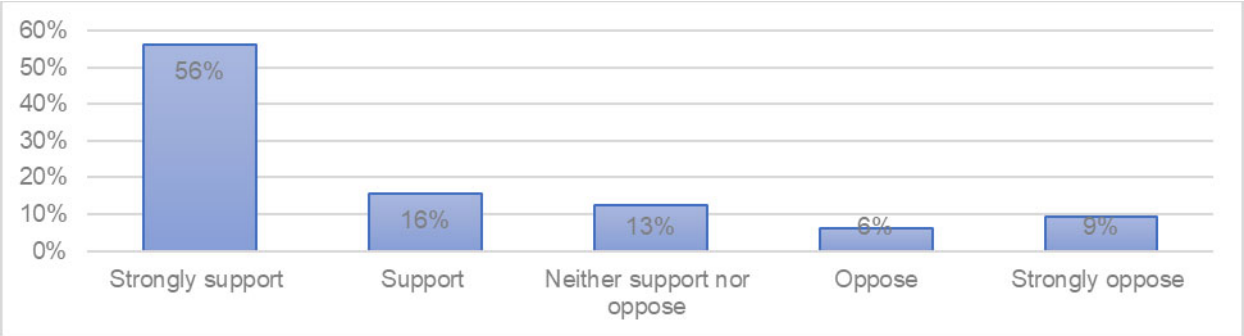
- Brentwood Borough Council (N=1; 5%*)
- Basildon Borough Council (N=1; 2%*)
- Castle Point Borough Council (N=1; 8%*)
- Southend-on-Sea City Council (N=1; 3%*)
- Chelmsford City Council (N=1; 3%*)

**Percentages shown as a proportion of respondents from this area.*

Q To what extent do you support or oppose the proposed policy update? (N=32)

Support or oppose	No.	%
Strongly support	18	56%
Support	5	16%
Neither support/oppose	4	13%
Oppose	2	6%
Strongly oppose	3	9%

Figure 6 To what extent do you support or oppose the proposed policy update? (N=32)



It was felt that the proposed policy update would make access fairer for all, with the current policy perceiving to go against the idea of gender-equitable family planning and acting as a 'postcode lottery' for residents.

"These services should be available to all across Mid and South Essex"

"All residents should access to the same service. It should not be a postcode lottery"

Others highlighted how vasectomy is a vital part of family planning, which allows men to take greater responsibility, and for some is a 'better option' than the female using contraceptives or undergoing sterilisation.

"My husband has been unable to access a vasectomy despite us having 5 children and not wanting to have anymore. I find it absurd that the funding is available for contraceptives for myself which have a detrimental effect on my health but there is no funding for a procedure that will have no negative effects on either of us."

For those that opposed the update or felt that further thought was needed, there was a feeling amongst some that NHS funding should not be used in this way.

"Once again can we really afford to give this treatment. Surely there are other more critical conditions that need the funding."

Several points for consideration were also raised with regards to the threshold criteria. These included:

- Referral for general anaesthetic should be individual approval, not group.
- Lack of consideration for those who may choose to have a general anaesthetic.
- Lack of mention of smoking / drugs / alcohol.

"Not considered 'why a patient might choose to want to have general' - anxiety? mental health issues? Should also be flexible to meet needs of people that may need support as above or if have disabilities with sensory issues."

A small number additionally considered it unfair how men do not have to undergo the same counselling processes as females pursuing sterilisation, with feeling that the criterion around this should be comparable.

"My husband has had a vasectomy and was subject to none of the counselling etc required for female sterilisation. This points to strong inequality in how men and women are considered to have ownership of this decision."

Q Please explain your response (N=30)*

Support / positive comments	**No.**	**%**
Agree with criteria and accessibility for all / fairer	11	37%
Allows men to have greater responsibility / better option for men	3	10%

to be sterilised		
Objections / further considerations	**No.**	**%**
Do not agree with NHS funding being used in this way / not a medical matter	5	17%
Disagreement with the threshold criteria	4	13%
Criteria should replicate that of female sterilisation i.e., counselling	2	7%
Other comments	**No.**	**%**
Other comment, including: Personal experience – not able to afford privately Local anaesthetic appropriate here	4	13%

**Due to the free text nature of this question, percentages do not equate to 100%.*

4.1.7 Clinical service - special fertility services

This section of the survey was completed by 154 individuals. Overall, 52% strongly support and 26% support the proposed policy update for special fertility services, whilst 2% neither oppose or support and 20% oppose it to some extent. The latter included individuals from:

- Southend-on-Sea City Council (N=5; 17%*)
- Chelmsford City Council (N=5; 15%*)
- Braintree District Council (N=4; 16%*)
- Brentwood Borough Council (N=4; 21%*)
- Basildon Borough Council (N=4; 8%*)
- Maldon District Council (N=4; 36%*)
- Rochford District Council (N=2; 29%*)
- Thurrock Council (N=1; 7%*)
- Other (N=1; 10%*)

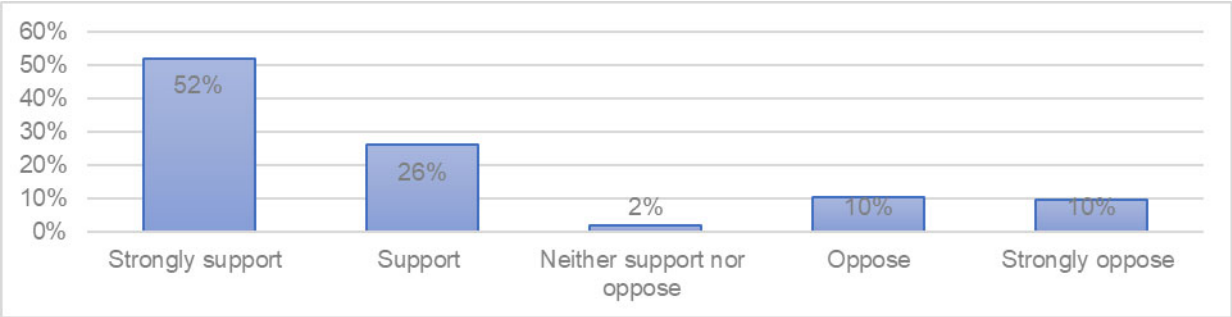
**Percentages shown as a proportion of respondents from this area.*

Q To what extent do you support or oppose the proposed policy update? (N=154)

Support or oppose	No.	%
Strongly support	80	52%
Support	40	26%
Neither support/oppose	3	2%

Oppose	16	10%
Strongly oppose	15	10%

Figure 7 To what extent do you support or oppose the proposed policy update? (N=154)



When asked to elaborate on their response, respondents expressed their agreement in providing equitable access for all residents and further providing greater opportunity for childless couples to have children.

> *"You pulled funding one year before my husband and I were told we required ICSI to conceive. Quite devastating for us. Although this policy change is too late for us, hopefully other couples will be helped!"*

> *"I have a very close friend who lives in Braintree and is currently having to pay thousands for IVF as no funded cycles are offered to her. She is going into debt to do this as her and her partner have been trying for over 10 years. It's heart-breaking to see them go through this and it would mean so, so much if they received NHS funding."*

> *"I feel everyone has the right to have children should they wish to and currently in the area it is only available to those who can conceive naturally or can afford to go privately. This has put extra stress and pressure on myself and my husband to try and save for private treatment especially in today's economic crisis."*

Others indicated how this policy currently affects them, or a member of their family, having been denied access to treatment and/or not being able to afford treatment privately.

> *"My partner and I tried for 2 years to have a baby without success. I am 35 years old and I am very concerned that I might need IVF and we won't be able to afford this without NHS funding."*

For those that opposed the update or felt that further thought was needed, disagreement with certain aspects of the threshold criteria was expressed. This included:

- Criterion around no living children in the current relationship / neither partner has children from previous relationships.
- Criterion around previously privately funded IVF cycles being considered within the total number of cycles offered by the ICB.
- Criterion around same sex couples having to have had six cycles of privately funded IUI.
- Age restriction of 40.
- Couples having to have a two-year period of infertility (suggestion that this should be less / one year).
- BMI being included as a criterion.

It was felt by these respondents that there is opportunity for the criteria to be more inclusive and provide more equitable access for same sex couples, single parents, blended families, and those who have accessed treatment privately.

"Privately funded prior IVF cycles should not count towards your entitlement."

"Appears unfair on same sex couples and people with children."

Further consideration was also felt to be needed in terms of the mental health support provided to couples throughout their journey, the number of IVF cycles offered and/or access for those who have experienced medical conditions earlier in life which have affected their fertility e.g., testicular cancer.

"It's a very overwhelming and emotional time for many, and there is not really any additional support or anyone to reach out to in this process."

"I have suffered with testicular cancer twice and am unable to have a baby naturally I therefore think I should be eligible for IVF."

Those who strongly objected to the proposed policy update felt that this is not a service that should be funded by the NHS.

Q Please explain your response (N=142)*

Support / positive comments	**No.**	**%**
Agree with accessibility for all / access shouldn't be a postcode lottery / important to ensure equality and fairness	70	49%
Affects my family / currently been denied / can't afford privately	5	4%
Objections / further considerations	**No.**	**%**
Disagreement with criterion re: no living children in the current relationship / neither partner has children from previous	17	12%

relationships		
Concerns about costs to the NHS / feeling that this is a non-essential service which should be privately funded	17	12%
Disagreement with criterion re: previously privately funded IVF cycles being considered within the total number of cycles offered by the ICB	12	8%
Disagreement with criterion re: same sex couples having to have had six cycles of privately funded IUI	9	6%
Mental health implications	8	6%
Two cycles of IVF is not sufficient / greater number required	7	5%
Disagreement with criterion – other, including: - Not inclusive enough - No mention of single parents - Full IVF cycle should include one egg collection and one fresh and frozen transfer	7	5%
Disagreement with BMI being used as a criterion	5	4%
Disagreement with age restriction of 40	5	4%
Disagreement with couples having to have a two-year period of infertility	4	3%
Consider support for those whose previous medical conditions have affected their fertility	3	2%
Other comments	**No.**	**%**
Other comments	5	4%

**Due to the free text nature of this question, percentages do not equate to 100%.*

4.1.8 Proposed policy update (general)

Survey respondents were given the option to select the clinical service areas that they wished to provide their views for or comment on the proposed policy update generally.

This section of the survey was completed by 12 individuals. Whilst six individuals either strongly supported or supported the policy update, four individuals oppose / strongly oppose them. Those in agreement felt the policy update would provide equitable access and promote fairness across the region.

> *"I believe that all patients should have the same choices since we have become one trust, but we still need to look at a patient as an individual"*

> *"Provision of NHS services should be harmonised nationally, there should be no difference in provision based on location."*

Those who oppose the policy update, felt strongly that NHS funding should not be used to provide these clinical services.

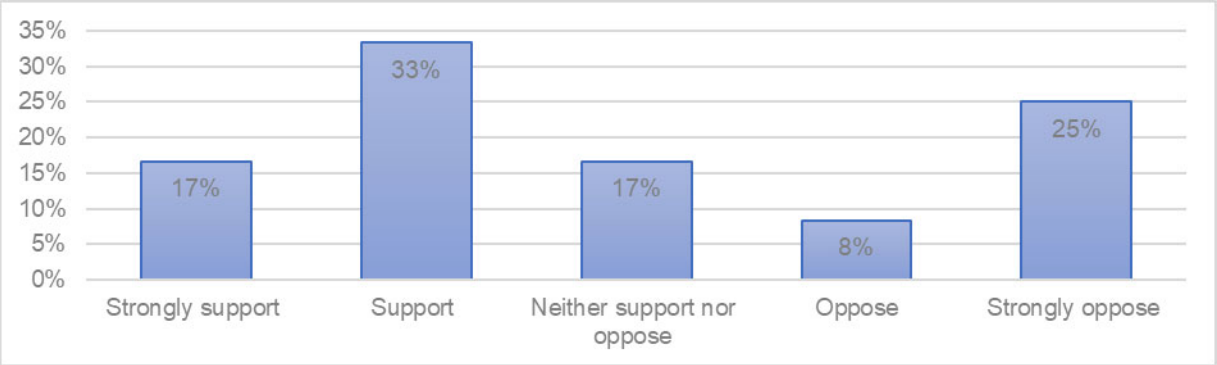
"With the NHS costing some £150 billion p.a. these types of services should be funded by the individual recipient."

"Concentrate on providing basic medical care i.e., hip/knee replacement, doctor appointments etc. Breast enlargement, reduction and alignment are vanity / cosmetic procedures and should be in the private sector."

Q To what extent do you support or oppose the proposed policy update? (N=12)

Support or oppose	No.	%
Strongly support	2	17%
Support	4	33%
Neither support/oppose	2	17%
Oppose	1	8%
Strongly oppose	3	25%

Figure 8 To what extent do you support or oppose the proposed policy update? (N=12)



Q Please explain your response (N=12)*

Comment	No.	%
Generally, in favour / agree with improving fairness and accessibility	7	58%
Should not be funded by NHS	3	25%
Other comment, including: More information needed about full funding	4	33%

Each patient must be looked at individually		

**Due to the free text nature of this question, percentages do not equate to 100%.*

4.1.9 Reviewing services (general)

In terms of reviewing these services, respondents were asked what they felt was important to them. The range of responses provided are shown in the table below with most commenting upon the importance of ensuring equitable access to these clinical services for all.

> *"For better equality for patients."*

> *"That all individuals are fairly treated despite relationship status, gender identity and sexuality."*

Furthermore, many comments were specifically made about the importance of providing equitable access to special fertility services, as well as disagreement / frustration with aspects of the proposed threshold criteria for this clinical service.

> *"Everyone gets the chance of having a child. It shouldn't matter that your postcode isn't right."*

> *"That all areas should be entitled to the same number of rounds and have the same criteria to qualify. Infertility is hard enough without having to worry about whether you are entitled to help or not and having to jump through endless hoops to get there."*

Specific comments about equality in access / the threshold criteria for the other clinical areas were also made, but to a lesser extent.

> *"For vasectomies to be funded fairly across Essex irrespective of district."*

> *"That you do not focus on obesity as being a disease that is self-inflicted because someone has eaten too many calories and is not exercising."*

Others felt it was important to consider the financial implications and ensuring best use of resources, the importance of patients' input, choice and communication, the mental and physical health implications and/or the time it will take to implement these changes.

> *"That NHS money is spent wisely on getting the waiting lists down for people who need medical care."*

> *"That there are not too many barriers, mental health appears not to be mentioned much."*

Comments were also made by some of the need to prioritise other 'essential' or 'basic' services such as primary care and access to GP appointments, cancer and

other health conditions that seriously affect the quality of life of individuals such as chronic pain and joint replacements.

"NHS is spending money on "luxury" services whilst failing to meet the needs of basic services."

"With reference to breast asymmetry, breast reductions and fertility treatment, unless any of these procedures are life-saving or represent value for money from future costs involved in NOT giving these procedures, they should be self-funded."

Q: What is important to you as we review these services? (N=191)*

Comment	No.	%
Accessibility and equality for all	69	36%
Service harmonisation / fairness – special fertility services	57	30%
Financial considerations / ensuring best use of resources	14	7%
Priority should be placed on essential services – cited clinical services should not be available on the NHS	14	7%
Importance of patients' input, choice, and communication	12	6%
Consideration of mental and physical health implications	10	5%
Waiting times / implementation of changes	7	4%
Service harmonisation / fairness – bariatric surgery	5	3%
Service harmonisation / fairness – vasectomy	3	2%
Everything / all valuable services	2	1%
Service harmonisation / fairness – breast reduction	2	1%
Other, including: If treatment to be paid for, make it affordable Systems should not be burdensome to clinicians nor divert from patient care	16	8%

**Due to the free text nature of this question, percentages do not equate to 100%.*

4.1.10 Additional paper response received

A late paper response to the consultation was received from an individual residing within Thurrock Council. This individual indicated that they might be affected by this policy in the future.

The individual was aged 65-74, White British and identified as a heterosexual woman. They stated having a physical or mental health condition / illness lasting or expected to last 12 months or more, and how this impacts a little on their day-to-day activities. In terms of financial status, they stated that they have more than enough money for basic necessities and a little spare that they can save or spend on extras or leisure'.

Their views on the different clinical areas are captured here.

Bariatric surgery - support

The respondent noted how the run up to this type of surgery would be intense and stressful for patients, with regard to the weight loss criterion.

Breast asymmetry - neither support nor oppose

The respondent is not affected by this policy but understands how stressful this would be for individuals going through this.

Breast reduction - strongly support

The respondent has seen the impact of this problem and believes it is necessary.

Female sterilisation - strongly support

The respondent agrees that women should have the right to choose but feels the pre-surgery programme should be *'correctly geared up for ease of use when people are completely sure of using this option'.*

Vasectomy - strongly support

The respondent feels that people should have the right to choose this and that this is effective in supporting population control.

IVF - neither support nor oppose

The respondent stated how this is a tough progress to go through '*in any version*'.

Overall, the respondent felt it would be good to have the same policies covering Mid and South Essex.

4.2 Feedback from the public events and focus groups

The following summarises the feedback from the public events and focus groups, in which twenty individuals were engaged with.

Some individuals had specific experience of the clinical areas - vasectomy, special fertility services, female sterilisation, and bariatric surgery.

Equality monitoring data collected from the individuals who attended the public events can be found in Section 3.3.

Table 1 Public events and focus groups

Public events dates	Location	No. of attendees
9th November 2022	Greys	0
10th November 2022	Witham	1
22nd November 2022	Basildon	1
24th November 2022	Southend	0
30th November 2022	Online	5

Focus groups	Detail	No. of attendees
21st November 2022	Microsoft Teams conversation	1
22nd November 2022	Online Men's Focus Group	10
15th December 2022	Bariatric Focus Group	1
15th December 2022	LGBT Mummies Group	1*
Total		**20**

**Participant presented collated feedback on behalf of the group.*

Overall, attendees were generally supportive of the proposed policy update. However, several queries and points for further considerations were raised generally, as well as specifically for the different clinical services. The greatest challenges were raised about special fertility services.

4.2.1 Proposed policy update – general comments / queries

Comments / queries raised about the policy update in general, included:

- What has the reaction been to the proposals so far? Has there been any feedback that has made you rethink?
- What are the financial implications of making these changes, and will this impact on the delivery of other services?
- Should every policy reflect co-morbidities?
- Are there plans to harmonise any other services across MSE? E.g., micro suction (ear syringing) considering the evidence that links this with cognitive ability / Alzheimer's Disease.
- What are the implications for the wider ICS area?

Further consideration was felt to be needed with regards to:

- The impact that these policies / health areas have on patients' mental health, as well as that of their partners and families.
- Communication of these policy changes among primary care colleagues.

4.2.2 Clinical service - bariatric surgery

One individual discussed their personal experience of bariatric surgery. Following a personal tragedy, this individual described how their weight gain '*went out of control*'. Despite successful attempts at losing weight, the individual was never able to maintain their weight loss. The individual described how their weight not only affected their physical health but their mental health and wellbeing.

The individual was referred for surgery by their GP and informed of an expectation to lose 10% of their excess weight. This caused concern for the individual as they were worried that losing the weight whilst waiting for surgery, might '*go against them*'.

Once accepted for surgery, the individual discussed the difficulties and frustrations they faced in terms attending their pre-operative appointments, with all of these being undertaken at a hospital in London (Homerton).

> *"If you miss an appointment or don't turn up, you're incidentally struck off. But the service cancelled without any prior notice which is really frustrating especially when you've taken time off work and bought travel tickets."*

The individual was therefore supportive of the proposed policy update and having services closer to home.

> *"Everything needed to be done at Homerton – ECG, blood tests, they could have been done closer to home."*

The importance of providing care closer to home was reinforced by individuals from the Bariatric Support Group who also stressed the difficulties they faced travelling to London for tests / procedures, particularly when there was a requirement for them to be accompanied.

> *"Only really need to go to Homerton to see surgeon and have op everything else could have been done locally."*

Despite pre-operative psychiatric assessments, the individual who shared their experience noted how they were not prepared for the changes to their body shape that would result from the surgery and the impact that this would have on her mental health and confidence. Although feeling in good physical health, their excess skin has led to sores and depression, affecting their ability to form personal relationships.

When considering the policy updates for bariatric surgery, several considerations were therefore raised:

- The need for greater flexibility for accessing the local weight management pathway / services e.g., appointment times to cater for those in full-time employment and/or with children.
- Ability for patients to access local services for pre-operative appointments / assessments to avoid them having to travel to London / Homerton.

- Provision of surgery to remove excess skin, and for this not to be viewed as a cosmetic procedure.

4.2.3 Clinical service - breast reduction

One individual, who lives in Witham, discussed their personal experience of seeking breast reduction surgery. Over the last nine years, this individual has requested surgery four times and was advised, during her latest consultation with her GP in 2022, that she would be referred but it would likely be rejected. The individual has sought advice privately but the cost of £7,000 for the surgery makes it inaccessible.

The individual discussed the negative impact that her condition has on her mental health.

Although the individual supports the proposed policy update and the funding that will now be available for patients in Mid Essex, she expressed concern that the threshold criteria will restrict and discriminate against some. It was therefore felt that greater flexibility is needed when considering the specific needs of each patient, including size / frame, mental health, neurodiversity, and the impact on existing health issues such as hiatus hernia and/or asthma.

> *"All of these [clinical areas] do need a process of some sort to balance but they do not reflect the individual. Everyone should get a fair trial and not try to be fixed into a box."*

Additionally, it was noted how '*going without a bra*' is not an option for some women with large breasts, and therefore the criterion around skin rashes is not applicable, and furthermore how there should be an option for part payment or income-based test to fund treatment.

Another individual additionally highlighted the importance of taking patients' mental and physical wellbeing into account, with it further questioned whether the changes would mean fewer people will qualify for the service.

4.2.4 Clinical service – vasectomy

The participants in the online men's focus group supported the proposed policy update for this clinical area.

4.2.5 Clinical service - female sterilisation

It was queried as to what will happen in circumstances where one partner wants to be sterilised, but their partner doesn't want them to have the procedure.

4.2.6 Clinical service - special fertility services

Special fertility services were discussed by a small number with experience of accessing these services through the NHS and privately. This included a

representative from LGBT Mummies Group and from the MSE Maternity and Neonatal Voices Partnership. The discussion with this representative was also recorded in a letter they sent after the discussion and this report draws on the record of the discussion and the letter.

Several concerns about the policy update were raised by these individuals, which would result in potential areas of inequalities and discrimination. It was therefore strongly felt that these need to be considered to help avoid further implications, including legal action.

> *"I would strongly suggest you reconsider the provision you have put forward and undertake a more in-depth review, to result in a more inclusive and fair approach, and to negate additional cost, legal issues and possible reputational risk which could lead to MSE being vilified in the press, and those communities being discriminated against seeking legal action on MSE."*

A summary of these issues / concerns is documented here:

- Concern was raised about the impact that the policy update will have on those who have self-funded IVF in the past, with it was questioned as to how this will be policed and what it will mean for those who have gone abroad for treatment. It was suggested that couples who have sought private provision in the past should be disregarded so that they can still access NHS service provision.

> *"If I wasn't pregnant now, I would still be unable to access IVF as I've had to go private as there were no other options for me and my partner for the past 7 years. This is unfair because if I had had an MRI privately and needed further MRI/treatment this would be possible. This does not happen for any other service access."*

If this criterion is to remain, the importance of managing communications around these changes was stressed.

- With current statistics showing that between 42-48% of parents are divorced, the policy update was felt to discriminate against infertile couples with children from previous relationships impacting on eligibility.
- The update was recognised to omit trans and non-binary people.
- The lack of access for single people and gay dads was felt to be discriminatory, although recognised as an issue that sits with NICE guidance.
- There was concern that the update which removes IUI funding completely does not follow national guidance as outlined in the Women's Health Strategy, and directly impacts on those requiring sperm donation.

Furthermore, the implications for those who have better fertility and may wish to have something less invasive, as well as those who may have medical conditions, meaning they can't undergo IVF, or are victims of domestic / sexual abuse who may not wish to have IVF due to how traumatic it could be, were discussed. Although IUI may have a lower success rate than IVF, it was noted how the procedure is less invasive, more cost effective and can be provided to any couple who in many cases may just need support with timing and some additional medical intervention to support a pregnancy.

"In my case we require donor sperm due to male factor infertility. The offering is for two rounds of IVF, yet I understood it's one vial of donor sperm. It sounds as though it means that someone in my circumstance would be directly impacted and not able to obtain the second round?"

- It was questioned why reciprocal IVF is not included, despite current laws that the UK are governed by stating that the partner of a same sex couple undergoing egg collection within a reciprocal IVF cycle is screened, tested and legally viewed as a 'Donor' of the egg.

"…therefore, if viewed as a Donor by law, why would MSE not provide same sex couples with the opportunity to have Reciprocal IVF as part of their funding? The 'Donor' of the egg may be part of the coupling, but by law are viewed as a Donor, therefore should also have access to egg donation - therefore Reciprocal IVF should then be offered. If not, then this would appear discriminatory based on sexual orientation, and we know this will create further division and shine a spotlight on MSE as a discriminatory Trust."

- In terms of embryos, questions were asked as to:
    - where these will be stored?
    - who claims of ownership of them?
    - who takes care of the cost while treatment is commencing, and once a pregnancy results who then incurs that cost? Furthermore, if no pregnancy happens, who pays for them to be stored?
- The proposal of two rounds of funded IVF for those aged 23-39 years and then one round for those aged 40-42 was noted to '*still fall short*' of the national guidelines of three rounds. Furthermore, it was felt to make no logical sense with evidence suggesting that those of advanced maternal age are at greater risk of lower pregnancy outcomes. To avoid age discrimination, it was suggested that the older age group should have equal access, if not greater access to improve success.
- There was concern that the proposed one sperm vial per round might cause implications should someone only create one embryo in one round.

"… therefore you as a Trust would have to purchase more sperm for the next attempt, the donor could retire, be bought up and no longer be available, and the couple would then have to find a new donor, and could cause serious delays, which could result in them not then meeting the criteria to access funding moving forward and the possibility of them being able to privately purchase additional vials for further siblings not be viable either - something Donor Conceived children stress is vital for them to be genetically related to their siblings if possible."

- In offering fertility treatment to those of advanced maternal age, it is felt that genetic testing must be considered to ensure embryos transferred are not abnormal. It was noted that by not offering this, there will be very real human implications and the cost of which to the NHS in support, care, time, salaries will by far exceed the cost of the testing, should MSE provide the testing.
- The BMI guidance of 30 and under was felt to be discriminatory against larger bodied women and people who wish to start a family but are being stopped due to their size. Furthermore, it was noted how certain health conditions such as endometriosis, prevent individuals from losing weight.

"They are being denied the funding to start their family, yet others who can try naturally, are not stopped from doing so? We are acutely aware that being of a larger BMI can impact & increase the risk of miscarriage & loss, however a further discussion is needed on this subject."

- Although the inclusion of same sex couples was felt to be a positive, it is argued that the vision for same sex couples to have to undergo up to six privately funded rounds of fertility treatment before being considered by MSE for fertility funding goes against the changes that have been brought in through the Women's Health Strategy, which addresses the inequalities and discriminatory access for same sex couples.
- Under the new proposals, some patients who weren't eligible for IVF treatment will now be. There is concern that if the proposals don't go ahead, the hopes of these patients will be dashed.

"I am pleased that this could happen for us. But what if the proposals don't go through and I'm not eligible, I'll feel let down and it's tough to mentally deal with that chance to be taken away again."

- Recognising the lack of mental health support provided to individuals on their fertility journey, it was felt imperative that this is considered, in addition to providing support to those who are not eligible to receive fertility treatment.

"If you were given a cancer diagnosis you would get a McMillian [sic] leaflet and signposting."

“Two rounds is very positive, but signposting is needed if there is negative news.”

- Questions were asked as to how MSE will prioritise who gets access first and whether this will this be based on time entering the system or by need? Furthermore, it was asked as to whether individuals from the two areas who haven’t been able to access special fertility services will be fast tracked for treatment.

“Two areas that haven’t has access to services for years need to be able to access quicker.”

- It was suggested that the proposals should consider surrogacy as an option.
- It is thought that the longer-term care implications for IVF patients must be considered, as patients receiving this type of treatment need more care / appointments with babies often needing longer-term care.
- It is thought that training is required for doctors and hospital staff to help improve knowledge and confidence, including greater awareness of genetic conditions that affect fertility.
- There was felt to be a lack of focus on male fertility within the document.
- It is thought that the terminology used in the document is confusing.

4.3 Equality and monitoring data for survey respondents / public event attendees

Survey respondents (N=210)

Public event attendees (N=7)

Age	No.	%	No.	%
16 to 24	1	0%	-	-
25 to 34	64	30%	1	14%
35 to 34	55	26%	2	29%
45 to 54	26	12%	-	-
55 to 64	24	11%	-	-
65 to 74	17	8%	1	14%
75 to 84	4	2%	-	-
85 and over	0	0%	-	-
Prefer not to say	20	9%	3	43%
Currently pregnant / been pregnant in last year	**No.**	**%**	**No.**	**%**
Yes	29	14%	-	-
No	138	65%	4	57%
Not applicable	20	9%	-	-
Prefer not to say	24	11%	3	43%
Ethnic group or background	**No.**	**%**	**No.**	**%**
White - English, Welsh, Scottish, Northern Irish or British	173	82%	3	43%
White - Irish	2	1%	-	-
Mixed or multiple ethnic groups - White and Black African	1	0%	-	-
Mixed or multiple ethnic groups - White and Asian	1	0%	-	-
Asian or British Asian - Indian	2	1%	-	-
Asian or British Asian - Pakistani	1	0%	-	-
Asian or British Asian - Chinese	1	0%	-	-
Black, Black British Caribbean or African - Caribbean	-	-	1	14%
Black, Black British Caribbean or African - African	3	1%	-	-
Arab	1	0%	-	-
Other	4	2%	-	-

Prefer not to say	22	10%	3	43%
Sexual orientation	**No.**	**%**	**No.**	**%**
Heterosexual or straight	175	83%	4	57%
Bisexual	8	4%	-	-
Gay or lesbian	2	1%	-	-
Prefer not to say	26	12%	3	43%
Gender identity match gender assigned at birth	**No.**	**%**	**No.**	**%**
Yes	184	87%	4	57%
No	2	1%	-	-
Prefer not to say	25	12%	3	43%
Identity	**No.**	**%**	**No.**	**%**
Woman (including trans woman)	166	79%	3	43%
Man (including trans man)	20	9%	1	14%
Non-binary	1	0%	-	-
Prefer not to say	24	11%	3	43%
Religion	**No.**	**%**	**No.**	**%**
Buddhist	1	0%	-	-
Christian	93	44%	2	29%
Jewish	1	0%	-	-
Muslim	1	0%	-	-
No religion	79	37%	2	29%
Other	6	3%	-	-
Prefer not to say	30	14%	3	43%
Main language	**No.**	**%**	**No.**	**%**
English	191	91%	4	57%
Prefer not to say	20	9%	3	43%
Physical / mental health conditions or illnesses lasting or expected to last 12 months or more	**No.**	**%**	**No.**	**%**
Yes	54	26%	4	57%
No	135	64%	-	-
Prefer not to say	22	10%	3	43%
Condition(s)/illness(es) reduce your ability to carry out day-to-day activities*	**No.**	**%**	**No.**	**%**
Yes, a lot	9	17%	-	-

Yes, a little	28	52%	-	-
No	16	30%	-	-
Prefer not to say	1	2%	-	-
Current financial situation	**No.**	**%**	**No.**	**%**
I have more than enough money for basic necessities, and a lot spare, that I can save or spend on extras or leisure	12	6%	2	29%
I have more than enough money for basic necessities, and a little spare, that I can save or spend on extras or leisure	98	46%	-	-
I have just enough money for basic necessities and little else	51	24%	-	-
I don't have enough money for basic necessities and sometimes or often run out of money	10	5%	-	-
Not known	1	0%	-	-
Prefer not to say	39	18%	5	71%

**Percentages calculated as a proportion of those who answered that they have a physical / mental health condition.*

5 Health Overview and Scrutiny Committees (HOSCs)

The ICB presented information about the public consultation to three health scrutiny committees.

1.5.1 On 3 November 2022 they presented a written update on the public consultation (Agenda item 6) **to Essex Health Overview Policy and Scrutiny Committee**.

The minutes state:

Committee received the report as written, with a further, verbal update, to be provided at the committee's February 2023 meeting.

1.5.2 On 3 November 2022 they presented information about the public consultation (Item 13) to **Thurrock Health and Wellbeing Overview and Scrutiny Committee**.

The minutes state:

> *RESOLVED*
>
> *1. The Health and Wellbeing Overview and Scrutiny Committee noted this update and supported the promotion of the consultation.*
>
> *2. Agreed to receive the analysis of public consultation at a future meeting.*

1.5.3 On 29 November the ICB presented information to **Southend People Committee**, under which health scrutiny falls (Item 7).

The minutes state:

> *Resolved:*
>
> *1. That the proposals of the Mid and South Essex Integrated Care Board (ICB) for the harmonisation of the provision of the service areas presented to the Committee, be noted.*
>
> *2. That the Committee support the promotion of the consultation on the harmonisation of service delivery by the ICB.*
>
> *3. That the ICB present an analysis of the results of public consultation with regard to the service harmonisation proposals, to a future meeting of the Committee.*

6 Miscellaneous responses

In addition to the survey responses and events/focus groups, 27 emails were received about the consultation. Many of these dealt with practical details such as online links not working, queries about being involved in focus groups and information about how the survey link had been passed on or requests to be able to pass it on.

An email was received from the South Essex Director of Social Services, asking whether any discussion had been held with the other two ICSs as equity across the whole of Essex would be the aim. This was responded to with detail about discussions that are in process.

An email was received from an individual who did not have confidence in the process of consultation based on previous experience. The response detailed how NHS Mid and South Essex ICB is committed to considering all comments from residents and stated that discussions are taking place in public.

7 Appendices

The Appendices are available as separate documents.

7.1 Appendix 1 – Consultation document

7.2 Appendix 2 – Survey questions

7.3 Appendix 3 – Consultation document – Easy Read