REPORT TO: Health & Social Care Policy and Performance

Board

DATE: 24th June 2025

REPORTING OFFICER: ICB Place Director (Halton)

PORTFOLIO: Health & Wellbeing

SUBJECT: Consultation on Proposed Changes to Fertility

Treatment Policies Across Cheshire and

Merseyside

WARD(S): Borough wide

1.0 PURPOSE OF THE REPORT

- 1.1 Proposals by NHS Cheshire and Merseyside ICB to harmonise the existing 10 Fertility Policies in place across the nine Local Authority Place areas in Cheshire and Merseyside into a single policy for Cheshire would result in some changes to existing access for patients registered with a GP Practice within Halton.
- 1.2 The ICB has duty to engage with Local Authority Health and Overview Scrutiny Committees (HOSC) to seek confirmation as to whether the HOSC believes this proposal is a substantial development or variation (SDV) to NHS services. If this is confirmed by HOSC then this triggers the requirement for the ICB to formally consult with the HOSC, in line with the s.244 Regulations² of the NHS Act 2006 (as amended by the Health and Care Act 2022

2.0 RECOMMENDATION: That the Board:

- confirm whether they believe the proposal represents a substantial development or variation (SDV) to local NHS services; and
- 2) confirm that they agree that the proposals represent an SDV in health services impacting on the patients and residents of Halton then the ICB will need to formally consult with the Committee. Subject to the decision of the HOSCs of each of the other eight Local Authorities within Cheshire and Merseyside this may need to be achieved by the formation of a Joint Overview and Scrutiny Committee as per the Cheshire and Merseyside protocol.

3.0 **SUPPORTING INFORMATION**

3.1 The purpose of this report is to inform the Committee that the Board

of NHS Cheshire and Merseyside Integrated Care Board (ICB), at its meeting on 29 May 2025, approved the recommendation that the ICB commences a period of public consultation regarding the proposal to implement a single Cheshire and Merseyside fertility policy which looks to harmonise access to sub-fertility services for patients registered with a GP Practice across Cheshire and Merseyside. Proposals incorporate changes to:

- the number of NHS funded IVF cycles available to patients
- changes to eligibility with regards Body Mass Index and Smoking
- changes to definition of childlessness
- changes to Intra Uterine Insemination commissioning
- wording on the lower and upper ages for fertility treatment.
- 3.2 The six week public consultation went live on 03 June 2025 and is due to finish on 15 July 2025. Following a period of conscious consideration of the findings of the consultation, it is intended that recommendations for approval regarding the single Fertility Policy for Cheshire and Merseyside will be presented to the ICB Board at its meeting on 25 September 2025.
- 3.3 The ICB has a duty to engage with Local Authority Health and Overview Scrutiny Committees (HOSC) to seek confirmation as to whether the HOSC considers this proposal is a substantial development or variation (SDV) to NHS services. If this is confirmed by HOSC then this triggers the requirement for the ICB to formally consult with the HOSC, in line with the s.244 Regulations² of the NHS Act 2006 (as amended by the Health and Care Act 2022).

4.0 BACKGROUND

4.1 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.

4.2 On formation of ICB on 01 July 2022, 10 fertility policies were inherited from the nine predecessor CCGs which covered patients registered with a GP Practice within the geographic areas of the nine Cheshire and Merseyside local authority area places. These policies were not harmonised which has meant that patients had different access to services and care, based on their postcode/where they were registered with a GP Practice. The ICBs Reducing Unwarranted Variation programme set out to harmonise this approach to ensure

¹ https://www.cheshireandmerseyside.nhs.uk/get-involved/meeting-and-event-archive/nhs-cheshire-and-merseyside-integrated-care-board/2025/29-may-2025/

- we work to address health inequalities and provide a consistent offer across Cheshire and Merseyside.
- 4.3 The patient population in scope of this single Cheshire and Merseyside Fertility policy is for patients with health-related fertility issues, who are struggling to have a live birth and require fertility treatments. The proposed Cheshire and Merseyside single policy has been reviewed in line with the latest evidence base and National Institute for Health and Care Excellence (NICE) guideline CG156. It is important to note that this will be an interim policy until new NICE guidance is published when a broader review of subfertility and assisted conception will be undertaken.
- 4.4 The main area of variation within the existing 10 policies is the number of In vitro fertilisation (IVF) cycles offered which ranges from 1 to 3 cycles depending on geographic area. The proposal out to consultation predominantly focuses on the options to harmonise the number of IVF cycles offered so that in the future people have the same level of access to NHS fertility treatment wherever they live in our area.
- 4.5 IVF is a type of fertility treatment that can help people who have difficulty getting pregnant. It involves an egg being fertilised by sperm outside of the body in a laboratory to create an embryo, which is then transferred into a uterus to achieve a pregnancy. NICE defines a 'full cycle' of IVF treatment as involving each of the following steps:
 - Ovarian stimulation: Using medications to stimulate the ovaries to produce multiple eggs
 - Egg and sperm retrieval: Mature eggs are collected from the ovaries
 - **Fertilisation**: Eggs are fertilised with sperm in a laboratory setting which then develop into embryos
 - Embryo transfer: One or more embryos are transferred into the uterus
 - **Embryo freezing**: Any additional good quality embryos created in the cycle will be frozen and stored for use at a later date.
- 4.6 A full cycle of IVF treatment only ends when either every viable embryo has been transferred, or one results in a pregnancy. 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.
- 4.7 Currently, depending on where the patient is registered with, will determine the number of IVF cycles that they are eligible for. Table

One outlines by Local Authority Place geography the number of NHS funded IVF cycles currently offered to people who are 39 or younger and the criteria for treatment.

Table One

Local Authority / Legacy CCG area	Cycles
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)

- 4.9 People aged 40 and up to 42 are currently offered one cycle in all of the above areas.
- 4.10 Currently, around 734 people in Cheshire and Merseyside access NHS IVF each year. This figure is based on the number of first cycles that take place. Treatment is provided by The Hewitt Fertility Centre at Liverpool Women's Hospital, which is part of NHS University Hospitals of Liverpool Group, and has facilities based in both Cheshire and in Merseyside. 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.
- 4.11 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.

Table Two

	IVF cycles	Subsequent FETs	
Number (average)	1.36	1.88 (All	frozen
Number (average)	1.30	transfers)	
Tariff	£4,862.34	£1,210.80	

4.12 Based on the 2024/25 actuals and forecast, data has been extrapolated from those Cheshire and Merseyside areas already providing 3 cycles to enable options to be modelled across all Cheshire and Merseyside area 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%.
- 4.13 Nationally there is variation in the number of IVF rounds funded by ICBs. Table Three shows the number of ICBs offering 1, 2 or 3 cycles funded by the NHS, excluding Cheshire and Merseyside.

Table Three

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

- 4.14 It is important to note that the majority of neighbouring ICBs offer one NHS funded IVF cycle, with the only exception Greater Manchester. Following a similar review undertaken, Greater Manchester are also undertaking a Public Consultation regarding the no of IVF cycles offered. The current picture is:
 - Lancashire and South Cumbria offer one IVF cycle.
 - Greater Manchester is currently varies from one to three.
 - West Yorkshire offer one IVF cycle.
 - Staffordshire and Stoke-on-Trent offer one IVF cycle.
- 4.15 It is also of note that other aspects within the proposed single Cheshire and Merseyside policy are proposals around harmonisation in accordance with the latest available NICE guidance and local clinical and operational knowledge. In summary, these incorporate:
 - changes to eligibility on Body Mass Index (BMI) (Wirral only)
 - change to eligibility based on smoking status (Halton, Knowsley, Liverpool, Sefton and St Helens)
 - changes to definition of childlessness (Cheshire East and Cheshire West only)
 - change to commissioning of Intra Uterine Insemination (Wirral only)
 - wording on the lower and upper ages for fertility treatment (all areas).

Proposals out to consultation

4.16 **IVF.** We are proposing that in the new single policy, everyone in Cheshire and Merseyside who is eligible for IVF would have **one** cycle paid for by the NHS. This cycle would include one fresh and one frozen embryo transfer, followed by the transfer of all good quality frozen embryos until there is a successful live birth. There would be no change for people aged between 40 and up to 42, as

- they are already offered one cycle in all of our areas.
- 4.17 If the change went ahead, once they had received a first cycle, people would no longer be able to have any additional cycles funded by the NHS. This would mean that in the future people registered with a GP practice in Halton would have access to one funded cycle of IVF, a reduction from the three cycles that are currently funded by the NHS.
- 4.18 Change to eligibility on BMI (body mass index). At the moment, nine out of ten Cheshire and Merseyside policies state that women need to have a BMI of between 19 and 29.9 in order to begin NHS fertility treatment. This is in line with national NICE guidelines, which recommend this weight range for the best chance of successful treatment. However, the current Wirral fertility policy is the only one that says that a male partner should also meet this BMI in order for a couple to be eligible. We are proposing that:
 - the new Cheshire and Merseyside policy would state that women intending to carry a pregnancy need a BMI of between 19 and 29.9 for fertility treatment to begin
 - men with a BMI of more than 30 would be advised to lose weight to improve their changes of conceiving, but this would not necessarily be a barrier to the couple accessing NHS fertility treatment.
- 4.19 If the new single policy was introduced, it would mean that there is no change for people registered with a GP practice in Halton with regards access to fertility treatment based on BMI.
- 4.20 **Change to eligibility on smoking.** NICE guidelines state that maternal and paternal smoking can adversely affect the success of fertility treatment. This includes passive smoking. However, our current fertility policies for Halton, Knowsley, Liverpool, Sefton and St Helens only make reference to the female partner needing to be a non-smoker. We are proposing that the new Cheshire and Merseyside policy will say:
 - that both partners will need to be non-smokers in order to be eligible for NHS fertility treatment. This would include any form of smoking, including the use of e-cigarettes and vapes. This is because of the impact of on treatment outcomes, and the increased risk of complications in pregnancy.
- 4.21 This update to would result in a change for people registered with a GP Practice in Halton.
- 4.22 Change to the definition of 'childlessness' in Cheshire East and Cheshire West. In the majority of areas in Cheshire and Merseyside, IVF will only be made available on the NHS where a couple has no living birth children or adopted children, either from a current or any previous relationship. This is consistent with the

majority of other areas across England too. This means that if someone had a baby through IVF, they would not be eligible for any further NHS funded IVF cycles either.

- 4.23 However, the current policies for patients registered with a practice in Cheshire East and Cheshire West state that where a patient has started a cycle of IVF treatment, they can have further embryo transfers to complete their current cycle, even if they achieve a pregnancy leading to a live birth or adopt a child during the cycle. We are proposing that the new policy would not include this wording, meaning that funding would only be made available where a couple have no living children.
- 4.24 **Change to IUI commissioning.** Intra uterine insemination (IUI), also sometimes known as artificial insemination, is a fertility treatment where sperm is put directly into the womb when a female is ovulating. Female same-sex couples are often asked to self-fund IUI before they can access NHS funded fertility treatment as a means to prove their infertility.
- 4.25 Currently in most areas of Cheshire and Merseyside, in line with NICE guidance, the use of NHS funded IUI is also permitted for treating each of the following groups:
 - people who are unable, or would find it difficult to, have vaginal intercourse because of a clinically diagnosed physical disability or psycho-sexual problem, who are using partner or donor sperm
 - people with conditions that require specific consideration in relation to methods of conception (for example, after sperm washing where the man is HIV positive)
 - people in same sex relationships.
- 4.26 However, the Wirral policy currently states that IUI is not routinely commissioned, and this does not reflect NICE recommendations nor is it consistent with neighbouring areas. In practice, NHS funded IUI is not carried out very often for example Cheshire and Merseyside data shows that a total of just 56 NHS funded IUIs have been provided at Liverpool Women's Hospital over the past six years, which is an average of just nine per year.
- 4.27 We are therefore proposing that the single Cheshire and Merseyside policy would allow NHS funded IUI in the groups listed above, across all areas.
- 4.28 Wording on the lower and upper ages for fertility treatment. We are also proposing that the new policy includes clearer wording around the upper and lower ages for fertility treatment. This is because our ten current policies all say that NHS IVF treatment should be available to those from 23 years old up to 42 years of age in Cheshire and Merseyside. However, we are proposing that the

new policy doesn't state a lower age limit, which would bring it in line with current NICE guidance. We are also proposing to use clearer wording around the upper age limit, to make it clear that people are eligible until their 43rd birthday. We don't believe that amending the wording for the upper and lower age limits will have a significant impact on the number of people accessing treatment, but it will bring our local approach in line with current NICE guidelines, and make sure there aren't different ways to interpret what the policy says.

Other Options Considered

In undertaking this work, a number of other options regarding IVF cycles were considered and which are outlined in Table Four. The Pros and Cons of each option are also outlined in Table Five. Appendix One to this report provides the full options appraisal document. Contained within Appendix One there are a number of equality Impact and Quality Impact Assessments for the options considering if the ICB was to offer one or two cycles of NHS funded IVF. Further detail around our other proposed changes that would be incorporated into the single Cheshire and Merseyside policy can be seen in Appendix Two.

Table Four Options for Consideration - IVF

		or Consideration - IVF			
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 offers 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	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. Appendix One covers the full policy 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 have 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	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)

Option	Description	Outcome	EIA feedback	QIA feedback	Financial impact
		recommendation and would attract negative publicity. A public consultation exercise would be required in 8 Places.		first cycle such as optimum dose of stimulation and best methods used for fertilisation. These are then implemented for subsequent attempts. Overall risk rating: 16 (High)	
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.	not affect protected characteristics.	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 2 nd IVF cycles for Cheshire East is equal to the existing number of 3 rd 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. 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)

Option	Description	Outcome	EIA feedback	QIA feedback	Financial impact
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.

Table Five Pros and Cons of each option

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. 	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

• 66% of ICBs across the country offer 1 cycle.	 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 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.
	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

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. 	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.

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 	 This offer is higher than our neighbouring ICB, NHS Cumbria and Lancashire who offer 1 cycle. (NHS Greater Manchester are in the process of harmonising their cycles offer). This offer is higher than the country average, with 66% 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.

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5.0 COMMUNICATION AND ENGAGEMENT

- 5.1 NHS Cheshire and Merseyside began a 6-week public consultation period on 03 June 2025, with the closing date being the 15 July 2025. The objectives of the consultation are:
 - to inform patients, carers/family members, key stakeholders, and the public of proposed changes to gluten free prescribing.
 - to engage with people who currently are undergoing fertility treatment as well as those who may be in scope of the policy, organisations which support them (where applicable), their carers/family members, and the wider public, to gather people's views about the proposed changes, including how individuals might be impacted.
 - to use these responses to inform final decision-making around the proposal.
- 5.2 A clear consultation communication plan has been approved by the ICB Board (Appendix Three). The public-facing information about the proposal details who is likely to be impacted and how, setting out the background to the issue and explaining why NHS Cheshire and Merseyside is proposing to make changes. A summary booklet has been produced to support this (Appendix Four). This information is accompanied by a questionnaire² containing both qualitative and quantitative questions, designed to gather people's views and perspectives on the proposals. Both the information questionnaire will be available in Easy Read format upon request. All materials have been made available on the NHS Cheshire and Merseyside website at: https://www.cheshireandmerseyside.nhs.uk/get-involved/currentconsultations-and-engagements/share-your-views-on-proposedchanges-to-fertility-treatment-policies-in-cheshire-and-merseyside/ with printed versions and alternative formats/languages available on request (via email or telephone). People who are unable to complete the questionnaire will be able to provide their feedback over the telephone.
- The consultation will be promoted across NHS Cheshire and Merseyside's internal and external communication channels. Wider partners and stakeholders, including providers of NHS services (hospitals, community and mental health providers and primary care), local authorities, Healthwatch, and voluntary, community, faith and social enterprise (VCFSE) organisations, will be asked to share information using their own channels, utilising a toolkit produced for this purpose.
- 5.4 While specific standalone events will not be organised as part of the consultation, if individual groups/networks request further

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² https://www.surveymonkey.com/r/9CKB7BH

information, NHS Cheshire and Merseyside will offer to attend meetings to provide additional briefings if required/appropriate.

- NHS Cheshire and Merseyside recognise that it is important to understand the effectiveness of different routes for reaching people, so that this can be utilised for future activity, and the questionnaire will ask people to state where they heard about the engagement. We will summarise this information along with other measures such as number of enquiries received and visits to the website page in the final consultation report.
- 5.6 When the consultation closes, the findings will be analysed and compiled into a report. The feedback report will be used to inform final decision-making about the proposal and will therefore be received by the Board of NHS Cheshire and Merseyside at its meeting on 25 September 2025. The outcome of this will be communicated using the same routes used to promote the consultation.
- Any formal response to the proposal/consultation by Local Authority HOSC would be requested to be provided prior to **12 September 2025** so as to help inform in a timely manner the final report to the Board of NHS Cheshire and Merseyside.

6.0 POLICY IMPLICATIONS

- 6.1 The ICB has a duty to engage with Local Authority Health and Overview Scrutiny Committees (HOSC) to seek confirmation as to whether the HOSC believes this proposal is a substantial development or variation to local NHS funded services. If this is confirmed by a HOSC then this triggers the requirement for the ICB to formally consult with the HOSC, in line with the s.244 Regulations of the NHS Act 2006 (as amended by the Health and Care Act 2022).
- A substantial development or variation is not defined in legislation. Guidance has suggested that the key feature is that it should involve a major impact on the services experienced by patients and/or future patients. Paragraph 5.2.3 of the Cheshire and Merseyside Protocol outlines the following criteria that Local Authorities should consider to help them with their determination:
 - Changes in accessibility of services: any proposal which involves the withdrawal or change of patient or diagnostic facilities for one or more speciality from the same location.
 - Impact on the wider community and other services: this could include economic impact, transport, regeneration issues.
 - Patients affected: changes may affect the whole population, or a small group. If changes affect a small group, the proposal may

- still be regarded as substantial, particularly if patients need to continue accessing that service for many years.
- Methods of service delivery: altering the way a service is delivered may be a substantial change, for example moving a particular service into community settings rather than being entirely hospital based.
- Potential level of public interest: proposals that are likely to generate a significant level of public interest in view of their likely impact.
- In considering substantial development or variation proposals local authorities need to recognise the resource envelope within which the NHS operates and should therefore take into account the effect of the proposals on the sustainability of NHS services, as well as on their quality and safety.
- Where a substantial development or variation impacts on the residents within one local authority area boundary, only the relevant local authority health scrutiny function shall be consulted on the proposal. Where a proposal impacts on residents across more than one local authority boundary, the NHS body/health service provider is obliged to consult all those authorities whose residents are affected by the proposals in order to determine whether the proposal represents a substantial development or variation.
- Those authorities that agree that any such proposal does constitute a substantial development or variation are obliged (under the Health and Social Care Act 2012 and the Local Authority (Public Health, Health and Wellbeing Boards and Health Scrutiny) Regulations 2013) to form a joint HOSC for the purpose of formal consultation by the proposer of the development or variation. Whilst each local authority must decide individually whether a proposal represents a substantial development/variation, it is only the statutory joint health scrutiny committee which can formally comment on the proposals if more than one authority agrees that the proposed change is "substantial".
- Determining that a proposal is not a substantial development / or variation removes the ability of an individual local authority to comment formally on the proposal. Once such decisions are made, the ongoing obligation on the proposer to consult formally on a proposal relates only to those authorities that have deemed the proposed change to be "substantial" and this must be done through the vehicle of the joint committee. Furthermore, the proposer will not be obliged to provide updates or report back on proposals to individual authorities that have not deemed them to be "substantial."
- 6.6 Committee members are also reminded that from 31 January 2024,

new rules⁴ came into place in respect of the aspect of health scrutiny that relates to substantial development or substantial variation of local health services. The new rules mean that from this date, local HOSCs or JOSCs are no longer able to formally refer matters to the Secretary of State for Health and Social Care where they relate to these substantial developments / variations. Instead, the Secretary of State themselves will have a broad power to intervene in local services – HOSCs will have the right to be formally consulted on how the Secretary of State uses their powers to "call in" proposals to make reconfigurations to local health services.

- Instead of the referral power, HOSCs/JOSCs and other interested parties can write to request (via a call-in request form) that the Secretary of State consider calling in a proposal. It is expected that requests are only to be used in exceptional situations where local resolution has not been reached.
- Other aspects of health scrutiny remain unchanged the power to require representatives of NHS bodies to attend formal meetings, the power to get information from NHS bodies and the power to require NHS bodies to have regard to scrutiny's recommendations.

7.0 FINANCIAL IMPLICATIONS

- 7.1 There are no financial implications to Halton Council in relation to the proposal.
- 7.2 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.
- 7.3 NICE recommends offering patients with infertility three 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 if the ICB offered three rounds of NHS funded IVF treatment across all of Cheshire and Merseyside).
- 7.4 If the ICB was to implement the proposed fertility policy where only one round of NHS funded IVF treatment was provided then 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 to the ICB of £1,315,732 per year.
- 7.5 Table Six provides month 7 activity for Cheshire and Merseyside and the forecast outturn for 2024/25 activity. 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 Liverpool

Women's Hospital.

Table Six

Table Six									
		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	\$0	end	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

8.0 IMPLICATIONS FOR THE COUNCIL'S PRIORITIES <u>(click here</u> <u>for list of priorities)</u>

Not applicable'

9.0 RISK ANALYSIS

None identified.

10.0 EQUALITY AND DIVERSITY ISSUES

10.1 Equality Impact Assessments and Quality Impact assessments have been prepared to support this consultation and are available within the documents in Appendix One. This outlines the possible impacts on protected characteristic groups, as well as mitigations.

11.0 CLIMATE CHANGE IMPLICATIONS

None identified.

12.0 LIST OF BACKGROUND PAPERS UNDER SECTION 100D OF THE LOCAL GOVERNMENT ACT 1972

12.1 References:

 Papers for the May 2025 meeting of the Board of NHS Cheshire and Merseyside ICB

https://www.cheshireandmerseyside.nhs.uk/getinvolved/meeting-and-event-archive/nhs-cheshire-andmerseyside-integrated-care-board/2025/29-may-2025/

- 2. National Health Service Act 2006, Section 244 https://www.legislation.gov.uk/ukpga/2006/41/section/244
- 3. Local Authority (Public Health, Health and Wellbeing Boards and Health Scrutiny) Regulations 2013, https://www.legislation.gov.uk/uksi/2013/218/contents/made
- 4. Rule changes reflect amendments to the local authority scrutiny function following the introduction of the Health and Care Act 2022 ('the 2022 Act'), which inserted schedule 10A into the National Health Service Act 2006 ('the NHS Act 2006'). Further detail at health-scrutiny

APPENDICES

Appendix One: Options Appraisal for the harmonisation of In

vitro fertilisation (IVF) cycles

Appendix Two: Additional proposals to changes to Fertility

Policies across Cheshire and Merseyside

Appendix Three: Communication Plan for Single Cheshire and

Merseyside Fertility Policy Consultation

Appendix Four: Cheshire and Merseyside Fertility Policy

Consultation Summary Booklet