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NHS
Cheshire and Merseyside

Appendix One

Subfertility Clinical Policy

Options Appraisal for harmonisation of

In vitro fertilisation (IVF) cycles

Glossary

Term	Definition
In vitro fertilisation (IVF)	A full cycle of IVF (with or without ICSI) is defined as one episode of ovarian stimulation and the transfer of all resultant fresh and/or frozen embryo(s). If there are any remaining frozen embryos, the cycle is only deemed to have ended when all these embryos have been used up or if a pregnancy leading to a live birth occurs or the patient adopts a child (i.e. in accordance with the ICB's policy on "Childlessness").
Embryo	A fertilised egg.
Egg collection	As part of the IVF cycle, eggs are collected from the womb. The collection involves attempts to retrieve all eggs within the stimulated follicles in the ovary.
Embryo transfer	After egg collection, the embryos are transferred into the womb. The best quality embryo available is transferred.
Frozen embryo transfer (FET)	Treatment involves freezing and storing embryos, the embryo(s) is warmed and transferred into the womb.
Intra-cytoplasmic sperm injections (ICSI)	Intra-cytoplasmic sperm injection. A common treatment for sperm-related male infertility. It is performed as part of IVF and involves the sperm being injected directly into the egg.
Intrauterine insemination (IUI)	Sperm is put directly into the womb when the female is ovulating. This can also be called artificial insemination.

1. Background

On formation of the Integrated Care Board (ICB), clinical policies were inherited from across the 9 places. This meant that patients had different access to services and care, based on their postcode. The Reducing Unwarranted Variation programme set out to harmonise this approach to ensure we work to address health inequalities and provide a consistent offer across Cheshire and Merseyside.

The NHS faces significant financial challenges, necessitating careful balancing of population needs, clinical risk, and commissioning decisions to address health inequalities. This paper is written in the context of ensuring commissioning decisions prioritise the most pressing needs of the population, recognising the potential for increased demand in areas like mental health, urgent care and community services, whilst addressing unwarranted variation and the need for a consistent offer.

At present each Place within NHS Cheshire and Merseyside (C&M) ICB has a separate unharmonised fertility policy and therefore unwarranted variation in access to these services exists.

The main area of variation within the policies is the number of In vitro fertilisation (IVF) cycles offered which ranges from 1 to 3 cycles. This document focuses on the options to harmonise IVF cycles. It is of note that other aspects within the policy are proposed to be harmonised in accordance with the latest available NICE guidance and local clinical and operational knowledge.

The scope of this policy is for patients with health-related fertility issues, who are struggling to have a live birth and require fertility treatments. This policy has been reviewed in line with the latest evidence base and NICE guideline CG156; it is important to note that this will be an interim policy until the new NICE guidance is published when a broader review of subfertility and assisted conception will be undertaken.

NICE recommends offering patients with infertility 3 cycles of IVF. The cost of this would equate to a total spend for the ICB of £5.78m. (The current spend is £5.043m so there would be an additional annual spend of circa £734k).

Due to the financial constraints of the ICB and the need to prioritise commissioning decisions and funding against the most critical needs, it is important that all options are considered which may not always result in adherence to guidance including NICE recommendations.

1.1 National Policy Position:

Nationally there is variation in the number of IVF rounds offered.

The table below shows the number of ICBs offering 1, 2 or 3 cycles excluding C&M:

CYCLES	No. ICBs	%
1	27	66%
2	7	17%
3	3	7%
Currently unharmonised position under review	4	10%

Source: ICB websites (March 2025)

It is important to note that the majority of neighbouring ICBs offer 1 IVF cycle, with the only exception Greater Manchester. Following a similar review undertaken, colleagues in GM are working up a proposal and plan for Public Consultation following discussion planned at their Board meeting in May.

- Lancashire and South Cumbria offer 1 IVF cycle.
- Greater Manchester is currently under review - varies from 1 to 3.
- West Yorkshire offer 1 IVF cycle.
- Staffordshire and Stoke-on-Trent offer 1 IVF cycle.

1.2 Current C&M Position

There are currently 10 subfertility policies across C&M. Depending on where the patient lives, will determine the number of IVF cycles that they are eligible for, the number of cycles range from 1 – 3. Below is the current offer:

Place / Legacy CCG	Offer
Liverpool	2 cycles (additional cycle available via an IFR)
St Helens	2 cycles
Warrington	3 cycles
Southport & Formby	3 cycles

South Sefton	3 cycles
Halton	3 cycles
Knowsley	3 cycles
Wirral	2 cycles
Cheshire East	1 cycle
Cheshire West	2 cycles (Unless IUI has been undertaken, then 1 cycle)*

*This document discusses IVF cycles; it does not include IUI cycles as activity is minimal.

Within Cheshire and Merseyside, we only have one provider for IVF, The Hewitt Fertility Centre at Liverpool Women's Hospital. Previously and until September 2023, Care Fertility provided fertility treatment for some of our Cheshire based patients at the Countess of Chester Hospital. Historic activity data from both sites has been used to model the proposal.

1.3 Current activity levels with cost to NHS C&M

This table below shows the month 7 activity and the forecast outturn for 2024/2025 activity.

		Based on LWH's Month 7 2024/25 actual position, forecasted to year-end using agreed				
	IVF		**FET**		**Total**	
Sub ICB Location	Actvity	Spend	Activity	Spend	Activity	Spend
Southport & Formby	48	£ 231,494	5	£ 6,227	53	£ 237,721
South Sefton	87	£ 415,617	9	£ 10,378	96	£ 425,995
Liverpool	322	£ 1,559,470	56	£ 68,497	378	£ 1,627,967
Knowsley	72	£ 350,088	14	£ 16,605	86	£ 366,694
Halton	39	£ 189,913	9	£ 10,378	48	£ 200,291
St Helens	46	£ 225,057	8	£ 10,378	54	£ 235,435
Warrington	51	£ 242,471	12	£ 14,530	63	£ 257,001
Cheshire E	101	£ 492,606	27	£ 32,185	128	£ 524,792
Cheshire W	115	£ 555,761	30	£ 36,311	145	£ 592,073
Wirral	117	£ 566,810	7	£ 8,303	124	£ 575,113
TOTAL	**998**	**£ 4,829,289**	**177**	**£ 213,793**	**1175**	**£ 5,043,081**

(Please note BI data still represents former CCG allocations and therefore Cheshire data is not split out into Cheshire East and Cheshire West. In the above table this split has been modelled based on previous years' activity as provided by LWH and Care Fertility).

2. Approach

As part of the CPH programme, a subfertility working group was convened to review the current policies and support the harmonisation. This multi-disciplinary working group included Secondary care local fertility specialists, GPs, health watch colleagues, commissioners, Equality & Diversity colleague and policy development specialists. The group reviewed each of the policy positions within the current policies and made recommendations in line with evidence base to shape the proposed policy, the policy has also been reviewed by the Clinical Network and feedback has been considered. A summary of these and the changes can be found in **Appendix 1.1**.

The data used is the 2024/25-month 7 activity reported by SLAM and the remainder of the year forecast outturn. The reason for using this data set is because the month 7 position will be used as the basis for the 2025/26 forecast and activity plan for LWH. The data provided is non patient identifiable, therefore, modelling has been carried out by C&M BI Team to determine the current allocation of first, and where applicable second and third cycles with the support and validation from operational and finance staff at LWH. The data modelling is available upon request by the Board.

Based on the data modelling an options appraisal process considered a do-nothing option, 1 cycle, 2 cycle and 3 cycle options. A do-nothing option was not supported by the group, this is because this would leave C&M in an unharmonised position and unwarranted variation would remain.

A 3-cycle option was also not supported by the group, this is because our data shows that 2 cycles would support majority of patients, and harmonising to 2 cycles would enable equity of access whilst maintaining current activity levels; a 3-cycle option would increase activity levels and which would impact LWH capacity to deliver and increase the annual cost of funding this service.

An Equality Impact Assessment and Quality Impact Assessment have been completed for the recommended option of 2 cycles and a 1 cycle option. This is to consider the impact on patients with protected characteristics and patient safety and experience.

2.1 Clinical effectiveness of IVF cycles

NICE Health Economics analysis describes the effectiveness of each cycle with regard to cumulative live birth rate and shows that whilst the chances of having a live birth increase with each cycle, the effectiveness and cost effectiveness of each cycle is reduced.

For example, in the case of an average 34-year-old, the 1st cycle is c 30% effective, the 2nd cycle is c 15% and the 3rd cycle is less than 10% effective.

2.2 Activity data and options modelling

To determine the average number of cycles and frozen embryo transfers (FET) each patient receives, historical data from Care Fertility and LWH has been used. This data along with outcome information and Tariff detail (as described in the table below) has been used to model the options with validation undertaken by LWH operational and finance teams.

An IVF cycle is deemed complete when all quality embryos have been transferred. The IVF cycle tariff allows for one fresh and one frozen embryo transfer, with any remaining required FET being charged at the subsequent FET tariff.

	IVF cycles	**Subsequent FETs**
Number (average)	1.36	1.88 (All frozen transfers)
Tariff	£4,862.34	£1,210.80

Based on the 2024/25 actuals and forecast, data has been extrapolated from those Places already providing 3 cycles to enable options to be modelled across all C&M Places based on %s of activity for each cycle:

- Percentage of patients receiving 1 cycle: 64%
- Percentage of patients receiving 2 cycles: 23%
- Percentage of patients receiving 3 cycles: 13%

2.3 Modelling of IVF cycles and FETs

Baseline – current unharmonised position

Sub ICB Location	1 cycle		2 cycle		3 cycle		Total	
	IVF	FET	IVF	FET	IVF	FET	IVF	FET
Southport & Formby	31	3	11	1	6	1	48	5
South Sefton	56	6	21	2	11	1	88	9
Liverpool	236	41	86	15	0	0	322	57
Knowsley	46	9	17	3	9	2	72	14
Halton	25	6	9	2	5	1	39	9
St Helens	34	6	12	2	0	0	46	8
Warrington	33	8	12	3	6	1	51	12
Cheshire E	101	27	0	0	0	0	101	27
Cheshire W	84	22	31	8	0	0	115	30
Wirral	85	5	31	2	0	0	116	7
TOTAL	**731**	**133**	**230**	**38**	**37**	**6**	**998**	**178**

1 cycle

The table below shows the modelled activity data if NHS C&M were to offer 1 cycle of IVF.

Sub ICB Location	1 Cycle		2 cycle		3 Cycle		Total	
	IVF	FET	IVF	FET	IVF	FET	IVF	FET
Southport & Formby	31	3	0	0	0	0	31	3
South Sefton	56	6	0	0	0	0	56	6
Liverpool	236	41	0	0	0	0	236	41
Knowsley	46	9	0	0	0	0	46	9
Halton	25	6	0	0	0	0	25	6
St Helens	34	6	0	0	0	0	34	6
Warrington	33	8	0	0	0	0	33	8
Cheshire E	101	27	0	0	0	0	101	27
Cheshire W	84	22	0	0	0	0	84	22
Wirral	85	5	0	0	0	0	85	5
TOTAL	**731**	**132**	**0**	**0**	**0**	**0**	**731**	**132**
Difference in activity (to baseline)							**-267**	**-46**

2 cycles

The table below shows the modelled activity data if NHS C&M were to offer 2 cycles of IVF.

Sub ICB Location	1 Cycle		2 cycle		3 Cycle		Total	
	IVF	FET	IVF	FET	IVF	FET	IVF	FET
Southport & Formby	31	3	11	2	0	0	42	5
South Sefton	56	6	21	2	0	0	77	8
Liverpool	236	41	86	16	0	0	322	57
Knowsley	46	9	17	3	0	0	63	12
Halton	25	6	10	2	0	0	35	8
St Helens	34	6	12	3	0	0	46	9
Warrington	33	8	12	3	0	0	45	11
Cheshire E	101	27	37	9	0	0	138	36
Cheshire W	84	22	31	8	0	0	115	30
Wirral	85	5	32	2	0	0	117	7
TOTAL	**731**	**132**	**269**	**50**	**0**	**0**	**1000**	**182**
Difference in activity (to baseline)							**2**	**4**

3 cycles

The table below shows the modelled activity data if NHS C&M were to offer 3 cycles of IVF.

	1 Cycle		2 cycle		3 Cycle		Total	
Sub ICB Location	**IVF**	**FET**	**IVF**	**FET**	**IVF**	**FET**	**IVF**	**FET**
Southport & Formby	31	3	11	2	6	0	48	5
South Sefton	56	6	21	2	10	1	87	9
Liverpool	236	41	86	16	44	7	366	64
Knowsley	46	9	17	3	9	2	72	14
Halton	25	6	10	2	4	1	39	9
St Helens	34	6	12	3	7	1	53	10
Warrington	33	8	12	3	6	1	51	12
Cheshire E	101	27	37	9	19	5	157	41
Cheshire W	84	22	31	8	15	4	130	34
Wirral	85	5	32	2	15	1	132	8
TOTAL	**731**	**132**	**269**	**50**	**135**	**23**	**1135**	**205**
Difference in activity (to baseline)							**137**	**27**

2.4 Guiding Principles

- To reduce unwarranted variation and harmonise access to services across Cheshire and Merseyside.
- Use the latest evidence base to develop harmonised policies.
- Consider sustainability of Cheshire and Merseyside ICB in context of financial requirements.

2.5 Strategic Context

The harmonisation of the policies and in particular IVF cycles meets the “Tackling health inequality, improving outcomes and access to services” and ‘Enhancing productivity and value for money’ strategic objectives:

Objective 1	
Objective	Tackling health inequality, improving outcomes and access to services
Current Arrangement	Inequity in the number of IVF cycles offered across C&M. Places currently offer either 1, 2 or 3 cycles and therefore there is unwarranted variation. There is a reputational risk, as we are one organisation, but patients are not being treated equitably, which is a risk to quality.
Gap/Business Needs	To harmonise the IVF rounds offered within the NHS C&M subfertility policy.

Objective 2	
Objective	Enhancing Productivity and Value for Money
Current Arrangement	Inequity in the number of IVF cycles offered across C&M. Places currently offer either 1, 2 or 3 cycles and therefore there is unwarranted variation.
Gap/Business Needs	To harmonise the IVF rounds offered within the NHS C&M subfertility policy whilst maintaining existing levels of activity and cost to support our Providers to continue to deliver against their operational plans.

3 Options and considerations:

Option	Description	Outcome	EIA feedback	QIA feedback	Financial impact
1	Do nothing • ***Discounted option***	This is not a viable option as this would leave the ICB and its patients with an unharmonised position and therefore unwarranted variation in access to fertility services.	Not completed	Not completed	**£5,043,081 per year**
2	NHS C&M offer patients 1 round of IVF treatment. • ***Executive Committee preferred option***	This option would disadvantage a cohort of patients who require additional cycles to have a live birth, as the average number of cycles that our patients have is 1.36. Clinically this is not supported due to the benefits in being able to take the learnings from an unsuccessful first cycle to improve chances of success in a second cycle. Whilst this option will reduce the cost of this service to the ICB, it is not supportive of NICE recommendation and would attract negative publicity. A public consultation exercise would be required in 8 Places.	The number of cycles does not affect protected characteristics. This option will affect those patients and families who are on a low income, if the patient does not have a successful live birth following a single round of IVF, they would have to self-fund to try again. This may mean they cannot have a biological child. **See Appendix 1.1 for EIA.**	There would be a negative impact for patients who are currently eligible for either 2 or 3 cycles. Without additional attempts at subsequent IVF cycles, there is a risk that patients would be detrimentally impacted and may not be able to have a biological child if they cannot afford to privately fund. Data shows the average number of IVF cycles that our patients are having is 1.36. Therefore, there is a risk that if those patients are not successful in the first IVF round, they would be disadvantaged by not being able to try a different approach in the second cycle. Knowledge is gained from the first cycle such as optimum dose of stimulation and best methods used for fertilisation. These are then implemented for subsequent attempts. **See Appendix 1.2 for QIA** **Overall risk rating: 16 (High)**	This would result in an estimated cost of **£3,728,347 per year.** Comparing this to the current position, this would result in estimated **savings of £1,315,732 per year.** (This cost includes the modelled cost of additional FETs – on average patients have an additional 1.88 FETs)

3	NHS C&M offer patients 2 rounds of IVF treatment. • ***Clinical Working Group Preferred Option***	This option is the preferred clinical option and is supported by the data that patients are having an average of 1.36 IVF cycles. Knowledge is gained from the first cycle such as optimum dose of stimulation and best methods used for fertilisation. These are then implemented for subsequent attempts. A public consultation would be required in 4 Places.	The number of cycles does not affect protected characteristics. **See Appendix 1.3 for EIA.**	According to the data analysis allowing 2 cycles of IVF would benefit the majority of patients, with the average number of IVF cycles being 1.36. Because the estimated number of 2nd IVF cycles for Cheshire East is equal to the existing number of 3rd cycles in Sefton, Knowsley, Warrington and Halton, the number of FETs is assumed to be the same based on this average. Once harmonised, this will mean that there is a consistent equitable offer for patients accessing subfertility treatments. See **Appendix 1.4** for QIA **Overall risk rating: 4 (Moderate)**	This would result in an estimated cost of **£5,084,437.** Comparing this to the current position, this would result in an estimated **cost increase of £40,357 per year.** (This cost includes the modelled cost of additional FETs – on average patients have an additional 1.88 FETs)
4	NHS C&M offer patients 3 rounds of IVF treatment. • ***Unsupported option***	This option is not supported because data suggests that the average number of IVF rounds is 1.36. Also, this option would require additional funding of over c.£734k pa and therefore does not support the ICB to meet its financial objectives.	The number of cycles does not affect protected characteristics.	Not completed as not supported.	This would result in an estimated cost of **£5,778,295.** Comparing this to the current position, this would result in an estimated **cost increase of £734,217 per year.**

3.4 Risks, Constraints & Dependencies

The following risks, constraints and dependencies have been highlighted as part of the development of the case for change.

Risks

The following risks have been identified:

Risk	Mitigating actions
Option 2: There is a risk of challenge during the public consultation from those patients in Knowsley, Halton, Warrington, Southport & Formby and South Sefton where currently 3 cycles are offered, and Liverpool, Wirral, Cheshire West and St Helens where currently 2 cycles are offered. If we reduce the number of cycles to 1, patients living in these Places may feel disadvantaged	There is an option to submit an Individual Funding Request if the patient could demonstrate clinical exceptionality. It should be noted however, that Liverpool Place have a policy of 2 cycles and 3 if clinical exceptionality is evidenced and there have been no instances of a 3rd IVF round approved. Whilst not a mitigation for these patients, reducing the IVF offer to 1 cycle would support the ICB to deliver savings in support of the financial challenge, and ensure that we can continue to provide this treatment across the whole of Cheshire and Merseyside
Option 2: If C&M ICB offers patients 1 cycle of IVF there is a risk that LWH would not receive enough income and therefore would not be sustainable as a Provider	This option would reduce LWH income by between £1m - £1.5m. A small element of this may be mitigated by planned productivity initiatives but would leave a deficit.
Option 3: There is a risk of challenge during the public consultation from those patients in Knowsley, Halton, Warrington, Southport & Formby and South Sefton where currently 3 cycles are offered, If we reduce the number of cycles to 2, patients living in these Places may feel disadvantaged.	C&M data shows that the average number of cycles patients have is 1.36, so the option to move to 2 cycles would support the majority of our patients. There is an option to submit an Individual Funding Request if the patient could demonstrate clinical exceptionality. It should be noted however, that Liverpool Place have a policy of 2 cycles and 3 if clinical exceptionality is evidenced and there have been no instances of a 3rd IVF round approved.
Option 3: There is a risk that unknown activity in non C&M Providers may mean that there is a significant number of CE patients having treatment out of area, due to geographical location.	Because of historic data reporting, we know that under £70,000 was spent in Cheshire with Greater Manchester providers. Assuming all of these are Cheshire E patients, there would be an estimated number of 4 patients requiring a 2nd cycle – Which would cost around £20k.
Option 3: If C&M ICB offers patients 2 IVF cycles, there is a risk that there will be increased activity levels for our provider Liverpool Women's Hospital. This increase will come from patients in Cheshire East who currently are eligible to 1 cycle. This would potentially increase waiting lists for treatment and will have a negative effect on women aged 40 and over, who are eligible for 1 cycle and may miss out on treatment due to a longer wait.	Offering 2 cycles of IVF for C&M patients will mean reducing the offer in Warrington, Halton, Sefton and Knowsley where patients are currently eligible for 3 cycles. Our data shows that the number of patients having 3 cycles per year and the estimated number of Cheshire East patients having a second cycle would result in minimal change to the activity levels and therefore minimal risk of introducing patient waiting lists. Patients in Cheshire East will sometimes choose to have their treatment in one of the Greater Manchester Trusts due to locality, so it is not expected that all of the estimated increased activity fall wholly on LWH.
All Options: Data from our providers has been used to inform the recommendations regarding the number of IVF cycles. There is a risk that this data may not be accurate as it is not patient identifiable – and is therefore based on averages.	To make for a richer data set, data has been collated and validated with LWH and Care Fertility. This will give a more accurate understanding of both Cheshire patients and Mersey patients. The options have been modelled using month 7 actuals with forecast end of year outturn for 2024/25 using SLAM data and verified by LWH finance and operational team.

Constraints

- The review is being undertaken in context of the reducing unwarranted variation recovery programme and the current financial climate.
- Due to the significance of the change, a public consultation exercise would be required in Cheshire and Merseyside to support either proposal to harmonise to one or two IVF cycles. In addition, it would be necessary to engage and consult with the Health Oversight and Scrutiny Committees in all affected Places for them to determine if this proposal is a significant development or variation. If so, a joint OSC would need to be formed. The availability and timing would largely be dictated by the Local Authorities, this would impact the timing of benefits delivery.
- Engagement/communication would also be required with local MPs.
- Consideration is needed regarding any delays to benefits delivery caused by the potential for 'call in' to the Secretary of State for Health & Care of any proposed service change – members of the public or organisations can write to the Secretary of State at any stage of the process.

Dependencies

- NHS C&M's communications and engagement team are currently focused on a number of pieces of public involvement work. Any public involvement requirements around IVF cycles will need to be considered alongside existing work plans.

4 Options Appraisal

For completeness, a range of options have been considered as part of the case for change, a brief description of the options, including subsequent actions required for Options 2, 3 or 4 is below:

Option 1: Do nothing (Option discounted)

Pros	Cons
• There would be no change in the ICB financial position.	• This would leave NHS C&M with an unharmonised position, patients would continue to have unequal access to IVF rounds. • There is an increased risk of challenge by Equalities and Human Rights commission re inequality in service access.

Option 2: Offer patients 1 cycle of IVF

Pros	Cons
• This offer is in line with most of our neighbouring ICBs offer. • Offering 1 cycle provides the greatest financial savings opportunity. • 661% of ICBs across the country offer 1 cycle.	• Data shows that the average number of cycles patients require is 1.36. Therefore offering 1 cycle would disadvantage patients who require an additional cycle. If the first cycle is not successful, observation and learnings are used to inform the second cycle in order to increase the potential for a successful live birth. This is especially relevant as patients are becoming more complex, are older, have comorbidities which affect their fertility or are under time pressure (e.g. fertility preservation). Although it is of note that patients could choose to fund this privately.

	• Risk of negative publicity for the ICB in those places that currently offer 2 or 3 cycles - patients will be generally dissatisfied, and this may result in an increase of complaints, therefore more time will need to be allocated to respond to these. • Patients on low income in 8 Places could be disadvantaged as they either receive 2 or 3 cycles currently, and if they fail to have a live birth in the first cycle, they would be required to self-fund which may not be financially possible. • A public consultation exercise would need to be held within 8 Places which would impact the time taken to implement and could be costly. • Does not match current NICE guidance of three cycles. • There is a sustained decline in birth rates across Cheshire and Merseyside. The OECD identifies a replacement fertility rate of 2.1 children per woman as necessary to maintain population levels. ONS data shows that the total fertility rate in C&M has been in consistence decline since 2021, falling to 1.49 in 2022. This trend presents significant long-term risks to the region's workforce and the sustainability of health and social services. Therefore, a reduction in cycles will undermine efforts to support population health and long-term system planning. • There is a risk on the mental health impact that childlessness has on couples, research shows that this is coupled with grief, depression and emotional stress which can impact on quality of life, this can be expected to increase. • Reducing NHS IVF cycles will potentially increase cost elsewhere as more patients will turn to cheaper IVF options in other countries with less regulation and potentially increasing the rates of multiple pregnancies, leading to maternal and neonatal morbidity and placing a greater financial and clinical burden on the NHS services downstream. • Data shows that 1 cycle of treatment (with subsequent FET's) gives a 56% chance of a live birth whereas with 2 cycles couples have a cumulative 68% chance of a live birth.

Option 3: Offer patients 2 cycles of IVF

Pros	Cons
• The average number of cycles patients currently have is 1.36, therefore the proposal of 2 cycles of IVF would support these findings and would enable learning to be taken from the first cycle and a different approach to be used for the second cycle with an aim to improving success. • Offering 2 cycles would be a positive for Cheshire East patients, as currently they are eligible for 1 cycle. • This option is supported by all clinicians including the Obs & Gynae clinical network and LWH Finance and Operational teams who will deliver the service.	• Patients in the 4 Places who offer 3 cycles, particularly if on low income, may feel they are disadvantaged by a reduction in the IVF cycle offer and this may generate negative publicity for the ICB. • A public consultation exercise would need to be held within 4 Places which would impact the time taken to implement. • Does not match current NICE guidance of three cycles, (NICE data shows that whilst the effectiveness of each cycle with regard to cumulative live birth rate increases with each cycle the effectiveness of each cycle is reduced). Our data modelling showing the average number of cycles per patient is 1.36. • This offer is higher than the national average (71% offering 1 cycle), our neighbouring ICB Cumbria and Lancashire offer patients 1 cycle of IVF. (Greater Manchester are in the process of harmonising their cycles offer). This would mean there is continued variation in access to subfertility services within the Northwest region and surrounding areas.

Option 4: Offer patients 3 cycles of IVF (Option discounted)

Pros	Cons
• Often if the first cycles are not successful, learnings are taken from this, and a different approach is used for the second and third cycles with an aim to improving success. • Offering 3 cycles would be a positive for Cheshire East, Cheshire West, Liverpool, St Helens and Wirral patients, currently they are eligible for 1 or 2 cycles. • A public involvement exercise could be a light touch communication approach. • Meets current NICE guidance, NICE data shows that whilst the effectiveness of each cycle with regard to cumulative live birth rate increases with each cycle, the effectiveness of each cycle is reduced.	• This offer is higher than our neighbouring ICB, Cumbria and Lancashire who offer 1 cycle. (Greater Manchester are in the process of harmonising their cycles offer). • This offer is higher than the country average, with 71% of ICBs offering 1 cycle. • This results in estimated additional cost to the ICB of £734k pa • The average number of cycles patients currently have is 1.36, therefore this option does not support data findings.

5.1 Financial Case

Options	Description (*Committed costs)	Recurrent cost annual	Comments
Option 1: Do nothing – Variation would remain in the number of IVF cycles offered across C&M	£5,043,081	£5,043,081	
Option 2: Offer patients 1 cycle of IVF across C&M	N/A	£3,728,347	This would result in estimated savings of £1,315,732 per year.
Option 3: Offer patients 2 cycles of IVF across C&M	N/A	£5,084,437	This would result in an estimated cost increase of £40,357 per year**.**
Option 3: Offer patients 3 cycles of IVF across C&M	N/A	£5,778,295	This would result in an estimated cost increase of £734,217 per year.

Annexes

Annex 1.1 **EIA for 1 IVF Cycle option**
Annex 1.2 **QIA for 1 IVF Cycle option (post panel review)**
Annex 1.3 **EIA for 2 IVF Cycles option**
Annex 1.5 **QIA for 2 Cycles option**

NHS
Cheshire and Merseyside

ANNEX 1.1

Equality Analysis Report

Pre-Consultation *(Use the same form but delete as applicable. If it is post-consultation it needs to include consultation feedback and results)*

C&M Wide

Start Date:	19/08/24	
Equality and Inclusion Service Signature and Date:	Nicky Griffiths	
Sign off should be in line with the relevant ICB's Operational Scheme of Delegation (*amend below as appropriate)		
***Place/ ICB Officer Signature and Date:**		
***Finish Date:**		
***Senior Manager Sign Off Signature and Date**		
***Committee Date:**		

1. Details of service / function:
Guidance Notes: Clearly identify the function & give details of relevant service provision and or commissioning milestones (review, specification change, consultation, procurement) and timescales.
This change concerns the number of IVF cycles within a harmonised sub-fertility policy. There is currently disparity across Cheshire and Merseyside on the number of IVF cycles offered as part of the sub-fertility policies: 1 cycle - Cheshire East 2 cycles – Liverpool, St Helens, Wirral, Cheshire West 3 cycles – Warrington, Southport & Formby, South Sefton, Halton, Knowsley The clinical policy harmonisation programme undertook an exercise to harmonise the number of cycles, and a working group set up to work through this. The working group proposed 1 or 2 cycles. Our data shows that the average number of cycles patients are currently having is 1.36. Following creation of the recovery programme, the review had to consider costing up both 1 and 2 cycles. This EIA considers the impact of a 1 IVF cycle policy.
What is the **legitimate aim** of the service change / redesign For example • Demographic needs and changing patient needs are changing because of an ageing population. • To increase choice of patients • Value for Money-more efficient service • Public feedback/ Consultation shows need/ no need for a service • Outside commissioning remit of ICB/NHS

- To ensure a harmonised approach across Cheshire and Merseyside for the number of IVF cycles offered within the sub-fertility policy.
- To ensure the ICB have had the opportunity to consider the risk and impact of reducing the number of IVF cycles to 1 across Cheshire and Merseyside in light of the current financial challenge.

2. Change to service.

To harmonise the number of IVF cycles across C&M – see above for current.

This EIA considers reducing to 1 cycle as there is a potential financial saving of @£1.2m

In addition, there are a number of other changes proposed to the policy to bring it in line with the latest evidence base including:

- The minimum age (23 years) has been removed as NICE no longer supports this.
- "Before the woman's 42nd birthday" has been changed to "before the woman's 43rd birthday" because this is consistent with NICE. NICE withdrew the recommendation for minimum age (23 years) in 2004, together with the increase of the upper age limit to forty-three.
- Some narrative has been changed to improve clarity and accuracy.
- The definition of childness confirms that any biological or adopted child would mean ineligibility for the policy.
- The right to a family has been confirmed to mean that once the patient has a successful live birth (baby has reached 12 months) they are no longer eligible for further treatment. This is only a change to E&W Cheshire whose current policy implies the patient can continue using the frozen embryos.
- BMI recommendations based on NICE guidance for women. Female partners will be required to achieve a BMI of 19-29.9 kg/m² before subfertility treatment begins. Women outside this range can still undergo investigations, but subfertility treatment will not commence until their BMI is within this range.
- Female and Male Smoking Status – The proposal is that both partners (i.e. female and/or male) should be confirmed non-smokers to access any subfertility treatment and must continue to be non-smoking throughout treatment. Providers should seek evidence from referrers and confirmation from patients. Providers should also include this undertaking on the consent form and ask patients to acknowledge that smoking could result in cessation of treatment. *Smoking increases the risk of infertility in women and men. Nicotine alone is known to affect development of the foetus and long-term safety data on e-cigarettes are unknown. Because of these concerns and issues, all forms of smoking (which includes cigarettes, e-cigarettes or NRT) are not permitted. Both partners are now included in the smoking restriction, and this is consistent with NICE guidance. The change to specify both partners and to include Nicotine Replacements could potentially result in a small number of patients being refused treatment. The change regarding Nicotine replacement is in relation to East and West Cheshire. Guidance states that all smoking and NRT can be harmful, including secondary smoking. This is **a change** in policy.
- Female and Male Drugs & Alcohol intake – Proposal: Male and female partners will be asked to give an assurance that their alcohol intake is within Department of Health guidelines, and they are not using recreational drugs. Any evidence to the contrary may trigger a pause in treatment with possible referral for a welfare of the child assessment and/or further information sought from the GP. The current Mersey policy applies to the person who is receiving treatment only whereas the other policies apply

to all partners whether they are receiving treatment or not. In addition, the evidence-based policy has been expanded to included situations where the clinician might have concerns about a potential alcohol/drug misuser and if this could have implications for the welfare of the child. This means that there is **some change**.

- Intra-uterine Insemination (IUI) / Donor Insemination (DI) – the position in Mersey policies will be introduced to Cheshire (change to number of cycles required before IVF) and Wirral (not routinely commissioned).
- Overseas Visitors eligibility for NHS- funded IVF treatment – a new section has been added to confirm the position for those patients applying for treatment if they are not ordinarily resident in the UK. The policy states that where a non-resident wishes to access IVF, they should be charged 150% of the National NHS tariff (or locally agreed price where applicable). IVF treatment charges should be made in advance of any treatment being given.
  If care is deemed an emergency by the Fertility Consultant, the provider and ICB can enter a risk share scheme and split 50% of the costs each. This is **a change** as is it an addition to the proposed policy but not a change to patient access as it reflects the existing process.

3. Barriers relevant to the protected characteristics

Guidance note: describe where there are potential disadvantages.

[ENTER RESPONSE HERE]

[COMPLETE DIFFERENTIAL MATRIX]

Protected Characteristic	Issue	Remedy/Mitigation
Age	• The minimum age (23 years) has been removed as NICE no longer supports this. • "Before the woman's 42nd birthday" has been changed to "before the woman's 43rd birthday" because this is consistent with NICE. NICE withdrew the recommendation for minimum age (23 years) in 2004, together with the increase of the upper age limit to forty-three. • Some narrative has been changed to improve clarity and accuracy**.** • Overall, this will result in a positive impact due to clarity and NICE evidence-based age guidelines, including the removal of the minimum age of twenty-three requirement, therefore widening access. *All age guidance is based on the evidence of successful fertility treatment. The changes proposed will mean a positive impact.	No action as this brings the policy in line with NICE guidance. This is a positive impact for patients and will increase the eligibility criteria for those patients under 23 and those over 42.

Protected Characteristic	Issue	Remedy/Mitigation
Disability (you may need to discern types)	The policy will have a positive impact on people who may have a disability as defined in the PSED / Equality Act 2010. This is because the policy has been designed so that fertility treatment is made available to those who have a medical condition and, or undergoing treatment that impacts on fertility. Treatment for cancer or other procedures which affect fertility are considered thoroughly within the policy. Cryopreservation of embryos, oocytes or semen is routinely commissioned before treatments or procedure (e.g. for cancer or other medically essential interventions such as a surgical procedure and/or administration of medication) which are known to affect fertility. This will be performed in accordance with the Human Fertilisation and Embryology Authority (HFEA) regulations and NICE guideline CG 156. Patients must satisfy the prevalent subfertility criteria when the time comes to use this stored material, and they must have been informed of this requirement before commencing cryopreservation. The cryopreserved material may be stored for 10 years or up to the female partner's 43rd birthday, whichever comes sooner. The ICB will ensure that communication needs are considered and factored into the Engagement and Consultation work.	No action
Gender reassignment	Eligibility for this treatment is that the patient must have a clinical reason for sub-fertility. Therefore, the policy is not inclusive for people who are proposing to undergo, or who are undergoing, or who have undergone gender reassignment. The policy is not clear, for example, where a male partner who has undergone gender realignment would be required to evidence subfertility if requesting fertility treatment (sperm donation) with a female partner. The policy needs to make clear the organisations position so that patients and staff have clear guidance. The proposed policy is an	This is an interim policy in order to harmonise the number of IVF rounds. Revised guidance is expected 2025 so the wider issues within the policy will be reviewed in a separate project.

Protected Characteristic	Issue	Remedy/Mitigation
	interim position because there is an expectation that NICE guidance will be reviewed and potentially could impact the stance the ICB propose on wider eligibility.	
Marriage and Civil Partnership	This group received protection under the Equality Act with regards to the main Equality Duty and it does not extend to service provision. The policy does not discriminate between marriage of either the opposite or same sex or Civil Partnerships. The policy does not have any criteria related to marital status and therefore this group is not a specific target for the Engagement and Consultation plan.	No action
Pregnancy and maternity	Key factors in the proposed policy regarding pregnancy and maternity include the storage periods and discontinuation of treatment after a live birth and the definition of childlessness. The Engagement and Consultation plan proposes to work with a range of groups including the Hewitt Fertility Centre. The HFC have also been represented on the working group.	Public consultation will take place once the ICB have approved an option, and comms will be provided to articulate the changes to the policy a part of this process.
Race	The working group considered the higher rates of Infant Mortality within the Black, Asian and other Ethnic groups. This factor was considered when agreeing that the proposed timescales for storage after a live birth would be 12 months. This is a positive impact. The policy proposal is - In accordance with the policy on “Childlessness”, the ICB will not fund storage of embryos and/or gametes following a live birth (or adoption of a child). However, the ICB will fund up to 12 months’ storage following the birth or adoption of a child to give the patient enough time to	The ICB will ensure that cultural sensitivities and language needs are considered and factored into the Engagement and Consultation work.

Protected Characteristic	Issue	Remedy/Mitigation
	decide whether they wish to self-fund, donate the stored material or consent to having any remaining gametes or embryos destroyed. However, the policy on “storage following a live birth” (above) also applies following a live birth (or adoption) and the patient is then permitted the 12 months’ period, beyond which NHS funding is no longer available.	
Religion and belief	Whilst there is a neutral impact in relation to the policy proposed, the ICB will ensure that religious and cultural sensitivities are considered and factored into the Engagement and Consultation work.	
Sex	The revision and harmonisation of the policy will result in a fairer, consistent, and clearer Subfertility policy across Cheshire and Merseyside. This will mean that couples accessing Fertility services will no longer be faced with disparity across the region. The policy has in the main been brought up to date with the best and latest guidance, NICE guidance CG 156. The harmonisation of the policy may mean that in some areas the number of cycles is increased, whilst in other areas they are reduced. This is unavoidable in ensuring equity. Both male and female patients will benefit from the clarity of position within the new policy. IVF Definition & Number of Cycles - The four policies are very similar but differ in terms of the number of cycles permitted. The definition of “IVF cycle” has been reviewed and is now more in line with NICE. The upper age limit has	Public engagement / consultation will take place once the ICB have approved progression of an option, and comms will be provided to articulate the changes to the policy a part of this process. This is an interim policy in order to harmonise the number of IVF rounds. Revised guidance is expected 2025 so the wider issues within the policy will be reviewed in a separate project.

Protected Characteristic	Issue	Remedy/Mitigation
	been increased to forty-three and the lower age limit of twenty-three has been removed. However, the ICB will need to agree its policy on the maximum number of permitted cycles which currently ranges from 1 to 3 cycles according to Place. For women aged <40, this option considers the maximum permitted cycles to be 1. The working group agreed that 1 or 2 cycles is appropriate. For information, over 90% of ICBs in England only permit two cycles (71% allow only one cycle). With regard to weight, the proposed policy now includes a statement that male partners with a BMI of over 30 should be informed that they are likely to have reduced fertility and should be encouraged to lose weight as this will improve their chances of a successful conception. Because this policy is the interim sub-fertility policy and eligibility is based on a clinical reason for sub-fertility, there is no change to provision for single sex couples therefore it may be that the policy disadvantages these patients as they have to self-fund some or all of the procedure.	
Sexual orientation	Because this policy is the interim sub-fertility policy and eligibility is based on a clinical reason for sub-fertility, there is no change to provision for single sex couples therefore it may be that the policy disadvantages these patients as they have to self-fund some or all of the procedure.	Public engagement / consultation will take place once the ICB have approved progression of an option, and comms will be provided to articulate the changes to the policy a part of this process
Whilst currently out of scope of Equality legislation it is also important to consider issues relating to socioeconomic status to ensure that any change proposal does not widen health inequalities. Socioeconomic status includes factors such as social exclusion and deprivation, including those associated with geographical distinctions (e.g. the North/South divide, urban versus rural). *Examples of groups to consider include:*		

Protected Characteristic	Issue	Remedy/Mitigation
refugees and asylum seekers, migrant, unaccompanied child asylum seekers, looked-after children/ care leavers, homeless people, prisoners and young offenders, veterans, people who live in deprived areas, People living in remote, and rural locations. *Health inclusion groups* *https://www.england.nhs.uk/about/equality/equality-hub/national-healthcare-inequalities-improvement-programme/what-are-healthcare-inequalities/inclusion-health-groups/* *For a more in-depth assessment of health inequalities please use the HEAT toolkit* https://www.gov.uk/government/publications/health-equity-assessment-tool-heat		
Refugees and asylum seekers	No impact	
Looked after children and care leavers	No impact	
Homelessness	No impact	
Worklessness	No impact	
People who live in deprived areas	No impact	
Carers	No impact	
Young carers	No impact	
People living in remote, rural and island locations	No impact	
People with poor literacy or health Literacy	No impact	
People involved in the criminal justice system: offenders in prison/on probation, ex-offenders.	No impact	
Sex workers	No impact	
People or families on a low income	If the patient does not have a successful live birth following a single IVF round, they would have to self-fund to try again. This may disadvantage those on a low income if they could not afford to self-fund as this may mean they cannot have a biological child.	Public engagement / consultation will take place once the ICB have approved progression of an option, and comms will be provided to articulate the changes to the policy a part of this process.
People with addictions and/or substance misuse issues	The proposed policy states that patients must demonstrate that their alcohol limits are within department of health guidelines and that they don't use recreational drugs. This is in line with	Public engagement / consultation will take place once the ICB have approved progression of an option, and comms will be provided to

Protected Characteristic	Issue	Remedy/Mitigation
	both the existing Mersey policy and NICE guidance. Technically those patients who have addictions could be disadvantaged by this clause, however, there is a safeguarding aspect to children in this environment.	articulate the changes to the policy a part of this process.
SEND / LD	No impact	
Digital exclusion	No impact	

4. What data sources have you used and considered in developing the assessment?

There has been extensive research carried out in the development of this policy. The Communication and Engagement plan will further inform the policy development. The policy has been written by a Public Health professional in conjunction with the Policy Harmonisation Steering Group and an Assisted Conception Working Group.

Key evidence includes the following:

- The main objectives of the Policy Harmonisation Group were to harmonise the policy positions across the region and to maintain consistency with the current NICE clinical guideline (CG 156) on fertility. The working group are aware that NICE are revising CG 156 which is due for publication in 2025. Because this represents a major revision, the ICB will review its policy again following publication of the revised CG 156.
  This policy has drawn on guidance issued by the Department of Health, Infertility Network UK and the NICE guidance (CG156) first published in February 2013 (updated in September 2017).
- https://fertilitynetworkuk.org/ & https://www.nice.org.uk/guidance/cg156/evidence/full-guideline-pdf-188539453https://www.nice.org.uk/guidance/cg156
- https://www.nice.org.uk/guidance/cg156/evidence/full-guideline-pdf-188539453 https://www.gov.uk/government/policies/reducing-drugs-misuse-and-dependence
- https://www.gov.uk/government/policies/reducing-harmful-drinking https://www.hfea.gov.uk/about-us/our-campaign-to-reduce-multiple-births/
- http://www.oneatatime.org.uk
- http://www.hfea.gov.uk/6195.html
- http://www.sexualhealthnetwork.co.uk/media/documents/HIV
- NHS cost recovery - overseas visitors - GOV.UK (www.gov.uk)

5. Involvement: consultation/ engagement

Guidance note: How have the groups and individuals been consulted with? What level of engagement took place? (If you have a consultation plan insert link or cut/paste highlights)

Once the options appraisal has been considered and a decision made on the number of IVF cycles, a public engagement / consultation exercise will be undertaken.

6. Have you identified any key gaps in service or potential risks that need to be mitigated

Guidance note: Ensure you have action for who will monitor progress.

Ensure smart action plan embeds recommendations and actions in Consultation, review, specification, inform provider, procurement activity, future consultation activity, inform other relevant organisations (NHS England, Local Authority).
This is an interim subfertility policy which aims to harmonise the C&M policies in line with NICE guidance and to harmonise the number of IVF cycles. There are other areas which are currently harmonised across C&M, and in line with guidance that haven't been addressed e.g. single sex assisted conception. Revised NICE guidance is expected in 2025 and the aim is to carry out a wider review at this time.

Risk	Required Action	By Who/ When
If the option of 1 IVF cycle round is approved, there is a risk of adverse publicity and a reputational risk for the ICB due to the reduction in access. This change impacts 8 of the 9 Places so negative feedback is likely.	A public engagement exercise will be carried out and messaging will be particularly important. It is worth noting that our neighbouring ICBs in the main offer 1 cycle.	Project Team supported by Comms
If option of 1 IVF cycle is accepted, patients who rely on that second cycle of IVF to have a biological baby will not be eligible. Therefore, we would be disadvantaging these patients. Patients in all Places except Cheshire East would be impacted by this option.	A public engagement exercise will be carried out and messaging will be particularly important. It is worth noting that our neighbouring ICBs in the main offer 1 cycle.	Project Team supported by Comms
Planned activity data from 2024/2025 for Liverpool Women's Hospital (LWH) has been used to model the financial impact on the number of cycles offered, there is a risk that the data may not be 100% accurate as it is not patient identifiable – therefore is based on assumptions and averages.	This planned activity data has been modelled up to predict the number of IVF cycles and fertility treatments that LWH should complete in 2024/25.	Project Team

7. Is there evidence that the Public Sector Equality Duties will be met (give details) Section 149: Public Sector Equality Duty (review all objectives and relevant sub sections)
PSED Objective 1: Eliminate discrimination, victimisation, harassment and any unlawful conduct that is prohibited under this act: (check specifically sections 19, 20 and 29)
PSED Objective 2: Advance Equality of opportunity. (check Objective 2 subsection 3 below and consider section 4)
Analysis post consultation
PSED Objective 2: Section 3. sub-section a) remove or minimise disadvantages suffered by people who share a relevant protected characteristic that are connected to that characteristic.
Analysis post consultation
PSED Objective 2: Section 3. sub-section b) take steps to meet the needs of people who share a relevant protected characteristic that are different from the needs of people who do not share it
Analysis post consultation
PSED Objective 2: Section 3. sub-section c) encourage people who share a relevant protected characteristic to participate in public life or in any other activity in which participation by such people is disproportionately low.
Analysis post consultation
PSED Objective 3: Foster good relations between persons who share a relevant protected characteristic and persons who do not share it. (consider whether this is engaged. If engaged consider how the project tackles prejudice and promotes understanding -between the protected characteristics)
Analysis post consultation
Health Inequalities: Have regard to the need to reduce inequalities between patients in access to health services and the outcomes achieved (s.14T);
[ENTER RESPONSE HERE]
PSED Section 2: Consider and make recommendation regards implementing PSED in to the commissioning process and service specification to any potential bidder/service provider (private/ public/charity sector)
Analysis post consultation
8. Recommendation to Board
Guidance Note: will PSED be met?
[ENTER RESPONSE HERE]
9. Actions that need to be taken
[ENTER RESPONSE HERE]

Annex 1.2 Quality Impact Assessment

NHS Cheshire and Merseyside

QUALITY IMPACT ASSESSMENT			
Project/Proposal Name	Unwarranted Variation Recovery Programme – Subfertility policy option 1 IVF round	Date of completion	06/05/2025
Programme Manager	Katie Bromley	Clinical Lead	Rowan Pritchard Jones

Background and overview of the proposals (can be copied from PID on Verto or from National/Regional commissioning guidance)

The Subfertility policy was included in the scope of the Clinical Policy Harmonisation programme, as currently each Place has its own policy and there is variation in access to these services across Cheshire and Merseyside. The Clinical Policy Harmonisation programme used an evidence-based approach to develop harmonised policies. There is currently disparity across Cheshire and Merseyside on the number of IVF rounds offered as part of the sub-fertility policies:
1 cycle - Cheshire East
2 cycles – Liverpool, St Helens, Wirral, Cheshire West
3 cycles – Warrington, Southport & Formby, South Sefton, Halton, Knowsley
The clinical policy harmonisation programme undertook an exercise to harmonise the number of cycles and a working group was set up to work through this. The working group proposed 1 or 2 cycles, an options appraisal is being undertaken to explore offering patients either 1 or 2 cycles of IVF.

Whilst NICE specifies 3 cycles should be offered, their Health Economics analysis describes the effectiveness of each cycle with regard to cumulative live birth rates and shows that whilst the chances of having a live birth increase with each cycle, the effectiveness and cost effectiveness of each cycle is reduced. For a woman aged 34, the birth rates for each cycle are estimated: 1 cycle: 30%, 2 cycles: 15%, 3 cycles 10%.
In addition, research shows that 73% of those ICBs that have already harmonised their position will fund only 1 cycle and 19% currently fund 2 cycles with <10% funding the full 3 cycles as recommended by NICE.

It is worth noting that our neighbouring ICBs offer the following:

- Lancashire and South Cumbria offer 1 IVF cycle.
- Greater Manchester currently under review.
- West Yorkshire offer 1 IVF cycle.
- Staffordshire and Stoke-on-Trent offer 1 IVF cycle.

Data from our provider Liverpool Women's Hospital shows that the average number of cycles that patients are currently having is 1.36 cycles (this was based on reviewing patient outcomes for patients receiving 2 and 3 IVF cycles over a 5 year period who did not have a live birth after the first cycle), therefore offering patients 2 cycles of IVF would enable the majority of our patients to achieve a successful outcome.

However, there is a requirement for the ICB to review its costs and use of resources, and therefore the option of reducing the offer to 1 cycle has been modelled and offers a potential saving of £1.3m.

To develop a harmonised policy, a decision needs to be made on the number of IVF cycles that patients are offered. An options appraisal is being undertaken to explore offering patients either 1 or 2 cycles. This QIA considers the impact of a 1 IVF cycle policy.

There are a number of other changes that have been made to bring the policy in line with NICE guidance e.g. minimum age, smoking status, weight requirements, definition of childness and right to a family definitions, which are documented in the corresponding EIA but where appropriate are called out in this document.

Reason For Change/Proposal
Currently C&M ICB has an unharmonised position with regard to the number of IVF cycles offered. A 2-cycle option is clinically recommended; however, a 1 cycle approach has been modelled due to our current financial situation and this reduction would offer savings. This option would mean reducing the offer in 8 Places, who all currently offer either 2 or 3 cycles. Only Cheshire East patients would not be affected by this option as they are already entitled to 1 cycle, this option would result in estimated savings of £1.3m per year.

Who is likely to be Impacted?	Public	X	Patients	X	Workforce		Other parts of the system	X
Please provide additional details, including scale	671 per year (2019 data)						
Who has been consulted with as part of the QIA development	There has been no formal consultation, a request to Board in May 25 is being made to request permission to progress a public consultation, however, the Obs & Gynae Clinical Network and Liverpool Women's Hospital Clinical, Operational and Finance Teams have all be involved in reviewing the options, proposed policy and supporting with activity and finance modelling.						
Financial Considerations	Current Costs		£5,043,081 per year		Proposed Costs		£3,727,350 per year

Place/Local Sign off:						
Sign off group	Stage 2 QIA Panel	Date of meeting	12/05/25	Post mitigation risk score *(Likelihood x Consequence)*	Safety	3
					Effectiveness	12
					Experience	16
					Workforce/system	15

Annex 1.2 Quality Impact Assessment

NHS Cheshire and Merseyside

Has an EIA been completed?	Y	Has a DPIA been completed?	Y – full DPIA not required	Have identified risks been added to risk register?	N

Risk scores above 12 in any area of quality, including patient safety, clinical effectiveness or experience will be taken to QIA panel and must be included within the corporate risk register.

Patient safety						
Will the project or proposal impact on patient safety?	Positive impact Improved patient safety, such as reducing the risk of adverse events is anticipated	Neutral Impact May have an adverse impact on patient safety. Mitigation is in place or planned to mitigate this impact to acceptable levels	Negative impact Increased risk to patient safety. Further mitigation needs to be put in place to manage risk to acceptable level	Pre-mitigation Identified Risk Score (Prior to Mitigations)		
				L	C	Total L x C
Please consider… • Will this impact on the organisation's duty to protect children, young people and adults? • Impact on patient safety? • Impact on preventable harm? • Will it affect the reliability of safety systems? N/A • How will it impact on systems and processes for ensuring that the risk of healthcare acquired infections to patients is reduced? N/A	There is no additional impact on adults and children at risk, however, the inclusion of males in the smoking and drug and alcohol intake criteria for Merseyside patients would have a positive impact on the child. If non-compliance evidence is found this could trigger a pause in treatment with possible referral for a welfare of the child assessment and/or further information sought from the GP. This is a positive impact on all patients including welfare of the child. The proposed policy is that both partners should be confirmed non-smokers due to the harmful impact nicotine	The proposals regarding the number of IVF cycles doesn't impact the risk of harm. If implemented the policy would impact patients positively as it would eliminate inequity across C&M.	For those patients who currently receive 2 or 3 cycles there may be an impact on their mental health if they were relying on NHS funded cycles to have a family, but aren't successful during the first cycle.	3	1	3

	has on fertility and foetal development. Likewise, the proposed policy on drug and alcohol intake applies to both partners as in the current Cheshire policy not just the partner undergoing treatment as in the current Mersey policy. This is a positive impact on all patients including welfare of the child.					

Mitigations					
Action	**Owner**	**Expected date of completion**	**Date completed**		
No specific mitigating actions identified for this section					
A comms and engagement approach would be developed to explain the rationale for the decision.	Katie Bromley	tbc			
		Post Mitigation Risk Score	3	1	3

Clinical Effectiveness	
Please confirm how the project uses the best, knowledge based, research	The proposed interim subfertility policy has, where possible, been developed using the latest NG156 NICE guidance and input from local expertise and knowledge. With regard to IVF cycles, it should be noted that NICE guidance (NG156) suggests 3 IVF cycles, however, this has been in place for over 10 years and processes are much improved. NICE Health Economics analysis describes the effectiveness of each cycle with regard to cumulative live birth rates and shows that whilst the chances of having a live birth increase with each cycle, the

	effectiveness and cost effectiveness of each cycle is reduced. For a woman aged 34, the birth rates for each cycle are estimated: 1 cycle: 30%, 2 cycles: 15%, 3 cycles 10%. The Working Group who helped develop the harmonised policy comprised fertility & GP clinicians who supported the review of number of IVF rounds based on this, however, 1 cycle is not an option that is supported clinically. C&M data shows that the average number of cycles is 1.36, with an average of 1.88 subsequent Frozen embryo transfers. For those patients who do not have a successful pregnancy after the first IVF round, there is an opportunity to learn from this and change the approach for the 2nd to increase the risks of success. If the ICB were to offer 1 cycle of IVF, this would remove this opportunity for those patients.					
Will the project or proposal impact on Clinical effectiveness?	**Positive impact** Clinical effectiveness will be improved resulting in better outcomes anticipated for patients	**Neutral Impact** May have an adverse impact on clinical effectiveness. Mitigation is in place or planned to mitigate this impact to acceptable risk levels	**Negative impact** Significant reduction in clinical effectiveness. Further mitigation needs to be put in place to manage risk to acceptable level	Identified Risk Score (Prior to Mitigations)		
				L	C	Total L x C
Please consider… • How does it impact on implementation of evidence based practice? • How will it impact on clinical leadership N/A • Does it reduce/impact on variation in care provision? • Does it affect supporting people to stay well? N/A • Does it promote self-care for people with long term conditions? N/A • Does it impact on ensuring that care is delivered in the most clinically and cost effecting setting? N/A • Does it eliminate inefficiency and waste by design? N/A • Does it lead to improvements in care pathways? N/A	Where possible, the harmonised policy has been brought in line with NICE guidance. The harmonisation of policy in regard to childlessness, weight, smoking and drugs and alcohol intake and approach to Intra-Uterine Insemination (IUI) and ovarian reserve testing should support more patients to be successful in treatment. Outcomes will be monitored in the same way as they are now.	There would be no change to number of cycles for Cheshire East patients. There is a risk that for those patients are not successful in the first IVF cycle, would be disadvantaged by not being able to try a different approach in the second cycle.	The C&M Clinical Network do not support a 1 cycle option. The clinically supported option would be to offer 2 cycles of IVF; however, this QIA considers the impact of 1 cycle. NICE guidance NG156 advises that 3 cycles should be offered. However, C&M data suggests that the numbers of patients requiring 3 cycles is minimal with the average number of cycles being 1.36. Therefore a 1 cycle option is difficult to provide a clinical evidence base for, however, this proposal	3	4	12

	The subfertility policy has been developed with a MDT working group that consisted of Local Fertility Specialists, GPs, Healthwatch, Commissioners who helped to shape the policy. The working group recommended 1 or 2 cycles of IVF. The policy has been shared with the relevant clinical networks who were supportive of the alignment to NICE guidance across the whole of C&M and supported the "interim" approach whilst waiting for revised NICE guidance to ensure new policy positions are developed using all evidence.		would bring NHS C&M in line with over 70% of the ICBs who have already harmonised their policies (4 others have yet to do so). NICE health economics analysis describes that the effectiveness of each cycle with regard to cumulative live birth rate is reduced with each cycle (although there is still a greater chance of a live birth). For an average 34 year old, the 1st cycle is c 30% effective, the 2nd cycle is c 15% and the 3rd cycle is less than 10%.			

Mitigations					
Action	**Owner**	**Expected date of completion**	**Date completed**		
There are no mitigating actions specific to this criteria					
		Post Mitigation Risk Score	3	4	12

Patient Experience				
	Positive impact	Neutral Impact	Negative impact	Identified Risk Score (Prior to Mitigations)

Annex 1.2 Quality Impact Assessment

NHS
Cheshire and Merseyside

Will the project or proposal impact on patient experience?	Improved patient and carer experience anticipated	May have an adverse impact on patient and carer experience. Mitigation is in place or planned to mitigate this impact to acceptable risk levels	Significant reduction in patient and carer experience. Further mitigation needs to be put in place to manage risk to acceptable levels	L	C	Total L x C
Please consider… • What is the impact on protected characteristics, such as race, gender, age, disability, sexual orientation, religion and belief for individual and community health, access to services and experience? • What impact is it likely to have on self-reported experience of patients and service users? (Responses to national/local surveys/complaints/PALS/incidents) • How will it impact on the choice agenda? N/A • How will it impact on the compassionate and personalised care agenda? N/A • How might it impact on access to care or treatment? N/A	The proposed harmonised policy will ensure that patients have equal access to subfertility treatments in Cheshire and Merseyside. It will remove the current variation in the number of IVF cycles offered. The proposed harmonised policy would have a positive impact on patients younger than 23 years who want to start treatment as this minimum age has been removed as per NICE guidance. Women aged 42 are included in the policy in line with NICE guidance – previously the cut off was up to 42nd birthday. The current Mersey position on IUI / Donor Insemination (DI) has been introduced to Cheshire (clarification to number of cycles required before IVF) and Wirral (not routinely commissioned) however, activity for these treatments is minimal.	With regard to IVF cycles, a 1 cycle approach would have a neutral impact on Cheshire East patients as their offer would be in line with all other Places. Definitions of childlessness and right to a family have been clarified, however, this doesn't change the policy position except in Cheshire where previously patients were able to continue to use any remaining eggs following a live birth. The Department of Health (DoH) position on Overseas Visitors is now included in the proposed policy statement, however, this is not a change to process as it reflects the existing rules.	With regard to IVF cycles, a 1 cycle approach would negatively impact those patients who would have had a second or third attempt at IVF. They will have a worsened patient experience if they are unsuccessful in their first cycle particularly if they are unable to self-fund further cycles, they will be unable to have a biological family. • Patients in Knowsley, Halton, South Sefton, Southport & Formby & Warrington who currently are eligible for 3 cycles. • Patients in Liverpool, St Helens, Cheshire West and Wirral currently eligible for 2 cycles. The likelihood of PALS and complaints are expected to increase in these Places if the offer is reduced.	4	4	16

			With regard to the definition of childlessness, the current Cheshire policy implies that even if a patient had a live birth or adopted a child, they could continue with using all frozen embryos. This was not aligned across C&M and is not usual practice, so this has been removed, therefore these patients could feel disadvantaged. Because the status of male partners with regard to smoking & alcohol and drug use has an impact on eligibility in the proposed policy, treatment will only be provided if both partners comply with the requirements. This cohort could feel disadvantaged by this revised approach; however, the smoking requirement follows NICE CG156: “smoking can adversely affect fertility and the success rates of assisted reproductive techniques (in both men and women).” And the drugs and alcohol are based on evidence that			

			alcohol and recreational drugs reduce the chance of conception in both men and women.			

Mitigations					
Action	**Owner**	**Expected date of completion**	**Date completed**		
A comms and engagement approach would be developed to explain the rationale for the decision.	K Bromley / Olivia Billington	Tbc			
		Post Mitigation Risk Score	4	4	16

Workforce/System						
Will the project or proposal impact on the workforce or system delivery?	Positive impact Improved patient and carer experience anticipated	Neutral Impact May have an adverse impact on patient and carer experience. Mitigation is in place or planned to mitigate this impact to acceptable risk levels	Negative impact Significant reduction in patient and carer experience. Further mitigation needs to be put in place to manage risk to acceptable levels	Identified Risk Score (Prior to Mitigations)		
				L	C	Total L x C

Please consider… • Capacity and demand on services • Changes in roles N/A • Training requirements • Staff experience & morale • Redundancies N/A • Opportunities (including staff development) N/A • Impact on other parts of the system, including changes in pathways or access N/A • Increased demand • Financial stability • Safety N/A	The relaunch of the revised policy would require strong communications with the provider in order to ensure any new elements were understood and implemented correctly.	The move to 1 cycle would negatively impact demand at our provider Liverpool Women's (LWH) as their current plans contain greater activity than is needed to deliver activity for 1 cycle.	It is likely that moving to 1 cycle will have a negative impact on staff experience and morale for those working in our Provider organisation as they were supportive of the 2 cycle option. LWH have confirmed that reducing to 1 cycle would have a detrimental financial impact of between £1m and £1.5m and whilst they can identify some productivity improvements, it won't mitigate this financial loss.	5	3	15

Mitigations					
Action	**Owner**	**Expected date of completion**	**Date completed**		
Discussions will be had with LWH to advise of the proposal	Katie Bromley	12/05/25			
		Post Mitigation Risk Score	5	3	15

Annex 1.2 Quality Impact Assessment

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Summary

Decision made	Pre Mitigated Score	Mitigated score	Impact
Progress	16	16	Catastrophic
Not progress	6	4	Moderate
Score summary (add to front page)			
Negligible and Low risk	Moderate risk	Major risk	Catastrophic risk
1-3	4 - 7	8 - 12	13 - 25

- The 'progressed' risk scores are applicable if the 1 cycle option is approved. The 'not progressed' risk scores are applicable if the 2 cycle option is approved. In line with the ICB Risk Management Strategy, an ICB wide risk score for a risk-in-common should mirror that of the highest domain risk score.

Risk Impact Score Guidance

LEVEL	DESCRIPTOR	DESCRIPTION – ICB LEVEL
5	Catastrophic (>75%)	**Safety** - multiple deaths due to fault of ICB OR multiple permanent injuries or irreversible health effects OR an event affecting >50 people. **Quality** – totally unacceptable quality of clinical care OR gross failure to meet national standards. **Health Outcomes & Inequalities** – major reduction in health outcomes and/or life expectancy OR major increase in health inequality gap in deprived areas or socially excluded groups **Finance** – major financial loss - >1% of ICB budget OR 5% of delegated place budget **Reputation** – special measures, sustained adverse national media (3 days+), significant adverse public reaction / loss of public confidence major impact on trust and confidence of stakeholders
4	Major (50% > 75%)	**Safety** - individual death / permanent injury/ disability due to fault of ICB OR 14 days off work OR an event affecting 16 – 50 people. **Quality** – major effect on quality of clinical care OR non-compliance with national standards posing significant risk to patients.

		Health Outcomes & Inequalities – significant reduction in health outcomes and/or life expectancy OR significant increase in health inequality gap in deprived areas or socially excluded groups **Finance** - significant financial loss of 0.5-1% of ICB budget OR 2.5-5% of delegated place budget **Reputation** - criticism or intervention by NHSE/I, litigation, adverse national media, adverse public significant impact on trust and confidence of stakeholders
3	**Moderate (25% > - 50%)**	**Safety** - moderate injury or illness, requiring medical treatment e.g., fracture due to fault of ICB. RIDDOR/Agency reportable incident (4-14 days lost). **Quality** – significant effect on quality of clinical care OR repeated failure to meet standards **Health Outcomes & Inequalities** – moderate reduction in health outcomes and/or life expectancy OR moderate increase in health inequality gap in deprived areas or socially excluded groups **Finance** - moderate financial loss - less than 0.5% of ICB budget OR less than 2.5% of delegated place budget **Reputation** - conditions imposed by NHSE/I, litigation, local media coverage, patient and partner complaints & dissatisfaction moderate impact on trust and confidence of stakeholders
2	**Minor (<25%)**	**Safety** - minor injury or illness requiring first aid treatment **Quality** – noticeable effect on quality of clinical care OR single failure to meet standards **Health Outcomes & Inequalities** – minor reduction in health outcomes and/or life expectancy OR minor increase in health inequality gap in deprived areas or socially excluded groups **Finance** - minor financial loss less than 0.2% of ICB budget OR less than 1% of delegated place budget **Reputation** - some criticism slight possibility of complaint or litigation but minimum impact on ICB minor impact on trust and confidence of stakeholders
1	**Negligible (<5%)**	**Safety** - none or insignificant injury due to fault of ICB **Quality** – negligible effect on quality of clinical care **Health Outcomes & Inequalities** – marginal reduction in health outcomes and/or life expectancy OR marginal increase in health inequality gap in deprived areas or socially excluded groups

	Finance - no financial or very minor loss **Reputation** - no impact or loss of external reputation

The likelihood of the risk occurring must then be measured. Table 2 below should be used to assess the likelihood and obtain a likelihood score. When assessing the likelihood, it is important to take into consideration the existing controls (i.e. mitigating factors that may prevent the risk occurring) already in place.

Table 2 - Risk Likelihood Score Guidance

1	2	3	4	5
Rare The event could only occur in exceptional circumstances (<5%)	**Unlikely** The event could occur at some time (<25%)	**Possible** The event may well occur at some time (25%> -50%)	**Likely** The event will occur in most circumstances (50% > 75%)	**Almost certain** The event is almost certain to occur (>75%)

The impact and likelihood scores must then be multiplied and plotted on table 3 to establish the overall level of risk and necessary action.

Table 3 - Risk Assessment Matrix (level of risk)

LIKELIHOOD of risk being realised	**IMPACT (severity)** of risk being realised				
	Negligible (1)	Minor (2)	Moderate (3)	Major (4)	Catastrophic (5)
Rare (1)	1	2	3	4	5
Unlikely (2)	2	4	6	8	10
Possible (3)	3	6	9	12	15
Likely (4)	4	8	12	16	20
Almost Certain (5)	5	10	15	20	25

Low Risk	Moderate Risk	High Risk	Extreme Risk	Critical Risk

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Risk Proximity
A further element to be considered in the risk assessment process is risk proximity. Risk proximity provides an estimate of the timescale as to when the risk is likely to materialise. It supports the ability to prioritise risks and informs the appropriate response in the monitoring of controls and development of actions.

A pragmatic approach to the use of risk proximity which supports leadership, decision making and reporting is used and is therefore determined to be applied to all Risks.

The proximity scale used is below:

Proximity and timescale for dealing with the risk	Within the current quarter	Within the financial year	Beyond the financial year
Rating	**A**	**B**	**C**

Likelihood, impact and proximity are dynamic elements and consequently all three must be reviewed and reassessed frequently in order to prioritise the response.

Sign off process			
Name	Role	Signature	Date
Olivia Billington	Project lead	Olivia Billington	06/05/25
Rowan Pritchard Jones	Clinical lead		
Katie Bromley	Programme manager	Katie Bromley	06/05/25
	PMO lead		
Once signed off by all above, then the QIA is submitted via qia@cheshireandmerseyside.nhs.uk **to QIA review group**			

PMO receipt					
Verto/PMO reference	N/A	Date QIA reviewed PMO		Reviewed by	

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This section to be completed following review at the QIA review group				
Meeting Chair	Date of Meeting	Approved	Rejected	Comments/feedback
Chris Douglas	12.05.2025	14.05.25		Recommendations made for amendments to QIA for panel to be reconsidered at a later date: 1) Psychological impact to the patient to be articulated in patient safety domain 2) Negative impact on clinical effectiveness is to be reworded and centred on evidence 3) Further work to be undertaken on the system/workforce domain 4) Clarification of scores across all domains required

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Annex 1.3

Equality Analysis Report
(Equality Impact Assessment)

Pre-Consultation *(Use the same form but delete as applicable. If it is post-consultation it needs to include consultation feedback and results)*

C&M Wide

Start Date:	21/08/2024	
Equality and Inclusion Service Signature and Date:		
Sign off should be in line with the relevant ICB's Operational Scheme of Delegation (*amend below as appropriate)		
***Place/ ICB Officer Signature and Date:**		
***Finish Date:**		
***Senior Manager Sign Off Signature and Date**		
***Committee Date:**		

1. Details of current service, function or policy:
Guidance Notes: Clearly identify the function & give details of relevant service provision and or commissioning milestones (review, specification change, consultation, procurement) and timescales.
This change concerns the number of IVF cycles within a harmonised subfertility policy. There is currently disparity across Cheshire and Merseyside on the number of IVF cycles offered as part of the subfertility policies: 1 cycle - Cheshire East 2 cycles – Liverpool, St Helens, Wirral, Cheshire West 3 cycles – Warrington, Southport & Formby, South Sefton, Halton, Knowsley. The clinical policy harmonisation programme undertook an exercise to harmonise the number of cycles, and a working group set up to work through this. The working group proposed either 1 or 2 cycles. Our data shows that the average number of cycles patients are currently having is 1.36 cycles. Following creation of the recovery programme, the review had to consider costing up both 1 and 2 cycles. This EIA considers the impact of 2 IVF cycles.
What is the **legitimate aim** of the service change / redesign For example • Demographic needs and changing patient needs are changing because of an ageing population. • To increase choice of patients • Value for Money-more efficient service

- Public feedback/ Consultation shows need/ no need for a service
- Outside commissioning remit of ICB/NHS

- To ensure a harmonised approach across Cheshire and Merseyside for the number of IVF cycles offered within the subfertility policy.
- To ensure the ICB have had the opportunity to consider the risk and impact of reducing the number of IVF cycles to 2 across Cheshire and Merseyside, as currently some Places offer 3 cycles.

2. Proposed change service, function or policy

Guidance Note: Describe the proposed changes. (New service, change to service specification or service delivery, change to policy / practice).

To harmonise the number of IVF cycles across C&M – see above for current offer.

This EIA considers allowing for patients to have 2 cycles of IVF.

Other policy positions have been updated to reflect NICE guidance to bring the policy in line with the latest evidence base, this has been covered in the EIA for 1 IVF cycle.

3. Barriers relevant to the protected characteristics

Guidance note: describe where there are potential disadvantages.

[ENTER RESPONSE HERE]

[COMPLETE DIFFERENTIAL MATRIX]

Protected Characteristic	Issue	Remedy/Mitigation
Age	• The minimum age (23 years) has been removed as NICE no longer supports this. • "Before the woman's 42nd birthday" has been changed to "before the woman's 43rd birthday" because this is consistent with NICE. NICE withdrew the recommendation for minimum age (23 years) in 2004, together with the increase of the upper age limit to forty-three. • Some narrative has been changed to improve clarity and accuracy. • Overall, this will result in a positive impact due to clarity and NICE evidence-based age guidelines, including the removal of the minimum age of twenty-three requirement, therefore widening access. *All age guidance is based on the evidence of successful fertility treatment.	No action as this brings the policy in line with NICE guidance. This is a positive impact for patients and will increase the eligibility criteria for those patients under 23 and those over 42.

Protected Characteristic	Issue	Remedy/Mitigation
	The changes proposed will mean a positive impact.	
Disability (you may need to discern types)	The policy will have a positive impact on people who may have a disability as defined in the PSED / Equality Act 2010. This is because the policy has been designed so that fertility treatment is made available to those who have a medical condition and or undergoing treatment that impacts on fertility. Treatment for cancer or other procedures which affect fertility are considered thoroughly within the policy. Cryopreservation of embryos, oocytes or semen is routinely commissioned before treatments or procedure (e.g. for cancer or other medically essential interventions such as a surgical procedure and/or administration of medication) which are known to affect fertility. This will be performed in accordance with the Human Fertilisation and Embryology Authority (HFEA) regulations and NICE guideline CG 156. Patients must satisfy the prevalent subfertility criteria when the time comes to use this stored material, and they must have been informed of this requirement before commencing cryopreservation. The cryopreserved material may be stored for 10 years or up to the female partner's 43rd birthday, whichever comes sooner. The ICB will ensure that communication needs are considered and factored into the Engagement and Consultation work.	No action
Gender reassignment	Eligibility for this treatment is that the patient must have a clinical reason for sub-fertility. Therefore, the policy is not inclusive for people who are proposing to undergo, or who are undergoing, or who have undergone gender reassignment. The policy is not clear, for example, where a male partner who has undergone gender realignment would be required to evidence subfertility if requesting fertility treatment (sperm donation) with a female partner. The	This is an interim policy in order to harmonise the number of IVF rounds. Revised guidance is expected in 2025 so the wider issues within the policy will be reviewed in a separate project.

Protected Characteristic	Issue	Remedy/Mitigation
	policy needs to make clear the organisations position so that patients and staff have clear guidance. The proposed policy is an interim position because there is an expectation that NICE guidance will be reviewed and potentially could impact the stance the ICB propose on wider eligibility.	
Marriage and Civil Partnership	This group received protection under the Equality Act with regards to the main Equality Duty and it does not extend to service provision. The policy does not discriminate between marriage of either the opposite or same sex or Civil Partnerships. The policy does not have any criteria related to marital status and therefore this group is not a specific target for the Engagement and Consultation plan.	No action
Pregnancy and maternity	Key factors in the proposed policy regarding pregnancy and maternity include the storage periods and discontinuation of treatment after a live birth and the definition of childlessness. The Engagement and Consultation plan proposes to work with a range of groups including the Hewitt Fertility Centre (HFC). The HFC have also been represented on the working group.	Public engagement / consultation will take place once the ICB have approved an option, and comms will be provided to articulate the changes to the policy a part of this process.
Race	The working group considered the higher rates of Infant Mortality within the Black, Asian and other Ethnic groups. This factor was considered when agreeing that the proposed timescales for storage after a live birth would be 12 months. This is a positive impact. The policy proposal is - In accordance with the policy on “Childlessness”, the ICB will not fund storage of embryos and/or gametes following a live birth (or adoption of a child). However, the ICB	The ICB will ensure that cultural sensitivities and language needs are considered and factored into the Engagement and Consultation work.

Protected Characteristic	Issue	Remedy/Mitigation
	will fund up to 12 months' storage following the birth or adoption of a child to give the patient enough time to decide whether they wish to self-fund, donate the stored material or consent to having any remaining gametes or embryos destroyed. However, the policy on "storage following a live birth" (above) also applies following a live birth (or adoption) and the patient is then permitted the 12 months' period, beyond which NHS funding is no longer available.	
Religion and belief	Whilst there is a neutral impact in relation to the policy proposed, the ICB will ensure that religious and cultural sensitivities are considered and factored into the Engagement and Consultation work.	
Sex	The revision and harmonisation of the policy will result in a fairer, consistent, and clearer subfertility policy across Cheshire and Merseyside. This will mean that couples accessing fertility services will no longer be faced with disparity across Cheshire and Merseyside. The policy has in the main been brought up to date with the best and latest guidance, NICE guidance CG 156. The harmonisation of the policy may mean that in some areas the number of cycles is increased, whilst in other areas they are reduced. This is unavoidable in ensuring equity. Both male and female patients will benefit from the clarity of position within the new policy. IVF Definition & Number of Cycles - The four policies are very similar but differ in terms of the number of cycles permitted. The definition of "IVF cycle" has been reviewed and is now more in line with NICE. The upper age limit has been increased to forty-three and the lower age limit of twenty-three has been removed. However, the ICB will need to agree its policy on the maximum number	Public engagement / consultation will take place once the ICB have approved an option, and comms will be provided to articulate the changes to the policy a part of this process. This is an interim policy in order to harmonise the number of IVF rounds. Revised guidance is expected 2025 so the wider issues within the policy will be reviewed in a separate project.

Protected Characteristic	Issue	Remedy/Mitigation
	of permitted cycles which currently ranges from 1 to 3 cycles according to Place. For women aged <40, this option considers the maximum permitted cycles to be 1. The working group agreed that 1 or 2 cycles is appropriate. For information, over 90% of ICBs in England only permit two cycles (71% allow only one cycle). With regard to weight, the proposed policy now includes a statement that male partners with a BMI of over 30 should be informed that they are likely to have reduced fertility and should be encouraged to lose weight as this will improve their chances of a successful conception. Because this policy is the interim sub-fertility policy and eligibility is based on a clinical reason for sub-fertility, there is no change to provision for single sex couples therefore it may be that the policy disadvantages these patients as they have to self-fund some or all of the procedure.	
Sexual orientation	Because this policy is the interim sub-fertility policy and eligibility is based on a clinical reason for sub-fertility, there is no change to provision for single sex couples therefore it may be that the policy disadvantages these patients as they have to self-fund some or all of the procedure.	Public engagement / consultation will take place once the ICB has approved an option, and a communication will be provided to articulate the changes to the policy a part of this process.
Whilst currently out of scope of Equality legislation it is also important to consider issues relating to socioeconomic status to ensure that any change proposal does not widen health inequalities. Socioeconomic status includes factors such as social exclusion and deprivation, including those associated with geographical distinctions (e.g. North/South divide, urban versus rural). *Examples of groups to consider include: refugees and asylum seekers, migrants, armed forces community, unaccompanied child asylum seekers, looked-after children, homeless people, prisoners and young offenders.* ***The Health Equity Assessment Tool (HEAT) can also be used as a tool to systematically address health inequalities to a programme of work and identify what action can be taken to reduce health inequalities.*** ***https://www.gov.uk/government/publications/health-equity-assessment-tool-heat***		

Protected Characteristic	Issue	Remedy/Mitigation
Refugees and asylum seekers	No impact	
Looked after children and care leavers	No impact	
Homelessness	No impact	
Worklessness	No impact	
People who live in deprived areas	No impact	
Carers	No impact	
Young carers	No impact	
People living in remote, rural and island locations	No impact	
People with poor literacy or health Literacy	No impact	
People involved in the criminal justice system: offenders in prison/on probation, ex-offenders.	No impact	
Sex workers	No impact	
People or families on a low income	An option of 2 cycles is more inclusive to those patients on low income. If the patient does not have a successful live birth following the first IVF round, they would have a second chance under a 2-cycle policy. C&M data shows that the average number of cycles needed is 1.36 so this option would be not disadvantage those on a low income.	Public engagement / consultation will take place once the ICB has approved an option, and communications will be provided to articulate the changes to the policy a part of this process.
People with addictions and/or substance misuse issues	The proposed policy states that patients must demonstrate that their alcohol limits are within department of health guidelines and that they don't use recreational drugs. This is in line with both the existing Mersey policy and NICE guidance. Technically those patients who have addictions could be disadvantaged by this clause, however, there is a safeguarding aspect to children in this environment.	Public engagement / consultation will take place once the ICB have approved an option, and communications will be provided to articulate the changes to the policy a part of this process.
SEND / LD	No impact	
Digital exclusion	No impact	

4. What data sources have you used and considered in developing the assessment?

There has been extensive research carried out in the development of this policy. The communication and engagement plan will further inform the policy development. The policy has been written by a Public Health professional in conjunction with the clinical policy harmonisation steering group and an assisted conception working group.

Key evidence includes the following:

- The main objectives of the policy harmonisation group were to harmonise the policy positions across the region and to maintain consistency with the current NICE clinical guideline (CG 156) on fertility. The working group are aware that NICE are revising CG 156 which is due for publication in 2025. Because this represents a major revision, the ICB will review its policy again following publication of the revised CG 156.
  This policy has drawn on guidance issued by the Department of Health, Infertility Network UK and the NICE guidance (CG156) first published in February 2013 (updated in September 2017).
- https://fertilitynetworkuk.org/ & https://www.nice.org.uk/guidance/cg156/evidence/full-guideline-pdf-188539453https://www.nice.org.uk/guidance/cg156
- https://www.nice.org.uk/guidance/cg156/evidence/full-guideline-pdf-188539453 https://www.gov.uk/government/policies/reducing-drugs-misuse-and-dependence
- https://www.gov.uk/government/policies/reducing-harmful-drinking https://www.hfea.gov.uk/about-us/our-campaign-to-reduce-multiple-births/
- http://www.oneatatime.org.uk
- http://www.hfea.gov.uk/6195.html
- http://www.sexualhealthnetwork.co.uk/media/documents/HIV
- NHS cost recovery - overseas visitors - GOV.UK (www.gov.uk)

5. Engagement / Consultation

Guidance note: How have the groups and individuals been engaged or consulted with? What level of engagement took place? (If you have a consultation plan insert link or cut/paste highlights)

Once the options appraisal has been considered and a decision made on the number of IVF cycles, a public engagement / consultation exercise will be undertaken.

6. Have you identified any key gaps in service or potential risks that need to be mitigated

Guidance note: Ensure you have action for who will monitor progress.
Ensure smart action plan embeds recommendations and actions in Consultation, review, specification, inform provider, procurement activity, future consultation activity, inform other relevant organisations (NHS England, Local Authority).

This is an interim subfertility policy which aims to harmonise the C&M policies in line with NICE guidance and to harmonise the number of IVF rounds. There are other areas which are currently harmonised across C&M, and in line with guidance that haven't been addressed e.g. single sex assisted conception. Revised NICE guidance is expected in 2025 and the aim is to carry out a wider review at this time.

Risk	Required Action	By Who/ When
If the option of 1 cycle of IVF is approved, there is a risk of adverse publicity and a reputational risk for the ICB due to a reduction in access. This would impact 8 of the 9 places, so negative feedback is likely.	A public engagement exercise will be carried out and messaging will be particularly important. It is worth noting that our neighbouring ICBs in the main offer 1 cycle.	Project team supported by Comms
If the ICB reduces the number of IVF cycles to 2, patients who rely on that third cycle of IVF to have a baby will not be eligible. This will affect patients in Knowsley, Halton, Warrington, Southport & Formby and South Sefton. Therefore, we would be disadvantaging these patients.	A public engagement exercise will be carried out and messaging will be particularly important. It is worth noting that our neighbouring ICBs in the main offer 1 cycle.	Project team supported by Comms
Planned activity data from 2024/2025 for Liverpool Women's Hospital (LWH) has been used to model the financial impact of the number of cycles offered, there is a risk that the data may not be 100% accurate as it is not patient identifiable – therefore is based on assumptions and averages.	This planned activity data has been modelled up to predict the number of IVF cycles and fertility treatments that LWH should complete in 2024/25.	Project team

7. Is there evidence that the Public Sector Equality Duties will be met (give details) Section 149: Public Sector Equality Duty (review all objectives and relevant sub sections)
PSED Objective 1: Eliminate discrimination, victimisation, harassment and any unlawful conduct that is prohibited under this act: (check specifically sections 19, 20 and 29)
Analysis post consultation
PSED Objective 2: Advance Equality of opportunity. (check Objective 2 subsection 3 below and consider section 4)
Analysis post consultation
PSED Objective 2: Section 3. sub-section a) remove or minimise disadvantages suffered by people who share a relevant protected characteristic that are connected to that characteristic.
Analysis post consultation
PSED Objective 2: Section 3. sub-section b) take steps to meet the needs of people who share a relevant protected characteristic that are different from the needs of people who do not share it
Analysis post consultation
PSED Objective 2: Section 3. sub-section c) encourage people who share a relevant protected characteristic to participate in public life or in any other activity in which participation by such people is disproportionately low.
Analysis post consultation
PSED Objective 3: Foster good relations between persons who share a relevant protected characteristic and persons who do not share it. (consider whether this is engaged. If engaged consider how the project tackles prejudice and promotes understanding -between the protected characteristics)
Analysis post consultation
PSED Section 2: Consider and make recommendation regards implementing PSED in to the commissioning process and service specification to any potential bidder/service provider (private/ public/charity sector)
Analysis post consultation
Health Inequalities: Have regard to the need to reduce inequalities between patients in access to health services and the outcomes achieved (s.14T);
[ENTER RESPONSE HERE]
8. Recommendation to Board
Guidance Note: will PSED be met?
[ENTER RESPONSE HERE]
9. Actions that need to be taken
[ENTER RESPONSE HERE]

Annex 1.4 Quality Impact Assessment

NHS Cheshire and Merseyside

QUALITY IMPACT ASSESSMENT			
Project/Proposal Name	Reducing Unwarranted Clinical Variation – Subfertility policy option (2 IVF cycles)	Date of completion	14/05/2025
Programme Manager	Katie Bromley	Clinical Lead	Rowan Pritchard Jones

Background and overview of the proposals (can be copied from PID on Verto or from National/Regional commissioning guidance)

The Subfertility policy was included in the scope of the Clinical Policy Harmonisation programme, as currently each Place has its own policy and there is variation in access to these services across Cheshire and Merseyside. The Clinical Policy Harmonisation programme used an evidence-based approach to develop harmonised policies. There is currently disparity across Cheshire and Merseyside on the number of IVF rounds offered as part of the sub-fertility policies:
1 cycle - Cheshire East
2 cycles – Liverpool, St Helens, Wirral, Cheshire West
3 cycles – Warrington, Southport & Formby, South Sefton, Halton, Knowsley
The clinical policy harmonisation programme undertook an exercise to harmonise the number of cycles and a working group was set up to work through this. The working group proposed 1 or 2 cycles, an options appraisal is being undertaken to explore offering patients either 1 or 2 cycles of IVF.

Whilst NICE specifies 3 cycles should be offered, their Health Economics analysis describes the effectiveness of each cycle with regard to cumulative live birth rates and shows that whilst the chances of having a live birth increase with each cycle, the effectiveness and cost effectiveness of each cycle is reduced. For a woman aged 34, the birth rates for each cycle are estimated: 1 cycle: 30%, 2 cycles: 15%, 3 cycles 10%.
In addition, research shows that 73% of those ICBs that have already harmonised their position will fund only 1 cycle and 19% currently fund 2 cycles with <10% funding the full 3 cycles as recommended by NICE.

It is worth noting that our neighbouring ICBs offer the following:

- Lancashire and South Cumbria offer 1 IVF cycle.
- Greater Manchester currently under review.
- West Yorkshire offer 1 IVF cycle.
- Staffordshire and Stoke-on-Trent offer 1 IVF cycle.

Data from our provider Liverpool Women's Hospital shows that the average number of cycles that patients are currently having is 1.36 cycles (this was based on reviewing patient outcomes for patients receiving 2 and 3 IVF cycles over a 5 year period who did not have a live birth after the first cycle), therefore offering patients 2 cycles of IVF would enable the majority of our patients to achieve a successful outcome.

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However, there is a requirement for the ICB to review its costs and use of resources, and this option would result in a cost increase of £40k per year. So a 1 cycle option has also been modelled, which would make an estimated £1.3m savings each year. To develop a harmonised policy, a decision needs to be made on the number of IVF cycles that patients are offered. An options appraisal is being undertaken to explore offering patients either 1 or 2 cycles. This QIA considers the impact of a 2 IVF cycle policy. There are a number of other changes that have been made to bring the policy in line with NICE guidance e.g. minimum age, smoking status, weight requirements, definition of childness and right to a family definitions, which are documented in the corresponding EIA but where appropriate are called out in this document.
Reason For Change/Proposal
Currently C&M ICB has an unharmonised position with regard to the number of IVF cycles offered. A 2-cycle option is clinically recommended; however, a 1 cycle approach has been modelled due to our current financial situation and this reduction would offer savings. A 2 cycle option would mean reducing the offer in 4 Places and increasing the offer in 1 Place, who all currently offer either 1 or 3 cycles. Those patients in Liverpool, St Helens, Cheshire West and Knowsley would not be affected.

Who is likely to be Impacted?	Public	X	Patients	X	Workforce	X	Other parts of the system	X
Please provide additional details, including scale	671 per year (2019 data)							
Who has been consulted with as part of the QIA development	There has been no formal consultation, a request to Board in May 25 is being made to request permission to progress a public consultation, however, the Obs & Gynae Clinical Network and Liverpool Women's Hospital Clinical, Operational and Finance Teams have all be involved in reviewing the options, proposed policy and supporting with activity and finance modelling.)							
Financial Considerations	Current Costs		£5,043,081 per year		Proposed Costs		£5,083,438 per year	

Place/Local Sign off:						
Sign off group	Not required	Date of meeting		Post mitigation risk score *(Likelihood x Consequence)*	Safety	1
					Effectiveness	4
					Experience	4
					Workforce/system	1
Has an EIA been completed?	Y	Has a DPIA been completed?	Y – full DPIA not required	Have identified risks been added to risk register?	N	

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Risk scores above 12 in any area of quality, including patient safety, clinical effectiveness or experience will be taken to QIA panel and must be included within the corporate risk register.

Patient safety						
Will the project or proposal impact on patient safety?	Positive impact Improved patient safety, such as reducing the risk of adverse events is anticipated	Neutral Impact May have an adverse impact on patient safety. Mitigation is in place or planned to mitigate this impact to acceptable levels	Negative impact Increased risk to patient safety. Further mitigation needs to be put in place to manage risk to acceptable level	Pre-mitigation Identified Risk Score (Prior to Mitigations)		
				L	C	Total L x C
Please consider… • Will this impact on the organisation's duty to protect children, young people and adults? • Impact on patient safety? • Impact on preventable harm? • Will it affect the reliability of safety systems? • How will it impact on systems and processes for ensuring that the risk of healthcare acquired infections to patients is reduced?	The proposed policy is that both partners should be confirmed non-smokers due to the harmful impact nicotine has on fertility and foetal development. Likewise, the proposed policy on drug and alcohol intake applies to both partners as in the current Cheshire policy not just the partner undergoing treatment as in the current Mersey policy. This is a positive impact on all patients including welfare of the child. There is no additional impact on adults and children at risk, however, the inclusion of males in the smoking and drug and alcohol intake criteria for Merseyside patients would have a positive impact on the child. If	The proposals regarding the number of IVF cycles doesn't impact the risk of harm, if implemented the policy would impact patients positively as it would eliminate inequity across C&M.	For those patients who currently receive 3 cycles there may be an impact on their mental health if they were relying on NHS funded cycles to have a family, but aren't successful during the first or second cycle.	2	1	2

	non-compliance evidence is found this could trigger a pause in treatment with possible referral for a welfare of the child assessment and/or further information sought from the GP. This is a positive impact on all patients including welfare of the child.					

Mitigations					
Action	**Owner**	**Expected date of completion**	**Date completed**		
Our modelling shows that patients have on average 1.36 cycles and a 2 cycle option is clinically supported.	Katie Bromley		Complete		
A comms and engagement approach would be developed to explain the rationale for the decision.			Tbc		
		Post Mitigation Risk Score	1	1	1

Clinical Effectiveness	
Please confirm how the project uses the best, knowledge based, research	The proposed interim sub-fertility policy has, where possible, been developed using the latest NG156 NICE guidance and input from local expertise and knowledge. It should be noted that NICE suggests 3 IVF cycles, however this guidance has been in place for over 10 years and fertility processes are much improved.

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	C&M data shows that the average number of cycles is 1.36, with an average of 1.88 subsequent Frozen embryo transfers. For those patients who do not have a successful pregnancy after the first IVF round, there is an opportunity to learn from this and change the approach for the 2nd cycle to increase success.					
Will the project or proposal impact on Clinical effectiveness?	**Positive impact** Clinical effectiveness will be improved resulting in better outcomes anticipated for patients	**Neutral Impact** May have an adverse impact on clinical effectiveness. Mitigation is in place or planned to mitigate this impact to acceptable risk levels	**Negative impact** Significant reduction in clinical effectiveness. Further mitigation needs to be put in place to manage risk to acceptable level	Identified Risk Score (Prior to Mitigations)		
				L	C	Total L x C
Please consider… • How does it impact on implementation of evidence based practice? • How will it impact on clinical leadership • Does it reduce/impact on variation in care provision? • Does it affect supporting people to stay well? • Does it promote self-care for people with long term conditions? • Does it impact on ensuring that care is delivered in the most clinically and cost effecting setting? • Does it eliminate inefficiency and waste by design? • Does it lead to improvements in care pathways?	Where possible, the harmonised policy has been brought in line with NICE guidance. For Cheshire East patients this will be positive, as patients will be eligible for an additional IVF cycle. Outcomes will be monitored the same way as they are currently. The harmonisation of policy in regard to childlessness, weight, smoking and drugs and alcohol intake and approach to Intra-uterine insemination and ovarian reserve testing should support more patients to be successful in treatment. Outcomes will be monitored in the same way as they are now.	For Liverpool, St Helens, Cheshire West and Wirral patients the number of IVF cycles eligible will remain at 2. For patients in Knowsley, Halton, S Sefton, Southport & Formby & Warrington patients this will have a negative impact as we are reducing the number of cycles from 3 to 2. Outcomes will be monitored in the same way as they are now.	This proposal is a higher offer than other ICB areas, with over 70% of the ICBs who have already harmonised their policies only offering 1 cycle (4 others have yet to do so). NICE guidance NG156 advises that 3 cycles should be offered. However, C&M data suggests that the numbers of patients requiring 3 cycles is minimal with the average number of cycles being 1.36. NICE health economics analysis describes that the effectiveness of each cycle with regard to cumulative live birth rate is reduced with each cycle (although there is still a greater chance of a live birth). For	2	3	6

	The subfertility policy has been developed with a MDT working group that consisted of Local Fertility Specialists, GPs, Healthwatch, Commissioners who helped to shape the policy. The working group recommended 1 or 2 cycles of IVF. The policy has been shared with the relevant clinical networks who also support the proposed policy including the 2-cycle option. The policy has been shared with the relevant clinical networks who were supportive of the alignment to NICE guidance across the whole of C&M and supported the "interim" approach whilst waiting for revised NICE guidance to ensure new policy positions are developed using all evidence.		an average 34 year old, the 1st cycle is c 30% effective, the 2nd cycle is c 15% and the 3rd cycle is less than 10%.			

Mitigations			
Action	**Owner**	**Expected date of completion**	**Date completed**
Our modelling shows that patients have on average 1.36 cycles and a 2 cycle option is clinically supported.	Katie Bromley		Complete
A comms and engagement approach would be developed to explain the rationale for the decision.			Tbc

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		Post Mitigation Risk Score	2	2	4

Patient Experience						
Will the project or proposal impact on patient experience?	Positive impact Improved patient and carer experience anticipated	Neutral Impact May have an adverse impact on patient and carer experience. Mitigation is in place or planned to mitigate this impact to acceptable risk levels	Negative impact Significant reduction in patient and carer experience. Further mitigation needs to be put in place to manage risk to acceptable levels	Identified Risk Score (Prior to Mitigations)		
				L	C	Total L x C
Please consider… • What is the impact on protected characteristics, such as race, gender, age, disability, sexual orientation, religion and belief for individual and community health, access to services and experience? • What impact is it likely to have on self-reported experience of patients and service users? (Responses to national/local surveys/complaints/PALS/incidents)? • How will it impact on the choice agenda? • How will it impact on the compassionate and personalised care agenda? • How might it impact on access to care or treatment?	The proposed harmonised policy will ensure that patients have equal access to subfertility treatments in Cheshire and Merseyside. It will remove the current variation in the number of IVF cycles offered. For patients in Cheshire East, they will be offered an additional cycle. Positive impact on patients younger than 23 years who want to start treatment as this minimum age has been removed as per NICE guidance. Women aged 42 are included in the policy in line with NICE guidance – previously the cut off was up to 42nd birthday. The current Mersey position on Intra-uterine	Patients in Knowsley, Halton, South Sefton, Southport & Formby & Warrington who currently are eligible to 3 cycles will be impacted neutrally, as data shows the average number of cycles to be 1.36 cycles – so the likelihood is that minimal patients would be having the cycles. For patients in Liverpool, St Helens, Cheshire West and Wirral it will have a neutral impact as these patients are currently eligible to 2 cycles – so there will be no change. Definitions of childlessness and right to a family have been clarified, however, this	The current Cheshire policy implies that even if a patient had a live birth or adopted a child, they could progress with using all frozen embryos. This was not aligned across C&M and is not usual practice, so this has been removed, therefore these patients could feel disadvantaged. Because the status of male partners with regard to smoking & alcohol and drug use has an impact on eligibility in the proposed policy, treatment will only be provided if both partners comply with the requirements. This cohort may feel disadvantaged by this revised approach, however, the smoking	2	3	6

	Insemination (IUI) / Donor Insemination (DI) has been introduced to Cheshire (clarification on the number of cycles required before IVF) and Wirral (not routinely commissioned)	doesn't change the policy position except in Cheshire where previously they were able to continue to use any remaining eggs. The DoH position on eligibility of Overseas Visitors is now included in the proposed policy statement, however, this is not a change to process as it reflects the existing rules.	requirement follows NICE CG156: "smoking can adversely affect fertility and the success rates of assisted reproductive techniques (in both men and women)." And the drugs and alcohol is based on evidence that alcohol and recreational drugs reduce the chance of conception in both men and women.			

Mitigations					
Action	**Owner**	**Expected date of completion**	**Date completed**		
Our modelling shows that patients have on average 1.36 cycles and a 2-cycle option is clinically supported.	Katie Bromley		Complete		
A comms and engagement approach would be developed to explain the rationale for the decision.			Tbc		
		Post Mitigation Risk Score	2	2	4

Workforce/System				
	Positive impact	Neutral Impact	Negative impact	Identified Risk Score (Prior to Mitigations)

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Will the project or proposal impact on the workforce or system delivery?	Improved patient and carer experience anticipated	May have an adverse impact on patient and carer experience. Mitigation is in place or planned to mitigate this impact to acceptable risk levels	Significant reduction in patient and carer experience. Further mitigation needs to be put in place to manage risk to acceptable levels	L	C	Total L x C
Please consider… • Capacity and demand on services • Changes in roles • Training requirements • Staff experience & morale • Redundancies • Opportunities (including staff development) • Impact on other parts of the system, including changes in pathways or access • Increased demand • Financial stability • Safety	The relaunch of the revised policy would require strong communications with the provider in order to ensure any new elements were understood and implemented correctly. It is likely that moving to 2 cycles would have a positive impact on staff experience and morale for those working in our Provider organisation as they were supportive of offering 2 cycles.			1	1	1

Mitigations

Action	Owner	Expected date of completion	Date completed		
There are no mitigating actions					
		Post Mitigation Risk Score	1	1	1

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Summary

Decision made	Pre Mitigated Score	Mitigated score	Impact
Progress	6	4	Moderate
Not progress	16	16	Catastrophic
Score summary (add to front page)			
Negligible and Low risk	Moderate risk	Major risk	Catastrophic risk
1-3	4 - 7	8 - 12	13 - 25

- The ‘progressed’ risk scores are applicable if the 2-cycle option is approved. The ‘not progressed’ risk scores are applicable if the 1-cycle option is approved. In line with the ICB Risk Management Strategy, an ICB wide risk score for a risk-in-common should mirror that of the highest domain risk score.

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Risk Impact Score Guidance

LEVEL	DESCRIPTOR	DESCRIPTION – ICB LEVEL
5	Catastrophic (>75%)	**Safety** - multiple deaths due to fault of ICB OR multiple permanent injuries or irreversible health effects OR an event affecting >50 people. **Quality** – totally unacceptable quality of clinical care OR gross failure to meet national standards. **Health Outcomes & Inequalities** – major reduction in health outcomes and/or life expectancy OR major increase in health inequality gap in deprived areas or socially excluded groups **Finance** – major financial loss - >1% of ICB budget OR 5% of delegated place budget **Reputation** – special measures, sustained adverse national media (3 days+), significant adverse public reaction / loss of public confidence major impact on trust and confidence of stakeholders
4	Major (50% > 75%)	**Safety** - individual death / permanent injury/ disability due to fault of ICB OR 14 days off work OR an event affecting 16 – 50 people. **Quality** – major effect on quality of clinical care OR non-compliance with national standards posing significant risk to patients. **Health Outcomes & Inequalities** – significant reduction in health outcomes and/or life expectancy OR significant increase in health inequality gap in deprived areas or socially excluded groups **Finance** - significant financial loss of 0.5-1% of ICB budget OR 2.5-5% of delegated place budget **Reputation** - criticism or intervention by NHSE/I, litigation, adverse national media, adverse public significant impact on trust and confidence of stakeholders
3	Moderate (25% > - 50%)	**Safety** - moderate injury or illness, requiring medical treatment e.g., fracture due to fault of ICB. RIDDOR/Agency reportable incident (4-14 days lost). **Quality** – significant effect on quality of clinical care OR repeated failure to meet standards **Health Outcomes & Inequalities** – moderate reduction in health outcomes and/or life expectancy OR moderate increase in health inequality gap in deprived areas or socially excluded groups **Finance** - moderate financial loss - less than 0.5% of ICB budget OR less than 2.5% of delegated place budget

		Reputation - conditions imposed by NHSE/I, litigation, local media coverage, patient and partner complaints & dissatisfaction moderate impact on trust and confidence of stakeholders
2	**Minor (<25%)**	**Safety** - minor injury or illness requiring first aid treatment **Quality** – noticeable effect on quality of clinical care OR single failure to meet standards **Health Outcomes & Inequalities** – minor reduction in health outcomes and/or life expectancy OR minor increase in health inequality gap in deprived areas or socially excluded groups **Finance** - minor financial loss less than 0.2% of ICB budget OR less than 1% of delegated place budget **Reputation** - some criticism slight possibility of complaint or litigation but minimum impact on ICB minor impact on trust and confidence of stakeholders
1	**Negligible (<5%)**	**Safety** - none or insignificant injury due to fault of ICB **Quality** – negligible effect on quality of clinical care **Health Outcomes & Inequalities** – marginal reduction in health outcomes and/or life expectancy OR marginal increase in health inequality gap in deprived areas or socially excluded groups **Finance** - no financial or very minor loss **Reputation** - no impact or loss of external reputation

The likelihood of the risk occurring must then be measured. Table 2 below should be used to assess the likelihood and obtain a likelihood score. When assessing the likelihood, it is important to take into consideration the existing controls (i.e. mitigating factors that may prevent the risk occurring) already in place.

Table 2 - Risk Likelihood Score Guidance

1	2	3	4	5
Rare The event could only occur in exceptional circumstances (<5%)	**Unlikely** The event could occur at some time (<25%)	**Possible** The event may well occur at some time (25%> -50%)	**Likely** The event will occur in most circumstances (50% > 75%)	**Almost certain** The event is almost certain to occur (>75%)

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The impact and likelihood scores must then be multiplied and plotted on table 3 to establish the overall level of risk and necessary action.

Table 3 - Risk Assessment Matrix (level of risk)

LIKELIHOOD of risk being realised	**IMPACT (severity)** of risk being realised				
	Negligible (1)	Minor (2)	Moderate (3)	Major (4)	Catastrophic (5)
Rare (1)	**1**	**2**	**3**	**4**	**5**
Unlikely (2)	**2**	**4**	**6**	**8**	**10**
Possible (3)	**3**	**6**	**9**	**12**	**15**
Likely (4)	**4**	**8**	**12**	**16**	**20**
Almost Certain (5)	**5**	**10**	**15**	**20**	**25**

Low Risk	**Moderate Risk**	**High Risk**	**Extreme Risk**	**Critical Risk**

Risk Proximity

A further element to be considered in the risk assessment process is risk proximity. Risk proximity provides an estimate of the timescale as to when the risk is likely to materialise. It supports the ability to prioritise risks and informs the appropriate response in the monitoring of controls and development of actions.

A pragmatic approach to the use of risk proximity which supports leadership, decision making and reporting is used and is therefore determined to be applied to all Risks.

The proximity scale used is below:

Proximity and timescale for dealing with the risk	Within the current quarter	Within the financial year	Beyond the financial year
Rating	**A**	**B**	**C**

Likelihood, impact and proximity are dynamic elements and consequently all three must be reviewed and reassessed frequently in order to prioritise the response.

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Sign off process			
Name	Role	Signature	Date
	Project lead		
	Clinical lead		
	Programme manager		
	PMO lead		
Once signed off by all above, then the QIA is submitted via qia@cheshireandmerseyside.nhs.uk **to QIA review group**			

PMO receipt					
Verto/PMO reference		Date QIA reviewed PMO		Reviewed by	

This section to be completed following review at the QIA review group				
Meeting Chair	Date of Meeting	Approved	Rejected	Comments/feedback