

Scrutiny Committee

Agenda

Date:	Thursday, 12th December, 2024
Time:	10.00 am
Venue:	Council Chamber, Municipal Buildings, Earle Street, Crewe CW1 2BJ

The agenda is divided into 2 parts. Part 1 is taken in the presence of the public and press. Part 2 items will be considered in the absence of the public and press for the reasons indicated on the agenda and in the report.

It should be noted that Part 1 items of Cheshire East Council decision-making meetings are audio recorded and the recordings are uploaded to the Council's website.

PART 1 – MATTERS TO BE CONSIDERED WITH THE PUBLIC AND PRESS PRESENT

1. **Apologies for Absence**

2. **Declarations of Interest**

To provide an opportunity for Members and Officers to declare any disclosable pecuniary interests, other registerable interests, and non-registerable interests in any item on the agenda.

3. **Minutes of Previous Meeting** (Pages 3 - 8)

To approve as a correct record the minutes of the previous meeting held on 16 September 2024.

4. **Public Speaking/Open Session**

There is no facility to allow questions by members of the public at meetings of the Scrutiny Committee. However, a period of 10 minutes will be provided at the beginning of such meetings to allow members of the public to make a statement on any matter that falls within the remit of the committee, subject to individual speakers being restricted to 3 minutes.

5. **Proposed Changes to NHS Funded Gluten Free Prescribing** (Pages 9 - 88)

To consider whether proposals would constitute being a Substantial Development of Variation of Service (SDV).

Contact: Jennifer Ashley
Tel: 01270 685705
E-Mail: jennifer.ashley@cheshireeast.gov.uk

6. **Macclesfield District General Hospital Intrapartum Maternity Services: Post Implementation Review** (Pages 89 - 154)

To receive the findings of the post implementation review of the return of intrapartum maternity services to Macclesfield District General Hospital.

7. **Leighton Hospital Expansion Programme** (Pages 155 - 176)

To receive an update on the Leighton Hospital expansion programme.

8. **Northwest Ambulance Service**

To receive an update from the North West Ambulance Service on response times and patient outcomes.

9. **Work Programme** (Pages 177 - 180)

To consider the Work Programme and determine any required amendments.

Membership: Councillors S Adams, D Brown, C Browne, N Cook, B Drake, H Seddon, M Sewart, M Simon, J Smith, J Snowball, S Corcoran, R Vernon (Vice Chair), L Wardlaw (Chair)

CHESHIRE EAST COUNCIL

Minutes of a meeting of the **Scrutiny Committee**
held on Monday, 16th September, 2024 in the Safety Central (Cheshire Fire
And Rescue Service, Cliff Lane, Lymm, Warrington, England, WA13 0TE

PRESENT

Councillor L Wardlaw (Chair)

Councillors P Redstone, D Brown, C Browne, N Cook, B Drake, H Seddon,
M Sewart, J Smith, S Corcoran and T Dean

OFFICERS IN ATTENDANCE

Richard Christopherson, Locality Manager – Community Safety
Sandra Murphy, Head of Adult Safeguarding
Katie Small, Democratic Services Manager

ALSO IN ATTENDANCE

Claire Jesson, Cheshire Constabulary
Jo Wilson, Crewe Fire Station Manager

17 APOLOGIES FOR ABSENCE

Apologies for absence were received from Councillors Sue Adams,
Margaret Simon and Judy Snowball.

Councillors Patrick Redstone and Mike Sewart were present as
substitutes.

18 DECLARATIONS OF INTEREST

There were no declarations of interest.

19 MINUTES OF PREVIOUS MEETING

RESOLVED:

That the minutes of the meeting held on Thursday 14 March 2024 be
approved as a correct record and signed by the Chair.

20 PUBLIC SPEAKING/OPEN SESSION

There were no registered public speakers.

21 SAFER CHESHIRE EAST PARTNERSHIP - UPDATE

The committee received a presentation from the Safer Cheshire East Partnership (SCEP), a statutory function governed by the Crime and Disorder Act 1998 which aims to bring partners together to ensure that Cheshire East remains a safe place to live, work and visit. Representatives from the Local Authority, Police, Cheshire Fire and Rescue Service, Probation, Youth Offending Team, Health and Voluntary Sector all work together as part of the SCEP which is funded by the Police and Crime Commissioner for Cheshire.

The committee were informed that the SCEP operates by using partners data, statistics and intelligence to inform the Community Safety priorities, issues, risks, emerging threats and identifies factors, known as the Strategic Intelligence Assessment (SIA). The data aids understanding about crime and disorder issues, explores further threats and opportunities and considers where a community safety partnership can make the most difference in the community. The SIA informs a Partnership Plan which has indicators to identify root causes, areas of risk and identify challenges for the next 12 months. In addition it was noted that the local authority has a constitutional duty to produce a plan to reduce crime and disorder.

Reviewed annually, the SIA information includes: Overall Crime data, Adults/Children at Risk, Sexual Offences, Domestic Abuse, Serious and Organised Crime, Violence with injury, Hate Crime, Environmental Crime, ASB, Cyber Crime, Fire Safety, Road Safety. By identifying intelligence, this allows the SCEP to have an understanding of areas of risk and challenge for Cheshire Constabulary.

Members were informed that the SCEP meets quarterly with wide representation of senior partners at a strategic level. Current priorities regarding safeguarding and police matters were discussed with the committee, along with how SCEP priorities link and work alongside the priorities of the Police and Crime Commissioner.

Representatives from Cheshire Fire and Rescue Service informed the committee of their Risk Management Plan, which spans over 4 years and highlights areas of improvements in operational response. In addition, the service has community engagement initiatives which includes supporting all Cheshire East Schools with having the opportunity to visit the facilities at Safety Central.

It was highlighted to the committee that the SCEP works closely with the Police and Crime Commissioner's Office, with priorities of the SCEP being aligned to the Strategic Policing Requirements set by the PCC's Office. Key projects supported by SCEP were also discussed with the committee, including training relating to Internet Scams and Taxi Driver Safeguarding,

The item was opened up for questions and discussions that included:

- SCEP Funding

- Road safety and mobile Smiley SIDs
- Implementation of 20 mph areas
- PCSO restructuring and local PC resources
- Activities to reduce anti-social behaviour
- Safeguarding training for Taxi Drivers
- Police resources at emergency operations

It was agreed that further information would be provided to members outside of the meeting in relation to;

- The collection and analysis of data in relation to victim satisfaction surveys undertaken by Cheshire Constabulary
- Illegal sales of vapes - what is being done regarding underage sales and strength of vapes? What involvement do Trading Standards have?
- What percentage of taxi drivers operating in Cheshire East are registered with Cheshire East Council?

The Chair highlighted several areas where further discussion would be welcomed next time the SCEP provide an update, these included,

- Modern Day Slavery is occurring in different types of businesses, do we monitor this and the types of business most likely to be involved?
- Why are crime statistics down? What has SCEP done to impact the reduction in crime?
- How does the SCEP board run their agenda? Is it Police or Council led? How is it time managed?
- What are the barriers for the implementation of acoustic speed cameras?

Following the conclusion of the committee meeting, members received a tour of the facilities of Safety Central.

RESOLVED:

That the presentation and update provided be received and noted.

22 REPORTING OF URGENT DECISION

RESOLVED:

That the committee noted that an urgent decision under Procedure Rules 2.10 and 2.11 was taken by the Chief Executive on 18 June 2024 to appoint Councillors Liz Wardlaw and Rob Vernon as the council's 2024-25 representatives on the Cheshire and Merseyside Joint Health Scrutiny Committee.

23 WORK PROGRAMME

The committee considered the Work Programme and noted the following updates:

- Following the cancellation of the June 2024 committee meeting, the 'Macclesfield Hospital Intrapartum Services – Post Implementation Review' item had been moved to be presented at the December 2024 meeting.
- A new item had been added to the Work Programme for the committee to receive an update on the Leighton Hospital Expansion Programme in December 2024.
- Review of Prevent and Channel Guidance will be moved to later meeting date, to be agreed with the Chair.
- The Scrutiny Committee recommend to the Highways and Transport Committee that a review of 20mph speed limits in residential areas across the borough be undertaken.
- That an item be added to the work programme in relation to 'Right Care, Right Person' following its implementation, review a year on, the impact it has had on residents and policing across the Cheshire East area.
- That an item be added to the work programme in relation to 'Vapes' and the multi agency approach to assess the impact of trading standards and illegal selling.
- That an item be added to the work programme in relation to 'Early Release from Prisons', to enable the committee to understand the impact on the Probation Service following the early release of two cohorts of Prisoners, and also the support being provided by Housing Partners and their commitment to residents in conjunction with Anti Social Behaviour.
- That an item be added to the work programme in relation to 'Cheshire & Merseyside Health Partnership'. Following the setting of a number of objectives, how is the partnership meeting the 2 objectives of 'improving population health and health care', and 'tackling health inequalities', –have they been achieved, and what is being done to achieve them.
- That an item be added to the work programme in relation to 'Domestic Abuse Related Deaths and Inquests at Coroners Courts'. The committee to scrutinise why it can take a significant amount of time for an inquest to be undertaken.

RESOLVED:

That the Work Programme be noted and additional items be added, with the Chair and Democratic Services to agree the appropriate timeframes for items to be presented.

The meeting commenced at 10.00 am and concluded at 11.25 am

Councillor L Wardlaw (Chair)

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OPEN

Scrutiny Committee

12 December 2024

Consultation on NHS funded Gluten free prescribing across Cheshire and Merseyside

Report of: NHS Cheshire and Merseyside Integrated Care Board

Ward(s) Affected: All of Cheshire East

1. Purpose of Report

- 1.1 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 28 November 2024,¹ approved the recommendation that the ICB commences a period of public consultation regarding the proposal to cease NHS funded gluten free prescribing (bread and bread mixes) across Cheshire and Merseyside.
- 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 change 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 Regulations](#)² of the NHS Act 2006 (as amended by the Health and Care Act 2022).

2. Executive Summary

- 2.1 The Board of NHS Cheshire and Merseyside Integrated Care Board (ICB), at its meeting on 28 November 2024, has approved the recommendation that the ICB commences a period of public consultation regarding its proposal to cease NHS funded gluten free prescribing (bread and bread mixes) across Cheshire and Merseyside. The paper outlining the proposal and rationale is appended to this paper (Appendix One) and is available at www.cheshireandmerseyside.nhs.uk. Contained within this Appendix is the following that was considered by the Board:
 - Cover paper
 - Gluten Free Prescribing Options Appraisal document
 - Communications and Engagement Plan
 - Equality, Diversity and Inclusion Impact Assessment
 - Quality Impact Assessment.

- 2.2 Currently across Cheshire and Merseyside there are differences in the prescribing availability of gluten free products for patients due to previous arrangements of the individual predecessor Clinical Commissioning Group (CCG) organisations. GP Practices within eight Places currently offer gluten free prescribing in line with the 2018 national Department of Health and Social Care (DHSC) consultation outcome, which was to reduce prescribing to bread and bread mixes only. It is of note that St Helens CCG and NHS Cheshire West CCG opted to withdraw prescribing completely (noting this was prior to the national Department of Health and Social Care (DHSC) consultation as detailed above). For Cheshire West Place, the area that was covered by the former NHS Vale Royal CCG did not opt to withdraw gluten free prescribing, and as such there are still parts of Cheshire West where gluten free prescribing (for bread and bread mixes) can be undertaken (Winsford, Northwich, Middlewich and surrounding area). As the ICB has commissioning responsibilities for all of Cheshire and Merseyside patients, work has been undertaken to rectify this position and recommend a harmonised approach to gluten free prescribing.
- 2.3 In Cheshire and Merseyside, c13,000 patients have a diagnosis of coeliac disease or other conditions which requires management through a gluten free diet. Most people choose to purchase their gluten free foods at supermarkets or other retailers however 2,314 Cheshire and Merseyside patients receive gluten free bread and bread mixes via prescription. Of the gluten free prescriptions issued, 99% are exempt from prescription charges, with 73% being due to age (under 16 or 18 if in full time education, or over 60 years old) and over 60% of these being over the age of 60. Further data can be seen in Tables One and Two.
- 2.4 Under the ICBs Unwarranted Variation Recovery programme, a number of options were considered in order to address the variation in gluten free prescribing. The option to maintain the current arrangements was not considered, due to the current unharmonised position, and the need to ensure equity across Cheshire and Merseyside. In order to achieve this, the two main options considered were to either fully prescribe across Cheshire and Merseyside at an estimated additional cost of £130k per year (increase annual spend on the service of c.£655k) or to withdraw prescribing completely, offering an estimated annual saving of £525k. The full options appraisal can be found in Appendix One of this report.
- 2.5 In the context of NHS Cheshire and Merseyside needing to consider how and where to allocate the fixed resources allocated by NHS England to best meet the healthcare needs of the population they serve, the Unwarranted Variation programme proposed to the Board of NHS Cheshire and Merseyside that gluten free prescribing is stopped across Cheshire and Merseyside due to the following rationale:
- availability of gluten free foods is much greater than it was when the original policies were implemented, and in the six years since the DHSC consultation. It should also be noted that bread is not classed as an essential

food item and people can maintain a healthy diet without bread through choosing naturally gluten free foods

- whilst the cost of gluten free bread is still more expensive than non-gluten free there are other gluten free products (e.g. pasta) which are the same price. In addition, improved food labelling and increased awareness enables people to make informed and healthy choices
- Coeliac UK now say that 40% of ICBs have stopped or reduced gluten free prescribing. Our research shows that 32% have stopped completely, 61% prescribe bread and bread mixes and 6% offer to under 18s only
- consideration was given to prescribing to under 18s only, however, Cheshire and Merseyside data shows that over 60% of gluten free prescriptions are for patients 60 years old, and therefore could be seen as discriminatory against the older population
- gluten free prescriptions are in the main received by patients who have exemptions from payment, with the majority of this being due to age (73%). Because age exemption does not take into account financial capacity, it is difficult to evidence the individual financial impact on the impacted patients.
- withdrawing prescribing has already been implemented fully in St Helens and part of Cheshire West and to date we are not aware of any unforeseen health consequences
- ceasing ICB funded gluten free prescribing across Cheshire and Merseyside would enable achievement of a harmonised policy and remove existing unwarranted variation in access to these products based on the rationale set out in this document. In addition, it would harmonise the approach to prescribing other foods for conditions impacted by “standard” products e.g. lactose intolerance, as NHS Cheshire and Merseyside does not currently prescribe food alternatives for other food allergies / intolerances
- a number of neighbouring ICBs including Lancashire and South Cumbria and Shropshire, Telford and Wrekin have already stopped prescribing.

2.6 NHS Cheshire and Merseyside will commence its public consultation on 28 January 2025 for a 6-week period, with the closing date being the 11 March 2025. It is anticipated that the outcome of the consultation and the recommendation for the Board to consider and decide upon will be undertaken at the meeting of the Board on 29 May 2025. The Board will receive the results of the consultation and any feedback report/opinion of Local Authority Health Scrutiny at this meeting to help inform its deliberations and decision. Any formal response to the proposal/consultation by Local Authority HOSC would be requested to be provided prior to the start of May 2025 so as to help inform in a timely manner the final report to the Board of NHS Cheshire and Merseyside, however the exact date will need to be agreed with the HOSC.

2.7 As outlined within the Local Authority (Public Health, Health and Wellbeing Boards and Health Scrutiny)³ regulations, and covered within the Cheshire and Merseyside [protocol](#)⁴ for the establishment of joint health scrutiny arrangements, where a proposal on changes to NHS services impact on more than one Local Authority area, it is for each individual authority to reach a view on whether the proposal is deemed to be a substantial development or variation for that Local Authority area, and where more than one Local Authority agrees that it does (for the same proposal) then regulations place a requirement on

those local authorities to establish a joint overview and scrutiny committee for the purposes of considering it (the proposal). The Cheshire and Merseyside protocol deals with the proposed operation of such arrangements for the Local Authorities of Cheshire and Merseyside.

- 2.8 Subject to the decision of the Cheshire East Scrutiny Committee, and that of the other Local Authority HOSCs in Cheshire and Merseyside, NHS Cheshire and Merseyside will make the necessary preparations to formally consult with the agreed scrutiny arrangements. The ICB is attending Local Authority HOSC meetings across Cheshire and Merseyside throughout December 2024, January 2025 and early February 2025 with regards these proposals.

Recommendations:

The Committee is asked to:

- consider and determine whether the proposal represents a substantial development or variation
- note that, subject to the decision of the Cheshire East Council's Scrutiny Committee and that of the other seven Local Authority HOSCs that NHS Cheshire and Merseyside will need to inform and/or consult with the relevant health scrutiny arrangements on the consultation and its outcome.

3. Background

- 3.1 Coeliac disease is an autoimmune condition associated with chronic inflammation of the small intestine, which can lead to malabsorption of nutrients. The complications of coeliac disease (which may or may not be present at diagnosis) can include osteoporosis, ulcerative jejunitis, malignancy (intestinal lymphoma), functional hyposplenism, vitamin D deficiency and iron deficiency. Other key information about coeliac disease includes:
- population screening studies suggest that in the UK 1 in 100 people are affected.
 - according to Coeliac UK, most people are diagnosed from 50 years old and coeliac disease is most common in people aged between 50-69 years old
 - people with conditions such as type 1 diabetes, autoimmune thyroid disease, Down's syndrome and Turner syndrome are at a higher risk than the general population of having coeliac disease.
 - first-degree relatives of a person with coeliac disease also have an increased likelihood of having coeliac disease.
 - according to NICE the prevalence in females is higher than in males (0.6% compared to 0.4%). Cheshire and Merseyside data reflects this with 65% of patients diagnosed with coeliac disease being female.

- 3.2 Across Cheshire and Merseyside, we have the following data available.

Table One: Total number of patients, registered with a GP Practice, diagnosed with coeliac disease by Place and by age

Place	Age Range										Grand Total
	0-9	10-19	20-29	30-39	40-49	50-59	60-69	70-79	80-89	90+	
Liverpool	44	196	314	280	227	293	391	305	200	18	2268
Cheshire East	52	200	216	293	231	293	351	304	216	45	2201
Wirral	43	163	193	267	200	288	317	258	157	35	1921
Cheshire West	45	171	199	219	231	235	331	273	161	31	1896
Sefton	22	113	101	162	102	224	258	187	126	26	1321
Warrington	31	108	97	117	106	178	173	126	68	15	1019
Knowsley	12	83	79	87	87	132	151	100	61	12	804
St Helens	14	65	84	100	86	120	137	121	61	14	802
Halton	14	72	77	91	78	95	108	100	42	7	684
Grand Total	277	1171	1360	1616	1348	1858	2217	1774	1092	203	12916

Source: EMIS, November 2024

Table Two: Total number of patients, registered with a GP Practice, currently receiving gluten free bread and/or bread mix prescriptions

Place	Age Range										Grand Total	% of total coeliac patients in Place
	0-9	10-19	20-29	30-39	40-49	50-59	60-69	70-79	80-89	90+		
Liverpool	16	61	28	20	34	67	120	104	66	5	521	23%
Cheshire East	19	64	18	23	22	38	97	98	67	6	452	21%
Wirral	13	42	20	27	28	48	81	75	55	7	396	21%
Sefton	9	34	13	19	10	53	69	74	49	6	336	18%
Warrington	11	24	8	8	8	19	37	35	23	8	181	14%
Knowsley	5	22	11	11	9	21	32	35	24	2	172	17%
Halton	4	17	3	14	10	22	28	31	9	3	141	18%
Cheshire West	2	8	5	3	11	10	18	19	11	2	89	11%
St Helens	0	0	0	0	0	0	0	1	1	0	2	0%
Grand Total	79	272	106	125	132	278	482	472	305	39	2290	

Source: EMIS, November 2024

3.3 Management of coeliac disease is a lifelong gluten free diet. Historically, availability of gluten free foods was limited and expensive, so patients obtained these products via prescribing, however, all major supermarkets now commonly stock a wide range of gluten free foods and the price differential is reducing as demand grows.

3.4 It is difficult to evidence the impact of stopping gluten free prescriptions for bread and bread mixes and understanding the impact on affected patients. Whilst there are known risks to not adhering to a gluten free diet, which could have long term health impacts and lead to greater demand on wider health services, there is now greater availability of gluten free foods in supermarkets and other retailers (both in store and on-line), improved food labelling and greater awareness of the impact of non-adherence, which all support the patient to make good food choices for a healthy diet.

- 3.5 It should be noted that although gluten free bread and bread mixes are still more expensive, the cost of these products has been reducing. It is also worth noting that bread is not an essential food item and there are many naturally occurring gluten free foods. Additionally, gluten intolerance individuals do not need to eat wheat based products to maintain good health.

4. Consultation and Engagement

- 4.1 The ICB is now engaging with Local Authority HOSCs across Cheshire and Merseyside to seek confirmation from each individual HOSC as to whether the HOSC believes this proposal triggers the requirement for the ICB to formally consult with them.
- 4.2 Subject to the decision of the Cheshire East Scrutiny Committee and that of the other Local Authority HOSCs in Cheshire and Merseyside, NHS Cheshire and Merseyside will make the necessary preparations to formally consult with the agreed scrutiny arrangements, and attend meetings on the date(s) arranged.
- 4.3 NHS Cheshire and Merseyside intends to begin a 6-week public consultation period from 28 January 2025, with the closing date being the 11 March 2025. The public consultation will present a single option – the cessation of NHS funded gluten free prescribing across Cheshire and Merseyside. 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 receiving gluten free bread and bread mixes on prescription, 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.
- 4.4 A clear consultation communication plan is being finalised, with the draft plan being available within Appendix One to this report. NHS Cheshire and Merseyside will produce clear and accessible public-facing information about the proposal, details of 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 a change. This information will be accompanied by a questionnaire containing both qualitative and quantitative questions, designed to gather people's views and perspectives on the proposals. Both the information and questionnaire will be available in Easy Read format. All materials will be made available on the NHS Cheshire and Merseyside website, 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.
- 4.5 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.

- 4.6 To ensure that those who would be most impacted by any potential change have an opportunity to share their views, NHS Cheshire and Merseyside will seek to work with colleagues in general practice and local pharmacies, to ensure that those who currently receive gluten free bread and bread mixes on prescription are made aware that the consultation is underway.
- 4.7 While specific standalone events will not be organised as part of the consultation, if individual groups/networks request further information, NHS Cheshire and Merseyside will offer to attend meetings to provide additional briefings if required/appropriate.
- 4.8 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.
- 4.9 When the consultation closes, the findings will be analysed and compiled into a report by an independent external organisation. 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 29 May 2025. The outcome of this will be communicated using the same routes used to promote the consultation.
- 4.10 Any formal response to the proposal/consultation by Local Authority HOSC would be requested to be provided prior to the start May 2025 so as to help inform in a timely manner the final report to the Board of NHS Cheshire and Merseyside, however the exact date will need to be agreed with the HOSC.

5. Reasons for Recommendations

- 5.1 For NHS Cheshire and Merseyside to understand better and plan accordingly how to inform and/or consult Local Authority HOSC across Cheshire and Merseyside, a decision is required by each Local Authority regarding whether:
 - they determine that the proposal to cease NHS funded gluten free prescribing is to be classed as a substantial development or variation, and
 - whether this triggers the need to establish a Joint HOSC in line with the Cheshire and Merseyside protocol.

6. Other Options Considered

- 6.1 No other options considered in relation to engagement with Local Authority HOSC.

7. Implications and Comments

- 7.1 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.
- 7.2 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.
- 7.3 Those authorities that agree that any such proposal does constitute a substantial development or variation are obliged 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”.
- 7.4 Determining that a proposal is not a substantial development/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”

Access to Information	
Contact Officer:	Matthew Cunningham Associate Director of Corporate Affairs and Governance NHS Cheshire and Merseyside matthew.cunningham@cheshireandmerseyside.nhs.uk
Appendices:	Appendix One: NHS Cheshire and Merseyside ICB Board Paper on Gluten Free prescribing proposal 28.10.24 Appendix Two: Protocol for the establishment of Joint Health Scrutiny Arrangements in Cheshire and Merseyside (June 2024)
Background Papers:	Protocol for the establishment of Joint Health Scrutiny Arrangements in Cheshire and Merseyside (June 2024)

References:

1. Papers for the 28 November 2024 meeting of the Board of NHS Cheshire and Merseyside ICB
<https://www.cheshireandmerseyside.nhs.uk/get-involved/meeting-and-event-archive/nhs-cheshire-and-merseyside-integrated-care-board/2024/28-november-2024/>
2. National Health Service Act 2006, Section 244
<https://www.legislation.gov.uk/ukpga/2006/41/section/244>
3. Paper to the Cheshire East Adults and Health Committee meeting (June 2024) on the Protocol for the establishment of Joint Health Scrutiny Arrangements in Cheshire and Merseyside
<https://moderngov.cheshireeast.gov.uk/documents/s118019/Appendix%20%20-%20Cheshire%20and%20Merseyside%20Joint%20Health%20Scrutiny%20Arrangements%20Protocol.pdf>
4. Local Authority (Public Health, Health and Wellbeing Boards and Health Scrutiny) Regulations 2013,
<https://www.legislation.gov.uk/uksi/2013/218/contents/made>

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Meeting of the Board of NHS Cheshire and Merseyside

28 November 2024

Proposal regarding ICB funded Gluten Free Prescribing across Cheshire and Merseyside

Agenda Item No: ICB/11/24/17

Responsible Director: Prof. Rowan Pritchard-Jones, Medical Director

Proposal regarding ICB funded Gluten Free Prescribing across Cheshire and Merseyside

1. Purpose of the Report

- 1.1 The purpose of the paper is to seek approval from the Board of NHS Cheshire Merseyside ICB to progress with the commencement of a period of public consultation, regarding ICB funded gluten free (GF) prescribing.
- 1.2 The approval will enable the commencement of a six-week consultation involving patients, public, staff and other key stakeholders, starting January 2025.

2. Executive Summary

- 2.1 Currently within NHS Cheshire and Merseyside there are differences in the prescribing of gluten free products for patients due to previous arrangements of the individual predecessor Clinical commissioning Group (CCG) organisations. As the ICB has commissioning responsibilities for all of Cheshire and Merseyside patients, work has been undertaken to rectify this position and recommend a harmonised approach to prescribing.
- 2.2 Across the 9 Places in Cheshire and Merseyside, there are GP Practices within 8 Places that currently offer gluten free prescribing in line with the 2018 national Department of Health and Social Care (DHSC) consultation outcome, which was to reduce prescribing to bread and bread mixes only. It is of note that St Helens CCG and NHS Cheshire West CCG opted to withdraw prescribing completely (noting this was prior to the national Department of Health and Social Care (DHSC) consultation as detailed above). For Cheshire West Place, the area that was covered by the former NHS Vale Royal CCG did not opt to withdraw prescribing, and as such there are still parts of Cheshire West where gluten free prescribing can be undertaken (Winsford, Northwich, Middlewich and surrounding area).
- 2.3 In Cheshire and Merseyside, over 13,300 patients have a diagnosis of coeliac disease or other conditions which requires management through a gluten free diet. Most people choose to purchase their gluten free foods at supermarkets or other retailers however 2,314 patients receive their gluten free bread and bread mixes via prescription. It should be noted that of the gluten free prescriptions issued, 99% are exempt from prescription charges, with 73% being due to age (under 16 or 18 if in full time education, or over 60 years old) and over 60% of these being over the age of 60.
- 2.4 Under the ICBs Unwarranted Variation Recovery programme, a number of options were considered in order to address the unwarranted variation. The option to maintain the current arrangements was not considered, due to the



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current unharmonised position, and the need to ensure equity across Cheshire and Merseyside. In order to achieve this, the two main options considered were to either fully prescribe across Cheshire and Merseyside at an estimated additional cost of £130k per year (increase annual spend on the service of c.£655k) or to withdraw prescribing completely, offering an estimated annual saving of £525k. (The full options appraisal can be found in Appendix One of this report).

- 2.5 Initially the review of the current gluten free prescribing policies was undertaken as part of the Clinical Policy Harmonisation programme which involved a clinical working group who recommended to reinstate prescribing across all of Cheshire and Merseyside which is in line with the DHSC consultation outcome. However, this position was not supported by the ICBs Finance, Investment and Our Resources Committee due to the financial challenges faced by NHS Cheshire and Merseyside.
- 2.6 In the context of NHS Cheshire and Merseyside needing to consider how and where to allocate the fixed resources allocated by NHS England to best meet the healthcare needs of the population they serve, the Unwarranted Variation programme has proposed that gluten free prescribing is stopped across Cheshire and Merseyside due to the following rationale:
- availability of gluten free foods is much greater than it was when the original policies were implemented, and in the six years since the DHSC consultation. It should also be noted that bread is not classed as an essential food item and people can maintain a healthy diet without bread through choosing naturally gluten free foods
 - whilst the cost of gluten free bread is still more expensive than non-gluten free there are other gluten free products (e.g. pasta) which are the same price. In addition, improved food labelling and increased awareness enables people to make informed and healthy choices
 - Coeliac UK now say that 40% of ICBs have stripped or reduced prescribing. Our research shows that 32% have stopped completely, 61% prescribe bread and bread mixes and 6% offer to under 18s only
 - consideration was given to prescribing to under 18s only, however, Cheshire and Merseyside data shows that over 60% of gluten free prescriptions are for patients 60 years old, and therefore could be seen as discriminatory against the older population
 - gluten free prescriptions are in the main received by patients who have exemptions from payment, with the majority of this being due to age (73%). Because age exemption does not take into account financial capacity, it is difficult to evidence the individual financial impact on the impacted patients.
 - withdrawing prescribing has already been implemented in St Helens and part of Cheshire West and to date we are not aware of any unforeseen consequences
 - ceasing ICB funded gluten free prescribing across Cheshire and Merseyside would enable achievement of a harmonised policy and remove existing unwarranted variation in access to these products based on the rationale set out in this document. In addition, it would harmonise the approach to prescribing other foods for conditions impacted by “standard” products e.g.



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lactose intolerance, as NHS Cheshire and Merseyside does not currently prescribe food alternatives for other food allergies / intolerances

- a number of neighbouring ICBs including Lancashire and South Cumbria and Shropshire, Telford and Wrekin have already stopped prescribing.

2.7 A decision to withdraw gluten free prescribing would require a public consultation, and which will also include engagement and/or consultation with our Local Authority colleagues through 8 of the 9 Local authority Health Overview and Scrutiny committees. Included in this report is the proposed engagement and consultation plan, subject to approval received from the Board (see Appendix Two).

2.8 The feedback from the consultation, together with that of the Local Authority Health Overview and Scrutiny Committees will inform the final proposal that will come to Board in 2025 for consideration and decision.

3. Ask of the Board and Recommendations

3.1 **The Board is asked to:**

- **approve** the commencement of a consultation exercise with the public and stakeholders regarding the proposed option to withdraw ICB funded gluten free prescribing across all of Cheshire and Merseyside.

4. Reasons for Recommendations

4.1 A decision by the Board to withdraw ICB funded gluten free prescribing needs to be informed with evidence including the outcome and outputs of a consultation exercise with the public and key stakeholders. It is a legal requirement and duty on the ICB to engage and consult with the public as well as local Health Overview and Scrutiny arrangements.

5. Background

5.1 Currently NHS Cheshire and Merseyside has unwarranted variation in the prescribing of gluten free products across all Places. St Helens CCG and Cheshire West CCG opted to withdraw prescribing completely prior to the national Department of Health and Social Care (DHSC) consultation the outcome of which was to reduce prescribing to bread and bread mixes only in 2018. For Cheshire West Place, the area that was covered by the former NHS Vale Royal CCG did not opt to withdraw prescribing, and as such there are still parts of Cheshire West where prescribing can be undertaken (Winsford, Northwich, Middlewich and surrounding area).

5.2 Coeliac disease is an autoimmune condition associated with chronic inflammation of the small intestine, which can lead to malabsorption of nutrients. Population screening studies suggest that in the UK 1 in 100 people are



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affected. The complications of coeliac disease (which may or may not be present at diagnosis) can include osteoporosis, ulcerative jejunitis, malignancy (intestinal lymphoma), functional hyposplenism, vitamin D deficiency and iron deficiency. People with conditions such as type 1 diabetes, autoimmune thyroid disease, Down's syndrome and Turner syndrome are at a higher risk than the general population of having coeliac disease. First-degree relatives of a person with coeliac disease also have an increased likelihood of having coeliac disease.

- 5.3 Management of coeliac disease is a lifelong gluten free diet. Historically, availability of gluten free foods was limited and expensive, so patients obtained these products via prescribing, however, all major supermarkets now commonly stock a wide range of gluten free foods and the price differential is reducing as demand grows. It should be noted that there have been a number of recent national news articles on the higher cost of these “free from” alternatives and the impact of withdrawing prescribing in context of cost-of-living increases.
- 5.4 Initially the former CCGs gluten free prescribing policies were reviewed as part of the Clinical Policy Harmonisation programme, the objective of which was to review existing policies and the latest evidence base to recommend a single set of policies which would enable all patients to have equitable access. Therefore, the option to continue with the current arrangements was discounted. The review of the gluten free prescribing policy involved a clinical working group who recommended to reinstate prescribing across all of Cheshire and Merseyside in line with the DHSC consultation outcome. However, as this would result in additional annual expenditure of c.£130k, this position was not supported by our Finance, Investments and Resources Committee due to the financial challenges faced by NHS Cheshire and Merseyside.
- 5.5 The review was then progressed under the Reducing Unwarranted Variation programme and the non-prescribing option was considered in context of the patient safety risks, and the requirement to support NHS Cheshire and Merseyside to deliver the financial objectives of the Recovery programme.
- 5.6 It is difficult to evidence the impact of stopping gluten free prescriptions for bread and bread mixes and understanding the impact on affected patients. Whilst there are known risks to not adhering to a gluten free diet, which could have long term health impacts and lead to greater demand on wider health services, there is now greater availability of gluten free foods in supermarkets and other retailers (both in store and on-line), improved food labelling and greater awareness of the impact of non-adherence, which all support the patient to make good food choices for a healthy diet.
- 5.7 The options appraisal paper was initially discussed with the Associate Directors of Quality where the proposal was acknowledged and supported for progression. It was subsequently presented to the Recovery Committee on 16 September 2024 and was then considered by the Strategy and Transformation (S&T) committee at the meeting on 19 September 2024. The S&T committee supported the recommendation to present the preferred option, to cease



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prescribing to the Board and that we progress to a public consultation to inform the outcome. It is of note that the options appraisal was also reviewed and considered by the Clinical Effectiveness Group on 2 October 2024 and the group supported progressing consulting of the proposed preferred option to withdraw prescribing across Cheshire and Merseyside.

6. [Link to delivering on the ICB Strategic Objectives and the Cheshire and Merseyside Priorities](#)

Objective One: Tackling Health Inequalities in access, outcomes and experience

- The proposal seeks to remove unwarranted variation in access to prescribing for gluten free bread and bread mixes. It is of note that prescriptions are not available for other food allergies / intolerances, so this will further remove unwarranted variation. GF goods are much more widely available in supermarkets and other retailers both in store and on-line and therefore more accessible to patients. Food labelling has improved so patients are able to identify naturally gluten free foods, and there is greater awareness of the impact of not following a GF diet, so patients are more informed to make healthy diet choices. In addition, it would harmonise the approach to prescribing other foods for conditions impacted by “standard” products e.g. lactose intolerance.

Objective Two: Improving Population Health and Healthcare

- The ICB has a duty to consider how and where to allocate the fixed resources that it receives from NHS England, and this proposal to stop prescribing GF bread and bread mixes will enable the ICB to save an estimated £525k per year which could be allocated to more critical services.

Objective Three: Enhancing Productivity and Value for Money

- The ICB has a duty to consider how and where to allocate the fixed resources that it receives from NHS England, and this proposal to stop prescribing GF bread and bread mixes will enable the ICB to save an estimated £525k per year which will support delivery of the financial recovery plan or allow funds to be reallocated to more critical services.

Objective Four: Helping to support broader social and economic development

- This proposal does not directly contribute to this objective.

7. [Link to achieving the objectives of the Annual Delivery Plan](#)

This proposal is aligned to the annual delivery plan through the Effective Use of Resource element contributing to the delivery of clinical policy harmonisation and supporting the finance efficiency and value programme.

8. Link to meeting CQC ICS Themes and Quality Statements

Theme One: Quality and Safety

Key to both the clinical policy harmonisation and unwarranted variation programmes is the focus on ensuring all Cheshire and Merseyside residents have equal access to services. In addition, sustainability of services must be considered when making decisions on how to spend limited resource. A QIA has been completed and reviewed by the Associate Directors of Quality who support the proposal to stop prescribing based on re-allocation of this resource to focus on other critical services. (The QIA is available in appendix four).

Theme Two: Integration

The proposal does not directly relate to this theme, however, in relation to the 'safe systems' quality statement, if supported by the Board the next step will be a public consultation which will enable the views of the population to help shape the outcome.

Theme Three: Leadership

If the proposal is supported by the Board, there will be a public consultation exercise through which we will work with wider partners and stakeholders, including providers of NHS services, local authorities, Healthwatch, and voluntary, community, faith and social enterprise (VCFSE) organisations to support us to engage with the right people. We will engage throughout with our Local Authority colleagues through the Health Overview and Scrutiny committees in the impacted Places. This relates to the 'partnerships and communities' quality standard.

9. Risks

- 9.1 It is difficult to evidence the impact of Coeliac patients not being able to access gluten free bread and bread mixes, but there are known risks to not adhering to a gluten free diet which could have long term health impacts and lead to greater demand on wider health services. An example given by Coeliac UK states it costs £195 a year per patient to support gluten free on prescription, but the average cost to the NHS of an osteoporotic hip fracture is £27,000.
- 9.2 Mitigation: A published DHSC Impact Assessment examines the issue of adherence in detail and concludes that adherence to a gluten free diet cannot be isolated to any single cause. Evidence shows that many factors are at play including product labelling, cost and information when eating out and managing social occasions. Adherence requires a range of knowledge and skills to avoid all sources of gluten. Gluten free foods are now much more readily available in supermarkets and other retailers, both in store and on-line, making them more accessible. In addition, there is improved food labelling across all foods and greater awareness of adherence to gluten free diet helping people to make healthy choices. It should be noted that although gluten free bread and bread mixes are still more expensive, the cost of these products has been reducing



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over time and there are other GF foods at comparable prices to standard foods for example 500g of GF pasta being the same price as 500g of standard pasta. It is also worth noting that bread is not an essential food item and there are many naturally occurring GF foods.

- 9.3 There is a reputational risk to the ICB if the proposal to stop prescribing is accepted. Due to the current cost of living, there have been a number of national articles on the increased cost of “free from” foods despite them being much more available. In addition, 99% of the cohort of patients receiving prescriptions have an exemption in that they do not pay for prescriptions so could be seen that we are disadvantaging our most vulnerable population.
- 9.4 Mitigation: A public consultation would be held in those Places who currently prescribe, the outcome of which will inform the final decision. It should be noted that the ICB does not prescribe food products for other conditions that are associated with or affected by types of food.

10. Finance

- 10.1 If the proposal is supported by the Board and implemented following a public consultation exercise, this would offer the ICB an estimated annual saving of £525k and a cost avoidance of a further £130k (the estimated cost of harmonising prescribing across all Places).
- 10.2 The public consultation exercise would be led by NHS Cheshire and Merseyside’s in-house communications and engagement team; however, it is anticipated that up to £12,000 one-off enabling funding will be required to support delivery. This would include analysis of consultation findings and production of a report to inform the final decision, and funding for additional formats, including easy read versions and other languages. It is standard practice for public consultation reports to be produced by an external organisation.

11. Communication and Engagement

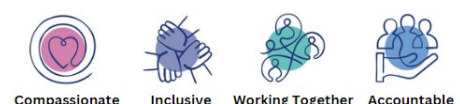
- 11.1 A supporting comms and engagement plan is available in appendix two.

12. Equality, Diversity and Inclusion

- 12.1 An equality, diversity and inclusion assessment (EIA) was undertaken and can be viewed in appendix three.

13. Climate Change / Sustainability

- 13.1 This proposal does not directly relate the ICB green plan or net zero obligations.



14. Next Steps and Responsible Person to take forward

- 14.1 If the recommendation to progress consulting on our proposal for ICB funded gluten free prescribing, a public consultation exercise will be held, with proposed start date of January 14th 2025 continuing for six-weeks until Tuesday February 2025.
- 14.2 Engagement will commence with Local Authority Health Overview and Scrutiny committees to determine how best to engage and/or consult with them.
- 14.3 Feedback on the consultation will inform the final recommendation put to the which will be presented to a future Board meeting for Board decision.
- 14.4 The work will be taken forward by the Reducing Unwarranted Variation Programme Team under the direction of Anthony Leo as Senior Responsible Officer, Professor Rowan Pritchard-Jones as Clinical Lead and Natalia Armes as Programme Director.

15. Officer contact details for more information

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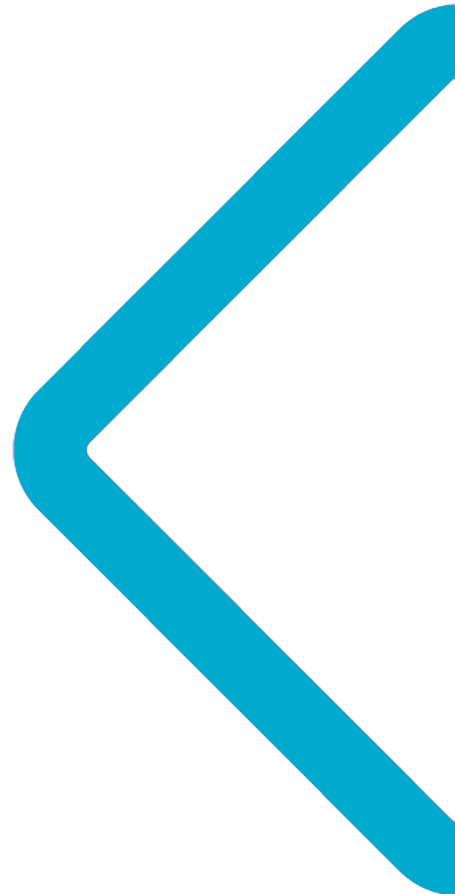
Natalia Armes, Chief of Staff for Medical Directorate and Associate Director of Digital Transformation and Clinical Improvement

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16. Appendices

- Appendix One:** Gluten Free Prescribing Options Appraisal document
- Appendix Two:** Communications and Engagement Plan
- Appendix Three:** Equality, Diversity and Inclusion Impact Assessment
- Appendix Four:** Quality Impact Assessment

**Options Appraisal ICB funded Gluten
Free products Prescribing across
Cheshire and Merseyside**



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Glossary

Term	Definition
Coeliac Disease	Coeliac disease is a lifelong autoimmune disease caused by a reaction to gluten. Once diagnosed, it is treated by following a gluten free diet for life
Gluten	Gluten is a protein found in wheat, rye and barley.

1 Executive Summary

Currently NHS Cheshire and Merseyside has unwarranted variation in the prescribing of gluten free products across all Places. St Helens CCG and Cheshire West CCG opted to withdraw prescribing completely (to note the footprint previously under Vale Royal CCG within Cheshire West Place still undertake some prescribing) prior to the national Department of Health and Social Care (DHSC) consultation the outcome of which was to reduce prescribing to bread and bread mixes only in 2018.

In Cheshire and Merseyside, over 13,300 patients have a diagnosis of coeliac disease or other conditions which requires management through a gluten free diet. Most people choose to purchase their gluten free foods at supermarkets or other retailers however 2,314 patients receive their gluten free foods via prescription. It should be noted that of the prescriptions issued, 99% are exempt from prescription charges, with 73% being due to age (under 16 or 18 if in full time education, or over 60 years old) and over 60% of these being over the age of 60.

Under the Unwarranted Variation Recovery programme, a number of options were considered in order to address the unwarranted variation, but the 2 main options were to either fully prescribe across Cheshire and Merseyside at an estimated additional cost of £130k per year (increase annual spend on the service of c.£655k) or to withdraw prescribing completely offering an estimated annual saving of £525k.

Initially the review of the current gluten free prescribing policies was carried out under the Clinical Policy Harmonisation programme and involved a clinical working group who recommended reinstating prescribing across all of Cheshire and Merseyside which is in line with the DHSC consultation outcome. However, this position was not supported by our Finance, Investments and Resources Committee due to the financial challenges faced by NHS Cheshire and Merseyside.

In the context of the financial challenge facing NHS Cheshire and Merseyside, the Unwarranted Variation programme has reviewed all options and are proposing that gluten free prescribing is stopped due to the following rationale:

- Availability of gluten free foods is much greater than it was when the original policies were implemented, and in the six years since the DHSC consultation. It should also be noted that bread is not classed as an essential food item and people can maintain a healthy diet without bread through choosing naturally gluten free foods.
- Whilst the cost of gluten free bread is still more expensive than non-gluten free there are other products (e.g. pasta) which are the same price. In addition, improved food labelling and increased awareness enables people to make informed and healthy choices.
- Coeliac UK now say that 40% of ICBs have stopped or reduced prescribing, our research shows that 32% have stopped completely, 61% prescribe bread and bread mixes and 6% offering to under 18s only.
- Consideration was given to prescribing to under 18s only, however, C&M data shows that over 60% of the population receiving prescriptions are over 60 years and therefore could be seen as discriminatory against the older population.
- Gluten free products are in the main received by patients who have exemptions from payment, with the majority of this being due to age (73%) and because exemption does not take into account financial capacity, it is difficult to evidence the individual financial impact on the impacted patients.
- Withdrawing prescribing has already been implemented in St Helens and part of Cheshire West and to date we are not aware of any unforeseen consequences.
- NHS Cheshire and Merseyside do not currently prescribe food alternatives for other food allergy / intolerances e.g. lactose intolerance.
- A number of our ICB neighbours including Lancashire and South Cumbria and Shropshire, Telford and Wrekin have already stopped prescribing.

A decision to withdraw gluten free prescribing would require a public consultation in 8 of the 9 Places including engagement with our Local Authority colleagues through Oversight and Scrutiny committees.

The options appraisal paper was initially discussed with the Associate Directors of Quality where the proposal was acknowledged and supported for progression. It was subsequently presented to the Recovery Committee on 16th September and was then considered by the Strategy and Transformation (S&T) committee at the meeting on 19th September. The S&T committee supported the recommendation to present the preferred option, to cease prescribing to the Board for approval to progress to a public consultation to inform the final decision.

It is of note that the options appraisal was also reviewed and considered by the Clinical Effectiveness Group on 2nd October and the group supported progress of the proposed option to withdraw prescribing across Cheshire and Merseyside.

The Board is asked to approve the recommendation to progress a proposal for a non-prescribing option for gluten free bread and bread mixes in order to commence a public consultation starting in January 2025. The feedback from this exercise, together with that of our Oversight and Scrutiny Committees will inform the decision whether to continue with this recommended option. In addition, the Board is asked to receive the feedback from this exercise at the first available board meeting.

2 Background

Currently NHS Cheshire and Merseyside has unwarranted variation in the prescribing of gluten free products across all Places. St Helens CCG and Cheshire West CCG opted to withdraw prescribing completely prior to the national Department of Health and Social Care (DHSC) consultation the outcome of which was to reduce prescribing to bread and bread mixes only in 2018. Further information about this consultation and the revised regulation subsequently put in place is available on the NHS England website ([NHS England » Prescribing Gluten-Free foods in Primary Care: Guidance for Clinical Commissioning Groups – frequently asked questions](#)). For Cheshire West Place, the area that was covered by the former Vale Royal CCG did not opt to withdraw prescribing, and as such there are still part of Cheshire West were prescribing can be undertaken (Winsford, Northwich, Middlewich and surrounding area).

Coeliac disease is an autoimmune condition associated with chronic inflammation of the small intestine, which can lead to malabsorption of nutrients. Population screening studies suggest that in the UK 1 in 100 people are affected. The complications of coeliac disease (which may or may not be present at diagnosis) can include osteoporosis, ulcerative jejunitis, malignancy (intestinal lymphoma), functional hyposplenism, vitamin D deficiency and iron deficiency. People with conditions such as type 1 diabetes, autoimmune thyroid disease, Down's syndrome and Turner syndrome are at a higher risk than the general population of having coeliac disease. First-degree relatives of a person with coeliac disease also have an increased likelihood of having coeliac disease.

Management of coeliac disease is a lifelong GF diet. Historically, availability of GF foods was limited and expensive, so patients obtained these products via prescribing, however, all major supermarkets now commonly stock a wide range of GF foods and the price differential is reducing as demand grows. It should be noted that there have been a number of recent national news articles on the higher cost of these "free from" alternatives and the impact of withdrawing prescribing in context of cost-of-living increases.

Initially the former CCGs gluten free prescribing policies were reviewed as part of the Clinical Policy Harmonisation programme and involved a clinical working group who recommended to reinstate prescribing across all of Cheshire and Merseyside in line with the DHSC consultation outcome.

However, as this would result in additional annual expenditure of C.£130k, this position was not supported by our Finance, Investments and Resources Committee due to the financial challenges faced by NHS Cheshire and Merseyside

The review was then progressed under the Unwarranted Variation programme and the non-prescribing option was considered in context of the patient safety risks, and the requirement to support NHS Cheshire and Merseyside to deliver the financial objectives of the Recovery Programme.

It is difficult to evidence the impact of stopping GF prescriptions and understanding whether the impacted patients would continue to follow a GF diet. Whilst there are known risks to not adhering to a GF diet, which could have long term health impacts and lead to greater demand on wider health services, there is greater availability of GF foods in supermarkets and other retailers, improved food labelling and greater awareness of the impact of non-adherence, which all support the patient to make good food choices for a healthy diet.

The options appraisal paper was initially discussed with the Associate Directors of Quality where the proposal was acknowledged and supported. It was subsequently presented to the Recovery Committee on 16th September and was then considered by the Strategy and Transformation (S&T) committee at the meeting on 19th September. The S&T committee supported the recommendation to present the preferred option, to cease prescribing to the Board and that we progress to a public consultation to inform the outcome. In addition, the Clinical Effectiveness Group also supported progression of the proposed option on 2nd October.

3 Approach

The gluten free prescribing policy was initially reviewed under the Clinical Policy Harmonisation Programme (CPH) the objective of which was to review existing policies and the latest evidence base to recommend a single set of policies which would enable all patients to have equitable access. The review of the gluten free prescribing policy focused on the published evidence base DH&SC and Coeliac UK recommendations with input from clinicians, dieticians and pharmacists and was led by the CPH Steering Group which includes commissioners, GP, Pharmacist and public health leads. An options appraisal was carried out to consider a number of options to harmonise the prescribing position and an EIA and QIA were developed to consider all options. Therefore, the option to continue with the current arrangements was discounted.

The CPH programme recommended that the harmonised policy be to implement gluten free prescribing in accordance with DHSC guideline, however, this comes at an additional annual cost of C.£130k and this was not able to be supported by the Finance, Investment and Resources Committee at the time. It is of note that this work was placed on hold, due to the financial pressures and pre-election activity so it was brought into the scope of the Reducing Unwarranted Variation Recovery Programme (noting that 3 members are consistent with the previous Clinical Policy Steering Group) and review has also been completed by the Deputy Medical Director and Clinical Lead for Reducing Unwarranted Variation (RUV) Programme.

In the context of the ICB financial recovery plan, the RUV programme carried out a further review which considered Cheshire and Merseyside data, prices and availability of GF foods in supermarkets and other retailers, both instore and on-line, improvements in food labelling and increased information via websites on how to maintain a GF diet. Following discussions on these findings with Place Clinical Directors and Associate Directors of Quality, the Reducing Unwarranted Variation Steering group **is recommending as a financial decision, prescribing is stopped across Cheshire and Merseyside** and this view is supported by the Deputy Medical Director and Programme Clinical Lead.

The group recognised that this goes against the latest published guidance, however, it should be noted that this is now 6 years old, and this is not a medicine or prescription for an essential food item (as it is for bread or bread mixes only). In addition, the group noted that this is a similar stance as taken with other food allergies / intolerances and dietary requirements where we do not offer alternative food items by prescription and increasing affordable gluten free products are available at supermarkets. This

recommendation would result in a financial saving of circa. £525k and avoid additional expenditure of £130k.

3.1 Current Cheshire and Merseyside Activity and Spend on Gluten Free Prescribing

Across Cheshire and Merseyside, 8 Places still have a Policy that includes GF prescribing at an annual cost of circa £525k for the year 2023/2024. Prior to the establishment of the ICB, two of the former CCGs (St Helens and West Cheshire) withdrew GF prescribing as a cost cutting policy, although it is of note that GP practices in the former Vale Royal CCG footprint still prescribe as shown within the table below.

Cheshire and Merseyside - Gluten Free Prescribing 2023/24

Row Labels	Sum of Items	Sum of Actual Cost	Weighted Pop	per 1,000 Wtd Pop.	
				Items	Actual Cost
Sefton	3816	£87,559	310666	12.28	£281.84
CHESHIRE EAST	4909	£97,731	429865	11.42	£227.35
Knowsley	2156	£46,220	196251	10.99	£235.52
Halton	1551	£32,413	149417	10.38	£216.93
Wirral	3724	£77,017	385940	9.65	£199.56
Liverpool	5953	£122,669	646320	9.21	£189.80
Warrington	1953	£41,160	232237	8.41	£177.23
CHESHIRE WEST & CHESTER	939	£19,396	410116	2.29	£47.29
St Helens	20	£413	231122	0.09	£1.79
Grand Total	25021	£524,579	2991933	8.36	£175.33

Gluten Free Prescribing Exemption in Cheshire and Merseyside

In Cheshire and Merseyside over 13,300 patients have a diagnosis of coeliac disease, with only 17.4% (2,314) receiving prescription gluten free food.

The table below details the breakdown of GF prescriptions across Cheshire and Merseyside and shows that 99% of prescriptions issued are currently exempt from prescription charges.

Row Labels	Chargeable at Current Rate		Exempt	
	Number of Items	Proportion	Number of Iter	Proportion
Cheshire East	21	1.03%	2020	98.97%
Cheshire West	11	2.72%	393	97.28%
Halton	6	0.93%	637	99.07%
Knowsley	5	0.57%	869	99.43%
Liverpool	24	0.96%	2465	99.04%
Sefton	5	0.32%	1556	99.68%
St Helens		0.00%	10	100.00%
Warrington	6	0.76%	785	99.24%
Wirral	14	0.93%	1488	99.07%
Cheshire and Merseyside	92	0.89%	10223	99.11%

Of these exemptions, 73% is due to age (under 16 or 18 if in full time education, or over 60 years old), with the majority being over the age of 60.

According to Coeliac UK, most people are diagnosed from 50 years old and coeliac disease is most common in people aged between 50-69 years old.

Row Labels	Exempt	
	Number of Items	Proportion
Aged 60 Or Over	6253	61.17%
No Declaration/Declaration Not Specific	1950	19.07%
Under 16 / Aged 60 Or Over	898	8.78%
Pre-Payment Certificate	315	3.08%
Aged 16-18 And In Full Time Education	311	3.04%
Medical Exemption	287	2.81%
Income Support	87	0.85%
Universal Credit	64	0.63%
HC2 Charges	19	0.19%
NHS Tax Credit Exemption Certificate	19	0.19%
Maternity Exemption	15	0.15%
Income Based Job-seekers Allowance	3	0.03%
HRT Pre-payment Certificate	1	0.01%
Pension Guarantee Credit	1	0.01%
Unassigned		0.00%

3.2 Current Prescribing Approaches across England (where available)

Coeliac UK state that 40% of ICBs have stopped or reduced prescribing. Where the information was published, our research shows that 32% have stopped completely with 61% prescribing bread and bread mixes, 6% prescribing to under 18s only and 6% prescribe bread only. (see appendix E).

The table below shows the policy stance of local ICBs:

Prescribe bread & bread mixes	Do not prescribe – all ages
<ul style="list-style-type: none"> Greater Manchester – all ages Staffordshire – for those under age of 18 only 	<ul style="list-style-type: none"> Lancashire and South Cumbria Shropshire, Telford and Wrekin

3.3 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

3.4 Strategic Context

The main objectives identified are:

Objective 1	
Objective	Tackling health inequality, improving outcomes and access to services
Current Arrangement	<p>7* of 9 Places currently offer gluten free prescribing in line with the national Department of Health and Social Care (DHSC) consultation the outcome of which was to reduce prescribing to bread and bread mixes only in 2018. It is of note that for the remaining 2 Places, St Helens CCG and Cheshire West CCG opted to withdraw prescribing completely (noting this was prior to the national Department of Health and Social Care (DHSC) consultation as detailed above).</p> <p>*For Cheshire West Place, the area that was covered by the former Vale Royal CCG did not opt to withdraw prescribing, and as such there are still part of Cheshire West were prescribing can be undertaken (Winsford, Northwich, Middlewich and surrounding area).</p> <p>In addition, there are other patients who are diagnosed with food related allergies / intolerance conditions who do not receive prescriptions to</p>

Objective 1	
	manage their diet and therefore could be argued that those patients are disadvantaged by a prescribing option.
Gap/Business Needs	In order to harmonise the position across C&M, there are 2 options, one to implement prescribing across all 9 Places at a potential additional cost of £130k per year; a total estimated cost of £655k per year or to withdraw prescribing across all 9 places at a potential saving of £525k per year.
Objective 2	
Objective	Enhancing quality, productivity and value for money
Current Arrangement	<p>7* of 9 Places currently offer gluten free prescribing in line with the national Department of Health and Social Care (DHSC) consultation the outcome of which was to reduce prescribing to bread and bread mixes only in 2018. It is of note that for the remaining 2 Places, St Helens CCG and Cheshire West CCG opted to withdraw prescribing completely (noting this was prior to the national Department of Health and Social Care (DHSC) consultation as detailed above).</p> <p>*For Cheshire West Place, the area that was covered by the former Vale Royal CCG did not opt to withdraw prescribing, and as such there are still part of Cheshire West were prescribing can be undertaken (Winsford, Northwich, Middlewich and surrounding area).</p> <p>In addition, there are other patients who are diagnosed with food related allergies / intolerance conditions who do not receive prescriptions to manage their diet and therefore could be argued that those patients are disadvantaged by a prescribing option.</p> <p>There is a risk to patient safety if patients do not follow a GF diet (quality) and potential impact on wider services in the future.</p>
Gap/Business Needs	In order to harmonise the position across C&M, there are 2 options, one to implement prescribing across all 9 Places at a potential additional cost of £130k per year; a total estimated cost of £655k per year or to withdraw prescribing across all 9 places at a potential saving of £525k per year.

4 Options and considerations

No	Description	Outcome	EIA Feedback*	QIA Feedback*	Financial Impact
1	Do nothing -discounted option	Inequity of prescribing for patients across C&M	No EIA completed	No change to current situation, but unwarranted variation across C&M	Current annual spend of circa £525,000 will be maintained
2	NHS C&M adopt prescribing to national guidelines across all Places	Harmonised C&M policy in line with evidence base. Public involvement exercise could be minimal as there has already been a full consultation by DHSC.	In line with DHSC EIA guidance following extensive public consultation and EIA completion (see appendix F). If not prescribed will be contrary to national published guidance, however, this EIA is now 8 years old. Minimal equality impact identified. (see appendix A)	Equity across C&M and improves access to patients in the Places who do not currently receive prescribed gluten free goods. Overall Risk rating: 1 Green – Low risk (see appendix B)	Estimated increase in spend of £130,000. Estimated annual spend £655,000
3	NHS C&M to withdraw prescribing across all Places	Harmonised C&M policy contrary to published guidance however, this is now 6 years old. Public consultation exercise would be required in 8 Places	A number of groups of patients could be at risk of dietary neglect as clear links were identified between: - age (those aged under 16, those aged 16, 17 and 18 in full time education, and those aged 60 or over are eligible for prescription exemptions) - Gender (reported cases of coeliac disease are two to three times higher in women than men), - pregnancy and maternity (e.g. Poorly controlled coeliac disease in pregnancy can increase the risk of developing pregnancy-related complications) (see appendix C)	Withdrawal of prescribing would impact those patients who receive free prescriptions who are likely to be vulnerable due to low income, holding medical certificates which implies wider health needs and age. There is a risk in this current economic climate that people on low income would consume non-GF bread and bread mixes which could have longer term health impacts and therefore increase health inequalities. (see appendix D)	Most current spend would cease leading to an estimated saving of £525,000 with further estimated cost avoidance of £130k Estimated annual spend £0

No	Description	Outcome	EIA Feedback*	QIA Feedback*	Financial Impact
			- Families on low income (due to eligibility for exemptions from prescription charges)	Overall Risk rating: 4 Amber – moderate	
4	Prescribe to under 18s only – discounted option	Harmonised policy but only for young people, therefore inequity of access for patients across C&M. Public consultation would be required in all 9 Places.	<p>This option is against published guidelines (& this would benefit less than 15% of the C&M population receiving GF prescriptions). A number of groups of patients could be at risk of dietary neglect as clear links were identified between:</p> <ul style="list-style-type: none"> - age and in particular those aged 60 or over are eligible for prescription exemptions - Children and young people are not financially independent so this option would support them to adhere to a GF diet - Gender (reported cases of coeliac disease are two to three times higher in women than men), - pregnancy and maternity (e.g. Poorly controlled coeliac disease in pregnancy can increase the risk of developing pregnancy-related complications) - Families on low income (due to eligibility for exemptions from prescription charges) 	<p>Withdrawal of prescribing would impact those patients who receive free prescriptions who are likely to be vulnerable due to low income, holding medical certificates which implies wider health needs and age. There is a risk in this current economic climate that people on low income would consume non-GF bread and bread mixes which could have longer term health impacts and therefore increase health inequalities.</p> <p>Whilst this option would support younger people, they make up less than 15% of the C&M population receiving GF prescriptions.</p>	<p>Based on 10% of current spend estimated costs would be £50,000 - £60,000 per annum. This results in a saving of £465,000 - £475,000</p>

4.1 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 with the achievement of the programme outcomes:

Risk	Mitigating actions
<p>It is difficult to evidence the impact of Coeliac patients not being able to access Gluten Free (GF) bread and bread mixes, but there are known risks to not adhering to a GF diet which could have long term health impacts and lead to greater demand on wider health services. An example given by Coeliac UK states it costs £195 a year per patient to support GF on prescription, but the average cost to the NHS of an osteoporotic hip fracture is £27,000.</p>	<p>A published DHSC Impact Assessment examines the issue of adherence in detail and concludes that adherence to a GF diet cannot be isolated to any single cause. Evidence shows that many factors are at play including product labelling, cost and information when eating out and managing social occasions. Adherence requires a range of knowledge and skills to avoid all sources of gluten. Gluten free foods are now much more readily available in supermarkets, with clear gluten free labelling. It should be noted that although GF bread and bread mixes are still more expensive the cost of these products has been reducing over time and there are other GF foods at comparable prices to standard foods for example 500g of GF pasta being the same price as 500g of standard pasta. It is also worth noting that bread is not an essential food item and there are many naturally free GF foods e.g. potatoes, rice.</p> <p>If the option to stop prescribing was accepted, signposting on how to adhere to a gluten free diet would be made available on the ICB website and GPs would continue to monitor these patients as usual.</p> <p>Also engagement with supermarkets in Cheshire and Merseyside would be undertaken to advise of the change in prescribing with a request for them to manage their stock levels accordingly.</p>
Risk	Mitigating actions
<p>There is a reputational risk to the ICB if the option to withdraw prescribing is accepted. Due to the current cost of living, there have been a number of national articles on the increased cost of “free from” foods despite them being much more available. In addition, 99% of the cohort of patients receiving prescriptions have an exemption in that they do not pay for prescriptions so</p>	<p>The ICB does not prescribe for other conditions that are associated with, or affected by the types of food they eat, so this would result in a fairer approach for these patients.</p> <p>A public consultation exercise would be held in those Places who currently prescribe in line with the approach in St Helens and the relevant area of Cheshire West.</p>

could be seen that we are targeting our most vulnerable population.	
<p>If the option to re-instate prescribing is accepted, there is a financial risk to the ICB in that an additional £130k per year would be required to support this, meaning an estimated annual spend of £655k.</p> <p>This may result in other critical funded services not being funded as a consequence of the further cost pressure.</p>	<p>Place based Medicines Management teams would review prescribing quantities to ensure they are in line with Coeliac UK guidance. This may mitigate some of the cost.</p> <p>Noting that this option is not the recommended option of the Reducing Unwarranted Variation Steering Group.</p>

Constraints

- The review is being undertaken in context of the recovery programmes.
- Due to the significance of the change, a public consultation exercise would be required if any option to withdraw prescribing was accepted. In addition, it would be necessary to engage and consult with the Oversight and Scrutiny Committees in all affected Places. A Joint OSC meeting would need to be formed, composed of the Local Authorities where the population would be impacted. The availability and timing of these meeting would be largely 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 SoS 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 Cheshire and Merseyside's communications and engagement team is currently focused on a number of pieces of public involvement work. Any public involvement requirements around gluten-free prescribing will need to be considered alongside existing work plans.
- Public involvement activity has resource implications. It is standard practice to commission independent analysis and reporting of feedback from public consultation, aside from any additional requirements around delivery of consultation activity. There is a need to scope out the requirements and identify the necessary budget.

5 Options Appraisal and Financial Case

For completeness a range of options have been considered as part of the case for change, a brief description of full range of options is below:

Option 1: Do nothing – 8 of 9 Places prescribe GF products, St Helens and part of Cheshire West do not prescribe (Option discounted)

Pros	Cons
<ul style="list-style-type: none"> The financial position of the ICB does not change. 	<ul style="list-style-type: none"> There is unwarranted variation across Cheshire and Merseyside in unequal access to GF bread and bread mixes for our patients. There is an increased risk of challenge by Equalities and Human Rights commission re inequality in service access. Financial impact remains at circa £525k per annum.

Option 2: Implement Prescribing of bread and bread mixes across whole of Cheshire and Merseyside

Pros	Cons
<ul style="list-style-type: none"> Harmonised access to GF bread and bread mixes across C&M In line with evidence base Supported by Quality and EDI Teams and Clinicians Review of the quantities prescribed in each Place could mitigate the additional cost 	<ul style="list-style-type: none"> Additional estimated annual cost of £130k making a total of estimated annual cost £655k per annum This may impact the ability to support other areas of need due to financial constraints across the Integrated Care System. There are other patients who suffer from other food allergies or intolerances who do not receive prescribed food goods, this option could be seen as increasing inequity for these patients.

Proposed next steps and estimated timeframe for Option 2:

- 1) Recovery Committee (September 16th) and Strategy & Transformation Committee (STC) (19th September) supported recommendation to withdraw prescribing
- 2) The recommendation from STC to be considered and decision to be ratified by Board – 28th November 24
- 3) Public Involvement exercise in St Helens and Cheshire (West Vale Royal GP Practices) (working assumption is this would be a communications exercise)
- 4) Harmonised policy to be launched across all Places – no change for 8 of 9 – December 24

Option 3: Withdraw Prescribing across whole of Cheshire and Merseyside

Pros	Cons
<ul style="list-style-type: none"> • Harmonised access to GF products across C&M • Financial benefit to the ICB of £525k per annum • Increased fairness in prescribing policies as NHS does not provide food on prescription for other groups of patients who conditions are associated with, or affected by, the type of food they eat. 	<ul style="list-style-type: none"> • Contrary to the latest published guidance, however, this is now 8 years old and the prices of GF goods have been reducing, therefore would be purely financial rationale • Concerns identified through the EIA and QIA process particularly around the impact on vulnerable patients (particularly age) and for those patients on low income the risk of increasing health inequalities. • Consultation required in 8 places. Time delay and potential cost to develop outcomes report. • Risk of negative publicity for ICB particularly in local press. • Increased risk of challenge by EHRC (as per above) • Increased risk of judicial review raised by individuals/organisations

Proposed next steps and estimated timeframe for Option 3:

- 1) Recovery Committee (September 16th and Strategy & Transformation Committee (19th September) support recommendation
- 2) Public consultation plan and materials to be developed.
- 3) The preferred option (subject to public consultation), and public consultation plan, to be approved by Board – 28th November 24
- 4) Public consultation exercise 8 weeks (subject to further discussion around timings and resources) – January 25 to February 25
- 5) Feedback and analysis report on consultation completed (approx. 4 weeks required) – March 25
- 6) Engagement with OSC on feedback from consultation exercise – to be confirmed
- 7) Feedback on consultation exercise presented to Board. Board asked to decide on whether to proceed with no GF prescribing approach – to be confirmed
- 8) Feedback on consultation exercise and Board decision presented to OSC - TBC
- 9) Subject to outcomes of public consultation and final decision-making, policy launch & benefits realisation start – to be confirmed

Option 4: Prescribe to under 18s only (Option discounted)

Pros	Cons
<ul style="list-style-type: none"> • Harmonised approach to prescribing of GF bread and bread mixes across C&M • Financial benefit to the ICB of £465,000 - £475,000 per annum • Would support the younger coeliac patients to follow a correct diet until adulthood. 	<ul style="list-style-type: none"> • Contrary to evidence base • Concerns identified through the EIA and QIA process around the impact on vulnerable patients particularly age (as over 60% of issued GF prescriptions are due to patients being aged 60+) and for those adult patients on low income as there is a risk of increasing health inequalities • Would require public engagement in all 9 Places • Risk of negative publicity for ICB particularly in local press. • This option does not provide a service for the majority of patients who are currently receiving GF prescriptions (15% under 19yo) • Increased risk of challenge by EHRC (as per above) • Increased risk of judicial review raised by individuals/organisations

5.1 Financial Case: Following the initial options assessment, Options 1 and 4 have been discounted.

Options	Description (*Committed costs)	Non-recurrent Year 1	Non-recurrent Year 2	Recurrent costs (Annual)	Comments
Option 1: Do nothing – 8 of 9 Places prescribe GF products, St Helens and part of Cheshire West do not	£525,000	£525,000	£530,000	£538,000 (yr 3)	Based on ONS population growth projection
Option 2: Implement Prescribing across whole of Cheshire and Merseyside	£650,000	£650,000	£661,700	£672,287 (yr 3)	Based on ONS population growth projection, however, could increase if cost of products or activity increases. Place prescribing Teams would also review prescribing quantities to ensure all in line with guidance.
Option 3: Withdraw Prescribing across whole of Cheshire and Merseyside	-£525,000	-£525,000	-£525,000	-£525,000	Provides a consistent approach to prescribing for food intolerances. Whilst this does not adhere to published guidance, this is now 6 years old. It is of note that the £525k is a cash releasing saving with a further cost avoidance of £130k.
Option 4: Prescribe to under 18s only	-£465,000 - £475,000	-£465,000 - £475,000	-£465,000 - £475,000	-£465,000 - £475,000	Not in line with published guidance and does not reflect the need of C&M demographics

6 Recommendation

In the context of the Recovery Programme and following further review and the formation of this options appraisal, the Reducing Unwarranted Variation Steering Group recommend the progression to public consultation of option 3, to withdraw prescribing of bread and bread mixes. This recommendation has also been discussed by the Deputy Medical Director and Associate Directors of Quality, and also with the Clinical Effectiveness Group who also support based on the QIA risk scores and EIA.

The context of this recommendation is that availability of GF foods has increased since the original policies were implemented, and whilst the cost of GF bread and bread mixes is still higher, some GF products (e.g. pasta) is the same price. Food labelling is much improved supporting patients to make healthy choices, and in addition, this is not a prescribed medication and bread and bread mixes are not considered an essential food item.

In addition, the withdrawal of prescribing of GF foods has already been implemented in St Helens and part of Cheshire West and so far, we are unaware of any unforeseen consequences; and NHS Cheshire and Merseyside do not prescribe products for other food alternatives for other food allergy / intolerances.

It should be noted that 99% of GF prescriptions issued are subject to payment exemption, the reason for the majority (73%) is that of age. A number of our ICB neighbours including Lancashire and South Cumbria and Shropshire, Telford and Wrekin have already stopped prescribing.

In accordance with the framework methodology established as part of the decommissioning policy, this has been undertaken for Gluten Free prescribing and the output is as follows:

The combined impact of the individual criterion scores, when put through the Prioritisation Framework tool is an overall score of 4.86. This equates to an overall assessment of "Consider Decommission / discontinue" indicating that this investment carries a relatively low priority within the context of financial recovery. (see appendix G).

The options appraisal paper was initially discussed with the Associate Directors of Quality where the proposal was acknowledged and supported. It was subsequently presented to the Recovery Committee on 16th September and was then considered by the Strategy and Transformation (S&T) committee at the meeting on 19th September. The S&T committee supported the recommendation to present the preferred option, to cease prescribing to the Board and that we progress to a public consultation to inform the outcome.

The recommendation to withdraw prescribing is also supported by the Recovery Committee and the Strategy and Transformation Sub-Committee based on the financial case and the QIA and EIA feedback. It is of note that the options appraisal was also reviewed and considered by the Clinical Effectiveness Group on 2nd October and the group supported progress of the proposed option to withdraw prescribing across Cheshire and Merseyside.

6.1 The Ask:

The Board are asked to:

- **approve** the recommendation put forward by the Reducing Unwarranted Variation Steering Group and supported by the Recovery Committee and Strategy and Transformation sub-committee to progress a proposal for a non-prescribing option for gluten free bread and bread mixes in order to commence a public consultation starting in January 2025. The feedback from this exercise, together with that of our Oversight and Scrutiny Committees will inform the decision whether to continue with this recommended option.

Appendices

Appendix A – EIA for option 2 – prescribe across all Places



Appendix A EIA
Clin070 GlutenFree S1

Appendix B – EIA for option 3 – stop prescribing across all Places



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Appendix C – QIA for option 2 – prescribe across all Places



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M%20ICB%20QIA%20

Appendix D – QIA for option 3 – stop prescribing across all Places



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HS%20Cheshire%20a

Appendix E – National Gluten Free Prescribing Offers (where available)

<https://westcheshireway.glasscubes.com/share/s/62deuiccpflvuqvc4kedtu31qo>

Appendix F – DHSC EIA

https://assets.publishing.service.gov.uk/media/5a823231e5274a2e87dc1a59/Equality_impact_assessment_-_GF_food.pdf

Appendix G – NHC C&M Decommissioning Framework review

<https://westcheshireway.glasscubes.com/share/s/ku6ksdqu610ekti92nuci6rj07>
<https://westcheshireway.glasscubes.com/share/s/v8q9qa836ob739m35697hq4d1e>

Gluten-free prescribing proposal

Draft plan for public consultation

Introduction and background

Gluten free (GF) products are sometimes prescribed to individuals who suffer from coeliac disease.

Updated national guidance on prescribing of GF products was introduced in 2018, with the intention of reducing previous variation in what was prescribed. The new guidance meant that GF products that fell outside the category of a bread or a mix were no longer prescribed at NHS expense. Local commissioners were encouraged to align their local policies with the amended regulations, but could also choose to restrict further by selecting bread only, mixes only or choose to end prescribing of all GF foods, if they felt this was appropriate for their population.

As the successor body to nine former clinical commissioning groups (CCGs), NHS Cheshire and Merseyside inherited each CCG's commissioning policies, including those for GF prescribing. Currently, there is not a single approach to prescribing of GF products across Cheshire and Merseyside. Seven areas or 'Places' (Cheshire East, Halton, Knowsley, Liverpool, Sefton, Warrington and Wirral) offer gluten free bread and bread mixes on prescription to eligible patients, while St Helens and Cheshire West do not offer this (although there are still some parts of Cheshire West where prescribing is undertaken – Winsford, Northwich, Middlewich and surrounding area).

On 28 November 2024, the Board of NHS Cheshire and Merseyside will be asked to give the go-ahead for a public consultation about a proposal to end ICB funded gluten free prescribing across Cheshire and Merseyside.

This document outlines NHS Cheshire and Merseyside's plan for holding a public consultation on this proposal from 14 January to 25 February 2025, pending the Board's approval. It should be read alongside the following paper being presented to Board: *Proposal for ICB funded Gluten Free Prescribing across Cheshire and Merseyside*, which contains additional background and rationale for the proposed change.

Objectives

The public consultation will present a single option – the cessation of GF prescribing across Cheshire and Merseyside. 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 receiving gluten free bread and bread mixes on prescription, 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.

Legal and statutory context

The main duties on NHS bodies to make arrangements to involve the public are set out in the National Health Service Act 2006, as amended by the Health and Care Act 2022 (section 14Z45 for integrated care boards).

Involvement also has links with separate duties around equalities and health inequalities (section 149 of The Equality Act 2010 and section 14Z35 of the National Health Service Act 2006). As part of our work, we need to involve people with protected characteristics, social inclusion groups and those who experience health inequalities.

The courts have established guiding principles for what constitutes a fair consultation exercise, known as the Gunning principles. These are:

1. Consultation must take place when the proposal is still at a formative stage.
2. Sufficient information and reasons must be put forward for the proposal to allow for intelligent consideration and response.
3. Adequate time must be given for consideration and response.
4. The product of consultation must be conscientiously taken into account.

Methods of engagement and materials

NHS Cheshire and Merseyside will produce clear and accessible public-facing information about the proposal, details of 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 a change.

This information will be accompanied by a questionnaire containing both qualitative and quantitative questions, designed to gather people's views and perspectives on the proposals. Both the information and questionnaire will be available in Easy Read format. All materials will be made available on the NHS Cheshire and Merseyside website, 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.

To ensure that those who would be most impacted by any potential change have an opportunity to share their views, NHS Cheshire and Merseyside will seek to work with colleagues in general practice and local pharmacies, to ensure that those who currently receive gluten free bread and bread mixes on prescription are made aware that the consultation is underway.

While specific events will not be organised as part of the consultation, if individual groups/networks request further information, NHS Cheshire and Merseyside will offer to attend meetings to provide additional briefings if required/appropriate.

Audiences

The following is an overview of key groups who we will seek to engage and/or communicate with during the consultation, either as a party with a direct interest or as a means of promoting the consultation to a wider audience.

Internal/NHS

- NHS Cheshire and Merseyside Integrated Care Board (ICB)
- NHS C&M staff
- General practice
- Primary care networks (PCNs)
- Local medical committees
- Local pharmacy committees
- NHS England

External

- General public in Cheshire and Merseyside
- People in Cheshire and Merseyside who currently receive prescriptions for GF bread and bread mixes (approx. 2,300)
- Local authorities
- Champs Public Health Collaborative
- MPs
- Local voluntary, community, faith and social enterprise organisations (VCFSEs)
- Local Healthwatch organisations
- Local/regional media outlets
- Coeliac UK (Liverpool, Cheshire and Warrington branches)

Governance and approvals

This plan has been developed by NHS Cheshire and Merseyside's Communications and Engagement team, which will also be responsible for leading public consultation activity. The plan will be presented to the Board of NHS Cheshire and Merseyside for approval before consultation commences.

Local authority scrutiny

NHS commissioners must consult local authorities when considering any proposal for a substantial development or variation of the health service. Subject to the board's approval of this plan, NHS Cheshire and Merseyside will commence discussions with each of the relevant local authorities.

Responding to enquiries

Members of the public will be directed to contact engagement@cheshireandmerseyside.nhs.uk with any enquiries about the consultation (a phone number will also be supplied). NHS Cheshire and Merseyside's Patient Experience

Team will be briefed on the engagement so that any enquiries that come through central routes can be directed appropriately.

Analysis, reporting and evaluation

When the consultation closes, the findings will be analysed and compiled into a report by an external supplier. The feedback received will be used to inform final decision-making about the proposal, and will therefore be received by a future meeting of the Board of NHS Cheshire and Merseyside. The outcome of this will be communicated using the same routes used to promote the consultation.

It's 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.

ENDS



Cheshire and Merseyside

Equality Analysis Report

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

Cheshire & Merseyside wide

Start Date:	October 2024	
Equality and Inclusion Service Signature and Date:	Nicky Griffiths	30 October 2024
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:	Katie Bromley	30 October 2024
*Finish Date:		
*Senior Manager Sign Off Signature and Date		
*Committee Date:	28 th November 2024	

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.
<p>In 2016 – 2017 the Department of Health and Social Care undertook a review of prescribing for gluten free products and following a public consultation recommended that prescribing was limited to bread and bread mixes only.</p> <p>When gluten free prescribing was first introduced, the availability of these foods was limited, however, all major supermarkets and other retailers stock gluten free foods both in store and on-line. In addition, food labelling has improved, and awareness has increased which means people are able identify which foods contain gluten and choose healthy options.</p> <p>Currently in Cheshire and Merseyside 7* out of 9 Places offer Gluten Free Prescribing for patients with diagnosed coeliac disease in line with DHSC guidelines (*St Helens CCG and part of Cheshire West CCG stopped prescribing around 5 years ago). Therefore, there is inequity across Cheshire and Merseyside.</p> <p>NHS Cheshire and Merseyside was created in July 2022 and, as the statutory body, took over commissioning responsibilities from the 9 former CCGS. NHS C&M has to consider how to use the fixed resource allocation from NHS England to enable them to fulfil their</p>

duties and have to decide how and where to allocate resources to best meet the healthcare needs of the population they serve.

Under the Policy Harmonisation programme, and based on the DHSC consultation and clinical opinion, the recommendation was to re-instate prescribing for bread and bread mixes however this would result in an estimated additional annual spend of £130k. However, because of the need for NHS Cheshire and Merseyside to consider how they allocate funding to ensure it is being allocated to areas of highest risk, a review has been undertaken regarding the continuation of spend on gluten free prescribing and a recommendation to Board to stop gluten free prescribing is being presented. This would of course be subject to a public consultation exercise in order to inform the final decision.

A number of other ICBs have stopped prescribing, one of our neighbouring ICBs Lancashire and South Cumbria do not offer this service, and as an ICB we do not prescribe other food products for patients with other food intolerances or allergies.

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 to prescribing food products for patients with coeliac disease and with other food intolerances / allergies
- To support the ICB to achieve financial savings - stopping prescribing across 8 places which would offer an estimated saving of £525k per year.
- To carry out a public consultation exercise to inform the final decision on gluten free prescribing

2. Change to service.

Currently 7* out of 9 Places offer Gluten free prescribing for bread and bread mixes, St Helens and Cheshire West CCG opted to stop this prior to the DHSC consultation. *For Cheshire West Place, the area that was covered by the former Vale Royal CCG did not opt to withdraw prescribing, and as such there are still part of Cheshire West were prescribing can be undertaken (Winsford, Northwich, Middlewich and surrounding area).

The proposal would stop prescribing across all of Cheshire and Merseyside. This proposal is based on the much wider availability of gluten free goods, which has increased in the 6 years since the DHSC consultation, the clearer food labelling which makes healthy choices easier and whilst bread is still more expensive than non gluten free options, the difference in price has reduced and bread is not required for a healthy diet.

3. Barriers relevant to the protected characteristics

Guidance note: describe where there are potential disadvantages.	
<p>Primarily this will affect patients with coeliac disease and related conditions. However, the eligibility criteria states that gluten free products will be commissioned for patients diagnosed as suffering from established gluten-sensitive enteropathies, including dermatitis herpetiformis and coeliac disease. Other impact on protected characteristic groups will be no different to that on other members of the public who suffer with this disease.</p> <p>Awareness raising about alternative gluten free available foods will be available via GPs.</p> <p>There is no evidence to suggest that any protected group has higher prevalence of gluten intolerance.</p> <p>Diabetics and patients with food allergies are the most immediate comparator where alternative foods are not prescribed by the NHS. Gluten intolerance patients do not need to eat wheat based products to maintain good health.</p> <p>Poorly controlled coeliac disease in pregnancy can increase the risk of developing pregnancy-related complications, such as giving birth to a low birth weight baby. However, if pregnant women adhered to Gluten Free diet and their disease is under control then pregnancy related risk would be similar to pregnant women without coeliac disease. Pregnant women with coeliac disease get advice on managing their condition from both General Practitioners and hospital doctors.</p> <p>Coeliac disease is 3 times more common in women than in men and so any policy changes will affect women more than men.</p> <p>This assessment recognises that advice needs to be given to the public on healthy eating for patients with coeliac disease and we need to particularly reach out to women with healthy eating messages - this may help to mitigate against some patients with coeliac disease may not adhere to gluten free diet.</p> <p>Consideration should also be given to older people (who tend to be less mobile) or less mobile people (e.g. due to physical disability) are more likely to find it difficult to source gluten free foods.</p>	

Protected Characteristic	Issue	Remedy/Mitigation
Age	<p>Coeliac UK have identified that it is key for younger people to have the right diet and have in the past supported stopping prescribing for all but under 18s.</p> <p>According to Coeliac UK, the majority of people are diagnosed from 50 years old</p>	C&M data shows that less than 12% of prescriptions are allocated on the basis of being under 18s, and therefore prescribing to just this group could be

	<p>and it is most common in people aged between 50 – 69 years. C&M data shows that 60% of GF prescriptions are allocated because patients are aged 60 and above and therefore our older age population may feel disadvantaged by stopping prescribing or prescribing for just under 18s.</p> <p>However, although only 11% of gf prescriptions are allocated to children and young people, they are not financially independent, and this data does not take into account their parents' financial capacity.</p> <p>According to Coeliac UK, non-adherence to a gluten free diet puts patients at a higher risk of long-term complications, including osteoporosis, ulcerative jejunitis, intestinal malignancy, functional hyposplenism, vitamin D deficiency and iron deficiency. This could lead to patients requiring additional care and support from NHS.</p> <p>An example given by Coeliac UK states it costs £195 a year per patient to support GF on prescription, but the average cost to the NHS of an osteoporotic hip fracture is £27,000.</p>	<p>seen as discriminatory for the older population.</p> <p>GF products are much more widely available in supermarkets and other outlets both in store and on-line, and improved food labelling means that patients are able to make more informed decisions about a healthy diet. In addition, bread is not necessary for a healthy diet as there are gluten free alternatives e.g. GF pasta, rice, potatoes etc.</p> <p>GP would continue to monitor patients and information is widely available on how to avoid gluten and follow a healthy diet.</p>
Disability (you may need to discern types)	<p>Currently, patients can get free NHS prescriptions if, at the time the prescription is dispensed, they:</p> <ul style="list-style-type: none"> • have a continuing physical disability that prevents them from going out without help from another person and have a valid MedEx • hold a valid war pension exemption certificate and the prescription is for an accepted disability. <p>People with coeliac disease, amongst these groups of people, may therefore be negatively impacted as a result of this proposal.</p> <p>People in this cohort may feel that this has a detrimental effect on their finances and so on their overall quality of life.</p> <ul style="list-style-type: none"> • People with learning difficulties may find the GF labelling confusing and could be at greater risk of not adhering to a GF 	<p>Many supermarkets now have outlets on-line offering home deliveries which would support those with mobility issues to access GF products.</p> <p>GPs could offer prescriptions through the Individual Funding Request (IFR) process if their patient could demonstrate exceptionality.</p> <p>GP would continue to monitor patients</p>

	<p>diet without these products being prescribed.</p> <ul style="list-style-type: none"> • Patient with mobility issues may struggle to get to shops to buy GF foods. 	
Gender reassignment	No greater impact	
Marriage and Civil Partnership	No greater impact	
Pregnancy and maternity	<p>Poorly controlled coeliac disease in pregnancy can increase the risk of developing pregnancy-related complications, such as giving birth to a low-birth weight baby.</p>	<p>Only 0.15% of the prescription exemptions are because of maternity exemption which implies the number of patients impacted is minimal.</p> <p>If pregnant women adhered to Gluten Free diet and their disease is under control then pregnancy related risk would be similar to pregnant women without coeliac disease. Pregnant women with coeliac disease get advice on managing their condition from both GPs and hospital doctors.</p> <p>The prescription exemption applies to pregnant women from the time they are pregnant to one year after either the due date or delivery date. This equality group will have short term effect.</p>
Race	No greater impact	
Religion and belief	No greater impact	

Sex	According to NICE the prevalence in females is higher than in males (0.6% compared to 0.4%). C&M data reflects this with 65% of patients being female. This could result in females being more impacted than men, and they feel that this has a detrimental effect on their finances and so on their overall quality of life.	Food labelling is much improved and supports people to make healthy choices. In addition, bread is not necessary for a healthy diet as there are gluten free alternatives e.g. GF pasta, rice, potatoes etc. There are many websites with information on how to remain GF. GP would continue to monitor patients
Sexual orientation	No greater impact	
<p>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). <i>Examples of groups to consider include: 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.</i></p> <p style="text-align: center;"><i>Health inclusion groups</i></p> <p style="text-align: center;">https://www.england.nhs.uk/about/equality/equality-hub/national-healthcare-inequalities-improvement-programme/what-are-healthcare-inequalities/inclusion-health-groups/</p> <p style="text-align: center;"><i>For a more in-depth assessment of health inequalities please use the HEAT toolkit</i></p> <p style="text-align: center;">https://www.gov.uk/government/publications/health-equity-assessment-tool-heat</p>		
refugees and asylum seekers	No greater impact	
Looked after children and care leavers	Children and young people in care are not financially independent and often rely on GF specific products.	
Homelessness	No greater impact	
worklessness	No greater impact	
People who live in deprived areas	No greater impact	
carers	No greater impact	
Young carers	No greater impact	
People living in remote, rural and island locations	There is a risk that people in more remote areas will not have the same access to	Many supermarkets offer on-line shopping and deliver to homes,

	supermarkets with gluten free alternatives to bread. People in this cohort may feel that this has a detrimental effect on their finances and so on their overall quality of life.	and bread is not necessary for a healthy diet as there are gluten free alternatives e.g. GF pasta, rice, potatoes etc. GP would continue to monitor patients
People with poor literacy or health Literacy	No greater impact	
People involved in the criminal justice system: offenders in prison/on probation, ex-offenders.	No greater impact	
<i>Sex workers</i>	No greater impact	
People or families on a low income	There is a risk that people or families on low income will not be able to adhere to a gluten free diet because the cost of GF bread and bread mixes compared to a standard loaf and flour is higher. People on low income who choose to purchase gluten free products because they can no longer obtain them on prescription may feel that this has a detrimental effect on their finances and so on their overall quality of life. The financial capacity of patients over 60 receiving prescription payment exemptions due to age is unknown and therefore still a risk that they will be impacted because of low income. Children and young people are at risk from not being able to adhere to a GF diet if the cost is too expensive. According to Coeliac UK a weekly gluten free food shop can be as much as 20% more expensive than a standard weekly food shop	C&M data shows that less than 2% of the prescription exemptions are because the patient is in receipt of tax credit or income based job seekers allowance. Whilst the cost of bread and flour is more expensive, there are other GF products e.g. pasta which is the same price as standard, and there are other natural GF foods. There are websites with information on how to maintain a GF diet. GP would continue to monitor patients
People with addictions and/or substance misuse issues	No greater impact	
SEND / LD	No greater impact	
Digital exclusion	No greater impact	

<p>4. What data sources have you used and considered in developing the assessment?</p>

NHS England Guidance: 'Prescribing Gluten-Free Foods in Primary Care: Guidance for CCGs' NICE guidance regarding coeliac disease: https://www.nice.org.uk/guidance/qs134 , Department of Health & Social Care website, Coeliac UK website, C&M prescribing data
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)
No engagement has taken place yet as the work to date has been an options appraisal to recommend an ICB proposal. This EIA is part of paper to ICB Board meeting to establish support for a non-prescribing option and at that point, if appropriate, public consultation would be initiated in order to inform the final decision.
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).

Risk	Required Action	By Who/ When
<p>If the option to withdraw prescribing is accepted, there is a risk that patients who previously received prescriptions will not adhere to a GF diet which could have significant health implications for them and will potentially increase demand (& cost) on future NHS Services.</p> <p>An example given by Coeliac UK states it costs £195 a year per patient to support GF on prescription, but the average cost to the NHS of an osteoporotic hip fracture is £27,000.</p>	<p>A published DHSC Impact Assessment examines the issue of adherence in detail and concludes that adherence to a GF diet cannot be isolated to any single cause. Evidence shows that many factors are at play including product labelling, cost and information when eating out and managing social occasions. Adherence requires a range of knowledge and skills to avoid all sources of gluten. Gluten free foods are now much more readily available in supermarkets, with clear gluten free labelling and greater awareness on healthy eating choices. Whilst bread and bread mixes are still more expensive than non GF products (according to Coeliac UK a gluten free loaf of bread is on average 4.3 times more expensive than a standard gluten containing loaf) it can be said that the cost of these products has been reducing over time and there are other GF products that are comparable prices to standard goods (e.g. 500g of GF pasta is the same price as 500g of pasta containing gluten). In</p>	<p>Medical Directorate would ensure this happened following a decision</p>

	<p>addition, there are naturally free gluten free products e.g. rice, potatoes.</p> <p>In C&M the majority of patients receiving GF Prescriptions are exempt from charges, with over 70% of this being due to age. Because this exemption does not take into account financial capacity it is difficult to evidence what the individual financial impact on the impacted patients would be. It should be noted that there are less than 2% of prescription exemptions identified as being on tax credits or income support.</p> <p>If the option to stop prescribing was accepted, information on how to adhere to a gluten free diet would be made available and GPs would continue to monitor these patients as usual.</p>	
<p>There is a reputational risk to the ICB if the option to withdraw prescribing is accepted. Due to the current cost of living, there have been a number of national articles on the increased cost of “free from” foods despite them being much more available. In addition, 99% of the cohort of patients receiving prescriptions have an exemption in that they do not pay for prescriptions so could be seen that we are disadvantaging our most vulnerable population.</p>	<p>See above regarding non-GF options.</p> <p>In addition, the ICB does not prescribe for other conditions that are associated with, or affected by the types of food they eat, so this would result in a fairer approach for these patients.</p> <p>A public consultation exercise would be held in those Places who currently prescribe in line with the approach taken in St Helens and West Cheshire CCG before a final decision is made.</p>	n/a

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]		

QUALITY IMPACT ASSESSMENT					
Project Name	Gluten Free Prescribing – Option 3 All Places Withdraw Gluten Free Prescribing				
Verto/PMO reference		Date of QIA	10/07/24	Date QIA reviewed	Stage 1 (local) 21/08/2024
					Stage 2 (regional) 06/09/24
Name of Project Manager	Katie Bromley	Name of Programme manager	Natalia Armes	Clinical Lead	Rowan Pritchard Jones
Confirm date discussed at PDG or appropriate Place forum	n/a ICB Wide Recovery Programme	Is this QIA part of an options appraisal?	Yes	Is the place of care expected to change?	n/a
Is this a permanent or temporary change? (e.g., a GRANT or a PILOT scheme?)	Permanent	If temporary – what are the expected timescales?	n/a	What will happen to the cohort of patients in progress when the service ends?	They will have to fund their own Gluten Free products
It is a nationally, or regionally, mandated service?	No	Is it identified as clinically essential?	No	Is it a statutory service? Y/N and details	No
Confirm if a Digital Impact Assessment has been undertaken	n/a	Confirm if a DPIA is required. (Remember this on all the data involved – not just the data held by NHS C&M)	n/a	An EIA is advised. Confirm if it has been undertaken.	Yes
Number of patients affected	2570 (23/24 data)	Mitigated quality risk if project progresses.	Moderate - 4	Mitigated Quality risk if project is NOT Progressed	Low - 1
Current costs	£520,000	Proposed costs	£0	Does it impact on another C&M Place?	8 of 9 Places: Liverpool Wirral Sefton

					Knowsley Warrington Halton Cheshire East Cheshire West (excluding GP practices in Cheshire West CCG footprint)
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Background and overview of the proposals (can be copied from PID on Verto or from National/Regional commissioning guidance)

In 2016 – 2017 the Department of Health and Social Care undertook a review of prescribing for gluten free products and following a public consultation recommended that prescribing was limited to bread and bread mixes only.

When gluten free prescribing was first introduced, the availability of these foods was limited, however, all major supermarkets and other retailers stock gluten free foods both in store and on-line. In addition, food labelling has improved, and awareness has increased which means people are able identify which foods contain gluten and choose healthy options.

Currently in Cheshire and Merseyside 7* out of 9 Places offer Gluten Free prescribing for patients with diagnosed coeliac disease in line with the national Department of Health and Social Care (DHSC) consultation the outcome of which was to reduce prescribing to bread and bread mixes only in 2018. It is of note that for the remaining 2 Places, St Helens CCG and Cheshire West CCG opted to withdraw prescribing completely (noting this was prior to the national Department of Health and Social Care (DHSC) consultation as detailed above).

*For Cheshire West Place, the area that was covered by the former Vale Royal CCG did not opt to withdraw prescribing, and as such there are still part of Cheshire West were prescribing can be undertaken (Winsford, Northwich, Middlewich and surrounding area. Therefore, there is inequity of access to these products across Cheshire and Merseyside.

NHS Cheshire and Merseyside was created in July 2022 and, as the statutory body, took over commissioning responsibilities from the 9 former CCGs. NHS C&M has to consider how to use the fixed resource allocation from NHS England to enable them to fulfil their duties and have to decide how and where to allocate resources to best meet the healthcare needs of the population they serve.

Under the Policy Harmonisation programme, and based on the DHSC consultation and clinical opinion, the recommendation was to re-instate prescribing for bread and bread mixes however this would result in an estimated additional annual spend of £130k. However, because of the need for NHS Cheshire and Merseyside to consider how they allocate funding to ensure it is being allocated to areas of highest risk, a review has been undertaken regarding the continuation of spend on gluten free prescribing and a recommendation to Board to stop gluten free prescribing is being presented. This would of course be subject to a public consultation exercise in order to inform the final decision.

QUALITY IMPACT ASSESSMENT

The purpose of the QIA is to help articulate the risks to patients as it is hard to evidence the impact of withdrawing Gluten Free prescribing.

Risks if the project did not go ahead.

If this option was not supported, this would leave unwarranted variation in access to these services.

Patient safety

QUALITY IMPACT ASSESSMENT

<p>Please confirm the specific patient groups affected.</p> <p>Advise the impact on health inequalities</p>	<p>There are over 13,300 patients diagnosed with Coeliac Disease and other conditions which would deem them eligible for gluten free prescribing. Most patients choose to purchase their GF products themselves, however, 2,314 patients receive their GF bread and bread mixes through a prescription. Currently 99% of patients currently receiving Gluten Free prescriptions are exempt from charges. The highest categories are as follows:</p> <p>Aged 60 or over – 61%</p> <p>Under 18 – 12%</p> <p>Pre-payment certificate – 3%</p> <p>Medical Exemption – 3%</p> <p>Non specified Declaration – 19%</p> <p>The data shows the biggest impact would be to patients over 60.</p>		
	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
<p>Explain how the project minimises the risk of harm and impacts patients. Include any risks</p>	<p>This would save the ICB over £500,000 per annum which could be spent on other priorities.</p>	<p>The majority of patients receiving prescriptions are exempt from charges, and this is mainly due to age. Because this exemption does not take into account financial capacity it is difficult to evidence that these patients would not be able to afford to purchase their own GF bread and mixes. The 2 CCGs that have withdrawn prescribing have advised that they have not experienced an increase in patients presenting with issues relating to not following a GF diet.</p>	<p>It is difficult to evidence the impact of Coeliac patients not being able to access Gluten Free (GF) bread and bread mixes, but there are known risks to not adhering to a GF diet which could have long term health impacts and lead to greater demand on wider health services.</p> <p>According to Coeliac UK, non-adherence to a gluten free diet puts patients at a higher at a higher risk of long-term complications, including osteoporosis, ulcerative jejunitis, intestinal malignancy, functional hyposplenism, vitamin D deficiency and iron deficiency. This could lead to patients requiring additional care and support from NHS.</p>

QUALITY IMPACT ASSESSMENT

Explain how the project may impact upon adults at risk and children and provide assurance that safeguarding process are in place with the provider		A gluten free diet may be maintained with items such as potatoes and rice, and bread is not essential	<p>The patient groups that will be most impacted by this decision are older adults (over 60yo) and young people (under 18 & in full time education). These patient groups may potentially be at greater risk (incl. osteoporosis / long term conditions for younger patients) if they do not adhere to a GF diet. It is of note, however, this policy only relates to bread and bread mixes and bread is not an essential food item as there are gluten free alternatives e.g. GF pasta, rice, potatoes etc. and improved labelling on food and website with information on how to maintain a healthy GF diet.</p> <p>Due to the current cost of living, there have been a number of national articles on the cost of “free from” foods despite them being much more available. In addition, 99% of the cohort of patients receiving GF prescriptions have an exemption in that they do not pay for prescriptions so could be seen that we are disadvantaging our most vulnerable population. Because 73% of these exemptions are due to age, and this exemption does not take into account financial capacity, it is difficult to evidence that these patients would not be able to afford to purchase their own GF bread and mixes</p>
Describe the impact on processes for reducing and	n/a	n/a	n/a

QUALITY IMPACT ASSESSMENT

preventing patient harms and Healthcare Associated Infections? (e.g., falls, pressure ulcers, MRSA / CDI, VTE, etc)			
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Clinical Effectiveness			
Please confirm how the project uses the best, knowledge based, research	<p>The review of GF prescribing was carried out initially by Pharmacists and Dieticians, with support from other clinicians as part of the CPH Steering Group and was then continued under the ICB Unwarranted Variation Programme due to the financial constraints. Evidence from Dept. Health & Social Care, Coeliac UK was also reviewed. The recommendation from DH&SC is now to prescribe only bread and bread mixes, however, in the “Prescribing Gluten-Free Foods in Primary Care: Guidance for CCGs” document, published following the consultation in 2018 it does state “CCGs may further restrict the prescribing of GF foods by selecting bread only, mixes only or CCGs may choose to end prescribing of GF foods altogether”.</p>		
	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
Explain if/how the project improves hospital flow or improves length of stay		These patients would not be treated in a hospital environment, so no impact on length of stay.	
Describe the impact on			It is difficult to evidence the impact of Coeliac patients not being able to access

clinical outcomes and how this will be monitored.			<p>GF bread and bread mixes, but there are known risks to not adhering to a GF diet which could have long term health impacts (e.g. osteoporosis, ulcerative jejunitis, intestinal malignancy, functional hyposplenism, vitamin D deficiency and iron deficiency), and lead to greater demand on wider health services. However, availability of gf products has improved, as has food labelling. Patients would continue to be supported by their GPs as usual.</p> <p>Feedback from the 2 CCGs who have withdrawn prescribing have not reported any unforeseen consequences.</p>
Does the project result in a higher likelihood of clinical recovery?			If patients cannot afford or cannot get to a supermarket to buy their own GF bread and bread mixes, there could be a negative impact on their long term health.
Does the project provide better access to wider care pathways?			No this would end prescribing
Does the project follow the latest NICE guidance/other relevant best practice evidence?			No. DH&SC and Coeliac UK guidance recommend prescribing bread and bread mixes
Describe the feedback of clinical leads	A number of clinicians have expressed support for the withdrawal, some noting that they have seen requests reduce over the last couple of years potentially due to wider availability of GF products in shops.	Where Clinical Leads support the withdrawal of prescribing, they have noted a potential financial impact to lower income patients.	The Dieticians who were part of the Clinical Policy Harmonisation programme did not support stopping prescribing through concern over those patients who may not follow a GF diet if not prescribed. However, feedback from those Places who have withdrawn

			prescribing is that they have not experienced unforeseen consequences. GPs would continue to support patients and information on how to maintain a GF diet is widely available
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Patient Experience			
Please confirm the specific patient groups affected and how they are impacted.	A policy not to prescribe gluten free products may have an impact on vulnerable patients because gluten free products, while readily available in supermarkets, are more expensive than standard products, and some patients may not be able to access supermarkets easily.		
	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
Explain how the project will impact on the experience of care and better access to services	Not prescribing GF products will save over £500k which can be invested in other services. In addition, GF products are also the only food product that is offered on prescription, but there are other food allergies that don't have this offer, so could argue that stopping prescribing further reduces unwarranted variation.	This option withdraws prescribing and therefore does not impact access to services, however for patients who currently receive prescriptions they may reflect that experience of care is impacted by this, but access to supporting services is unchanged.	

QUALITY IMPACT ASSESSMENT

Describe any consultation or engagement with the population that has occurred or is planned.		Public consultation would take place following a decision from the ICB Board as to whether withdrawing prescriptions would be considered	
Describe any change of location or setting of care.	n/a	n/a	n/a

QUALITY IMPACT ASSESSMENT

Have any risks been identified in the following areas? (please list risk and escalation process)				
Area	Risk identified	If escalated, identify where escalated to	Date escalated	Mitigations put in place
Staff Experience	no			
Service Delivery	no			
Disinvestment	no			
Contingency plans	no			
Interdependency	no			
Sustainability	no			

QUALITY IMPACT ASSESSMENT

RISKS where the project is progressed				
	Comment to explain rationale (include mitigations where applicable)	Likelihood of risk (L) (see table below)	Risk Impact / Consequence (C) (see table below)	Multiplication Total L x C
Quality risk to progress project	If the option to withdraw prescribing is accepted, there is a risk that patients who previously received prescriptions will not adhere to a GF diet due to affordability of free from products, which could have significant health implications for them and will potentially increase demand on health services as a result. There is a risk that this will widen health inequalities in deprived areas.	2	3	6
MITIGATED RISK to progress project				
Quality risk to progress project	<p>In line with Cheshire West CCG actions when they stopped prescribing, we would improve the information and advice available to patients with coeliac disease that will help them to have a healthy, nutritious and balanced diet with all the necessary vitamins and minerals.</p> <p>Coeliac patients can still eat all naturally gluten-free foods such as meat, fish, fruit, vegetables, rice, and potatoes. We will provide advice to the following:</p> <p>Coeliac UK website for guidance and advice NHS Choices Website BBC website on gluten free diet The Eatwell Guide - NHS.</p> <p>Engage with supermarkets within C&M footprint to advise of prescribing decision with ask of them to manage their stock levels.</p>	2	2	4

RISKS if project is NOT progressed				
	Comment to explain rationale (include mitigations where applicable)	Likelihood of risk (L)	Risk Impact / Consequence (C)	Multiplication Total for not progressing project

QUALITY IMPACT ASSESSMENT

		See table below	See table below	L x C
Quality risk if project does not proceed	<p>If the option to withdraw prescribing is not supported, then C&M have unwarranted variation in access to these products.</p> <p>The alternative option is to re-instate prescribing, however, there is a financial risk to the ICB in that an additional £130k would be required to support this and a total estimated annual expenditure of £650k.</p>	1	1	1
MITIGATED RISK if project is NOT progressed				
Mitigated quality risk to progress project	Place based Medicines Management teams would review prescribing quantities to ensure they are in line with Coeliac UK guidance. This may mitigate some of the cost.	1	1	1

Summary

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

Risk Impact Score Guidance

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

		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%)

QUALITY IMPACT ASSESSMENT

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.

QUALITY IMPACT ASSESSMENT

Sign off process			
Name	Role	Signature	Date
Katie Bromley	Project lead		4/9/24
Sinead Clarke	Clinical lead		4/9/24
Natalia Armes	Programme manager		4/9/24
	PMO lead		
Once signed off by all above, then the QIA is submitted to QIA review group			

This section to be completed following review at the QIA review group					
Name	Role	Approved	Rejected	Signature	Date
ADs of Quality	QIA review group chair (after group meeting)	Yes			6/9/24
Denise Roberts (supported by Maxine Dickinson)	AD of Quality	Yes			21/08/24
	C&M ICB QIA lead (if necessary)				

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PROTOCOL FOR THE ESTABLISHMENT OF JOINT HEALTH SCRUTINY ARRANGEMENTS IN CHESHIRE AND MERSEYSIDE

1. INTRODUCTION

1.1 This protocol has been developed as a framework for the operation of joint health scrutiny arrangements across the local authorities of Cheshire and Merseyside. It allows for:

- scrutiny of substantial developments and variations of the health service; and,
- discretionary scrutiny of local health services.

1.2 The protocol provides a framework for health scrutiny arrangements which operate on a joint basis only. Each constituent local authority should have its own local arrangements in place for carrying out health scrutiny activity individually.

2. BACKGROUND

2.1 The relevant legislation regarding health scrutiny is:

- Health and Social Care Act 2012,
- The Local Authority (Public Health, Health and Wellbeing Boards and Health Scrutiny) Regulations 2013; and
- The Health and Care Act 2022.

This is supplemented by relevant guidance:

- Local Authority Health Scrutiny (DHSC, updated 2024)
- Statutory guidance: “Reconfiguring NHS services – ministerial intervention powers” (DHSC, 2024).

2.2 In summary, the statutory framework authorises local authorities individually and collectively to:

- review and scrutinise any matter relating to the planning, provision and operation of the health service; and,

- consider consultations by a relevant NHS commissioning body or provider of NHS-funded services on any proposal for a substantial development or variation to the health service in the local authority's area.

2.3 Ultimately the regulations place a requirement on relevant scrutiny arrangements to reach a view on whether they are satisfied that any proposal that is deemed to be a substantial development or variation is in the interests of the health service in that area. In instances where a proposal impacts on the residents of one local authority area exclusively, this responsibility lays with that authority's health scrutiny arrangements

alone.

2.4 Where such proposals impact on more than one local authority area, each authority's health scrutiny arrangements must consider whether the proposals constitute a substantial development or variation or not.

The regulations place a requirement on those local authorities that agree that a proposal is substantial to establish, in each instance, a joint overview and scrutiny committee for the purposes of considering it. This protocol deals with the proposed operation of such arrangements for the local authorities of Cheshire and Merseyside.

2.5 Whilst it is recognised that the previous power of a health scrutiny committee or joint health scrutiny committee to refer a service change proposal to the Secretary of State for Health and Social Care has been removed, such committees will now possess the ability to request formally that the Secretary of State "call-in" a service change proposal. The ability to "call-in" a proposal should only be used in exceptional circumstances where all efforts to resolve issues locally have been exhausted.

3. PURPOSE OF THE PROTOCOL

3.1 This protocol sets out the framework for the operation of joint scrutiny arrangements where:

- a) an NHS commissioning body or health service provider consults with more than one local authority on any proposal it has under consideration, for a substantial development/variation of the health service;
- b) joint scrutiny activity is being carried out on a discretionary basis into the planning, provision and operation of the health service.

3.2 The protocol covers the local authorities of Cheshire and Merseyside

including:

- Cheshire East Council
- Cheshire West and Chester Council
- Halton Borough Council
- Knowsley Council
- Liverpool City Council
- St. Helens Metropolitan Borough Council
- Sefton Council
- Warrington Borough Council
- Wirral Borough Council

3.3 Whilst this protocol deals with arrangements within the boundaries of Cheshire and Merseyside, it is recognised that there may be occasions when consultations/discretionary activity may affect adjoining regions/ areas. Arrangements to deal with such circumstances would have to be determined and agreed separately, as and when appropriate.

4. PRINCIPLES FOR JOINT HEALTH SCRUTINY

4.1 The fundamental principle underpinning joint health scrutiny will be cooperation and partnership with a mutual understanding of the following aims:

- To improve the health of local people and to tackle health

inequalities (outcome-focussed);

- To ensure that scrutiny activity adopts an appropriate balance between a focus on future service delivery and a focus on responding to immediate concerns/ issues (balanced)
- To represent the views of local people and ensure that these views are identified and integrated into local health service plans, services and commissioning (inclusive);
- To scrutinise whether all parts of the community are able to access health services and whether the outcomes of health services are equally good for all sections of the community (evidence-informed); and,
- To work with NHS bodies and local health providers to ensure that their health services are planned and provided in the best interests of the communities they serve, taking into account any potential impact on health service staff (collaborative).

5. SUBSTANTIAL DEVELOPMENT OF /VARIATION TO SERVICES

5.1 Requirements to consult

5.1.1 All relevant NHS bodies and providers of NHS-funded services (1) are required to consult local authorities when they have a proposal for a substantial development or substantial variation to the health service.

5.1.2 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.

(1) This includes NHS England and any body commissioning services to the residents of Cheshire and Merseyside, plus providers such as NHS Trusts, NHS Foundation Trust and any other relevant provider of NHS funded services which provides health services to those residents, including public health.

5.1.3 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.

5.1.4 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.

5.1.5 Those authorities that agree that any such proposal does constitute a substantial development or variation are obliged to form a joint health overview and scrutiny committee for the purpose of formal consultation by the proposer of the development or variation.

5.1.6 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”.

5.1.7 Determining that a proposal is not a substantial development/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”.

5.1.8 For the avoidance of doubt, if only one authority amongst a number being consulted on a proposal deem it to be a substantial change, the ongoing process of

consultation on the proposal between the proposer and the remaining authority falls outside the provisions of this protocol.

5.2 Process for considering proposals for a substantial development/variation

5.2.1 In consulting with the local authority in the first instance to determine whether the change is considered substantial, the relevant NHS commissioning body / provider of NHS-funded services is required to:

- Provide the proposed date by which it requires comments on the proposals
- Provide the proposed date by which it intends to make a final decision as to whether to implement the proposal- publish the dates specified above
- Inform the local authority if the dates change (2)

5.2.2 NHS commissioning bodies and local health service providers are not required to consult with local authorities where certain 'emergency' decisions have been taken. All exemptions to consult are set out within regulations. (3)

(2) Section 23 of the Local Authority (Public Health, Health and Wellbeing Boards and Health Scrutiny) Regulations 2013

(3) Section 24 ibid

5.2.3 In considering whether a proposal is substantial, all local authorities are encouraged to consider the following criteria:

- 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.

5.2.4 These criteria will assist in ensuring that there is a consistent approach applied by each authority in making their respective decisions on whether a proposal is

“substantial” or not. In making the decision, each authority will focus on how the proposals impacts on its own area/ residents.

6. OPERATION OF A STATUTORY JOINT HEALTH OVERVIEW AND SCRUTINY COMMITTEE

6.1 General

6.1.1 A joint health overview and scrutiny committee will be made up of each of the constituent local authorities that deem a proposal to be a substantial development or variation. This joint committee will be formally consulted on the proposal and, in exceptional circumstances, formally request that the Secretary of State to “call-in” a proposal, where local consultation has failed to resolve significant outstanding issues.

6.1.2 A decision as to whether the proposal is deemed substantial shall be taken within a reasonable timeframe and in accordance with any deadline set by the lead local authority (see section 6.6), following consultation with the other participating authorities.

6.2 Powers

6.2.1 In dealing with substantial development/variations, any statutory joint health overview and scrutiny committee that is established can:

- require relevant NHS bodies and health service providers to provide information to and attend before meetings of the committee to answer questions
- make comments on the subject proposal by a date provided by the NHS body/local health service provider
- make reports and recommendations to relevant NHS bodies/local health providers
- require relevant NHS bodies/local health service providers to respond within a fixed timescale to reports or recommendations
- carry out further negotiations with the relevant NHS body where it is proposing not to agree to a substantial variation proposal.

6.2.2 A joint health overview and scrutiny committee has the ability to request the Secretary of State to “call-in” a service change proposal where it has not been possible to resolve significant outstanding issues during the course of local consultation. The ability to request the “call-in” of a proposal should only be exercised in exceptional circumstances where all possible efforts to resolve the matter locally have been exhausted, as outlined in 6.2.3 and 6.2.4 below.

6.2.3 Where a committee has made a recommendation to a NHS commissioning body/local health service provider regarding a proposal and the NHS body/provider

disagrees with the recommendation, the local health service provider/NHS body is required to inform the joint committee and attempt to enter into negotiation to try and reach an agreement.

6.2.4 In any circumstance where a committee disagrees with a proposal for a substantial variation, there will be an expectation that negotiations will be entered into with the NHS commissioning body/local health service provider in order to attempt to reach agreement.

6.2.5 Where local authorities have agreed that the proposals represent substantial developments or variations to services and agreed to enter into joint arrangements, it is only the joint health overview and scrutiny committee which may exercise these powers.

6.2.5 An ad-hoc statutory joint health overview and scrutiny committee established under the terms of this protocol may only exercise the powers set out in 6.2.1 to 6.2.4 above in relation to the statutory consultation for which it was originally established. Its existence is time limited to the course of the specified consultation and it may not otherwise carry out any other activity.

6.3 Membership

6.3.1 The participating local authorities must ensure that those Councillors nominated to a joint health overview and scrutiny committee produce a membership that reflects the overall political balance across the participating local authorities. However, political balance requirements for each joint committee established may be waived with the agreement of all participating local authorities, should time and respective approval processes permit.

6.3.2 A joint committee will be composed of Councillors from each of the participating authorities within Cheshire and Merseyside in the following ways:

- where 4 or more local authorities deem the proposed change to be substantial, each authority will nominate 2 elected members
- where 3 or less local authorities deem the proposed change to be substantial, then each participating authority will nominate 3 elected members.

(Note: In making their nominations, each participating authority will be asked to ensure that their representatives have the experience and expertise to contribute effectively to a health scrutiny process)

Local authorities who consider change to be 'substantial'	No' of elected members to be nominated from each authority
4 or more	2 members

3 or less	3 members
-----------	-----------

6.3.3 Each local authority will be obliged to nominate elected members through their own relevant internal processes and provide notification of those members to the lead local authority at the earliest opportunity.

6.3.4 To avoid inordinate delays in the establishment of a relevant joint committee, it is suggested that constituent authorities either arrange for delegated decision-making arrangements to be put in place to deal with such nominations at the earliest opportunity, or to nominate potential representatives annually as part of annual meeting processes to cover all potential seat allocations.

6.5 Quorum

6.5.1 The quorum of the meetings of a joint committee shall be one third of the full membership of any Joint Committee, subject to the quorum being, in each instance, no less than 3.

6.5.2 There will be an expectation for there to be representation from each authority at a meeting of any joint committee established. The lead local authority will attempt to ensure that this representation is achieved.

6.6 Identifying a lead local authority

6.6.1 A lead local authority should be identified from one of the participating authorities to take the lead in terms of administering and organising a joint committee in relation to a specific proposal.

6.6.2 Selection of a lead authority should, where possible, be chosen by mutual agreement by the participating authorities and take into account both capacity to service a joint health scrutiny committee and available resources. The application of the following criteria should also guide determination of the lead authority:

- The local authority within whose area the service being changed is based; or

- The local authority within whose area the lead commissioner or provider leading the consultation is based.

6.6.3 Lead local authority support should include a specific contact point for communication regarding the administration of the joint committee. There will be an obligation on the key lead authority officer to liaise appropriately with officers from each participating authority to ensure the smooth running of the joint committee.

6.6.4 Each participating local authority will have the discretion to provide whatever support it may deem appropriate to their own representative(s) to allow them to make a full contribution to the work of a joint committee.

6.7 Nomination of Chair/ Vice-Chair

The chair/ vice-chair of the joint health overview and scrutiny committee will be nominated and agreed at the committee's first meeting.

6.8 Meetings of a Joint Committee

6.8.1 At the first meeting of any joint committee established to consider a proposal for a substantial development or variation, the committee will also consider and agree:

- The joint committee's terms of reference;
- The procedural rules for the operation of the joint committee;
- The process/ timeline for dealing formally with the consultation,

including:

- the number of sessions required to consider the proposal;

and,

- the date by which the joint committee aims to reach its final conclusion on the proposal – which should be in advance of the proposed date by which the NHS commissioning body/service provider intends to make its final decision on it.

-

6.8.2 All other meetings of the joint committee will be determined in line with the proposed approach for dealing with the consultation. Different approaches may be taken for each consultation and could include gathering evidence from:

- NHS commissioning bodies and local service providers;
- patients and the public;
- voluntary sector and community organisations; and
- NHS regulatory bodies.

6.9 Reports of a Joint Committee

6.9.1 A joint committee is entitled to produce a written report which may include recommendations. As a minimum, the report will include:

- An explanation of why the matter was reviewed or scrutinised.
- A summary of the evidence considered.
- A list of the participants involved in the review.
- An explanation of any recommendations on the matter reviewed or scrutinised.

The lead authority will be responsible for the drafting of a report for consideration by the joint committee.

6.9.2 Reports shall be agreed by the majority of members of a joint committee and submitted to the relevant NHS commissioning body/health service provider.

6.9.3 Where a member of a joint health scrutiny committee does not agree with the content of the committee's report, they may produce a report setting out their findings and recommendations which will be attached as an appendix to the joint health scrutiny committee's main report.

7. DISCRETIONARY HEALTH SCRUTINY

7.1 More generally, the Health and Social Care Act 2012 and the 2013 Health Scrutiny Regulations provide for local authority health scrutiny arrangements to scrutinise the planning, provision and operation of health services.

7.2 In this respect, two or more local authorities may appoint a joint committee for the purposes of scrutinising the planning, provision and operation of health services which impact on a wider footprint than that of an individual authority's area.

7.3 Any such committee will have the power to:

- require relevant NHS commissioning bodies and health service providers to provide information to and attend before meetings of the committee to answer questions.
- make reports and recommendations to relevant NHS commissioning bodies/local health providers.
- require relevant NHS commissioning bodies/local health service providers to respond within a fixed timescale to reports or recommendations.

7.4 Ordinarily, a discretionary joint committee would not have the ability to request the Secretary of State for Health and Social Care “call-in” a service change proposal. However, please note section 8.3 below.

7.5 In establishing a joint committee for the purposes of discretionary joint scrutiny activity, the constituent local authorities should determine the committee’s role and remit. This should include consideration as to whether the committee operates as a standing arrangement for the purposes of considering all of the planning, provision and operation of health services within a particular area or whether it is being established for the purposes of considering the operation of one particular health service with a view to making recommendations for its improvement. In the case of the latter, the committee must disband once its specific scrutiny activity is complete.

7.6 In administering any such committee, the proposed approach identified in sections 6.3 – 6.9 of this protocol should be followed, as appropriate.

8. SCRUTINY OF CHESHIRE AND MERSEYSIDE INTEGRATED CARE SYSTEM

8.1 Further to this protocol and in particular section 7 above, the nine local authorities have agreed to establish a discretionary standing joint health scrutiny committee in response to the establishment of the Cheshire and Merseyside Integrated Care System.

8.2 A separate Joint Scrutiny Committee Arrangements document has been produced in line with the provisions of this protocol to outline how the standing joint committee will operate.

8.3 In summary, the “Cheshire and Merseyside Integrated Care System Joint Health Scrutiny Committee” has the following responsibilities:

- To scrutinise the work of the Integrated Care System in relation to any matter regarding the planning, provision and operation of the health service at footprint level only; and
- To consider the merits of any service change proposals that have been deemed to be a substantial variation in services by all nine authorities.

9. CONCLUSION

9.1 The local authorities of Cheshire and Merseyside have adopted this protocol as a means of governing the operation of joint health scrutiny arrangements both mandatory and discretionary. The protocol is intended to support effective consultation with NHS commissioning bodies or local health service providers on any proposal for a substantial development of or variation in health services. The

protocol also supports the establishment of a joint health overview and scrutiny committee where discretionary health scrutiny activity is deemed appropriate.

9.2 The protocol will be reviewed regularly, and at least on an annual basis to ensure that it complies with all current legislation and any guidance published by the Department of Health and Social Care.



Return of inpatient intrapartum maternity services: Post Implementation Review

January 2024

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Executive Summary

Inpatient intrapartum maternity services at Macclesfield DGH were suspended in March 2020 in preparation for an anticipated surge in critical care demand linked to the COVID-19 pandemic.

Initially it was hoped that the suspension would only be for a 6-month period, however this was extended on a number of occasions, and, ultimately, services remained suspended for just over three years.

Throughout the suspension, women were given the option to choose which site they wanted to attend, with most delivering at neighbouring 'host' hospitals in Stockport, Wythenshawe and Crewe. A small number of women chose other options including Royal Stoke Hospital or home birth. Most antenatal and post-natal care continued to be provided by East Cheshire NHS Trust (ECT) at MDGH and in the community across eastern Cheshire.

ECT remained committed to returning services when safe to do so. Throughout most of 2022 and into 2023 the trust worked tirelessly, including significant work with partners across the NHS as well as Cheshire East Council, to be able to achieve this and in June 2023 the trust celebrated the re-opening of intrapartum services under the headline "Macc is Back!"

This report captures the significant programme of work undertaken that led up to the return of services and sets out the key lessons learned to inform future service changes.

Board members, staff, partners, key stakeholders, and patient representatives who were involved in the project were all invited to take part in this Post Implementation Review, which has taken place three months after the return of the service.

In summary, feedback regarding the implementation process has been broadly positive, and there are lessons to be learned from the maternity experience that could be useful for future projects.

These can be summarised as:

- The importance of ongoing engagement:
 - With staff, including face to face, to listen to and understand their perspectives,
 - With clinical leadership, ensuring they play a role in feeding in to and out of a project,
 - With patients, ensuring patient voice is central to the service change, and wherever possible patients, or patients' groups are involved in co-producing service change.
- To take time to map out all the wider stakeholders affected by the changes, their drivers and motivations, and ensuring that they are fully engaged in the development and implementation of plans.
- Each project needs to establish appropriate governance arrangements that are proportionate to the scale and complexity of the task. Involving external partners in this governance should be considered for all projects.
- It is important for any major project to understand any external decision-making factors. To take time to understand any critical dependencies required to secure the service change and that all relevant decision makers are appropriately and effectively engaged.
- Project may need to appoint a Senior Responsible Officer and Clinical Lead to help lead any given project, these leaders need appropriate levels of authority and decision making to help drive the project.
- Snagging issues and unintended consequences should be expected and where possible anticipated.

The return of intrapartum maternity services to Macclesfield DGH after a significant suspension is great news for current and future expectant women and their families and should be celebrated. Everyone involved in this project are to be thanked and congratulated for their hard work and determination.

1 Introduction and purpose

- 1.1 Intrapartum maternity services at Macclesfield District general Hospital (MDGH) were suspended in March 2020 in preparation for a surge in critical care demand linked to the COVID-19 pandemic.
- 1.2 East Cheshire NHS Trust (ECT) remained committed to returning services when safe to do so and worked tirelessly, including significant work with partners across the NHS as well as Cheshire East Council, to be able to achieve this.
- 1.3 This Post Implementation Review focusses on the programme of work that led to the successful return of services in June 2023. In doing so, the report provides details of the background to the suspension, a high-level overview of the arrangements for intrapartum services pre-suspension as well as arrangements during the suspension, and our plans for a safe and sustainable service moving forwards.
- 1.4 The report details the programme of work undertaken to return services and captures the views of people involved in the work, reflecting on the approach taken by ECT and our partners and whether improvements could have been made. The report also reflects on the first three months of running the service including any successes, any emerging issues and any unintended consequences caused by the return of services.
- 1.5 The report concludes with several lessons that future projects should consider when planning significant service changes.

2 Background

2.1 Service Provision at East Cheshire Trust up to 2019/20

Prior to the COVID-19 pandemic, ECT's maternity and gynaecology services were delivered from the Macclesfield site. Facilities include:

- Ante natal unit,
- Inpatient maternity unit with:
 - Delivery suite comprising of three standard and two water-birth ensuite rooms,
 - Triage assessment bay with 6 beds,
 - 22 antenatal/postnatal beds,
- Dedicated obstetrics theatre.

In addition, community midwifery antenatal and postnatal clinics were held in locations across eastern Cheshire with a homebirth service also available.

ECT had six substantive consultants (with an established budget for 6.8) who shared obstetrics and gynaecology commitments, and all contributed to the on-call rota. Complex foetal-maternal medicine was jointly managed through relationships with neighbouring specialist units at St Mary's in Manchester and Liverpool Women's Hospital.

The maternity service supported the births of around 1,500 babies a year (4 per day), supported by a Level 1 neonatal unit. In 2019, ECT's maternity service was rated 'Good' by the CQC in all five areas.

2.2 Decision making leading up to closure of the maternity unit at Macclesfield MDGH

In March 2020, at the start of the COVID-19 pandemic, NHS England instructed trusts to prepare for and respond to large numbers of inpatients requiring respiratory support, particularly mechanical ventilation. Almost immediately, ECT had concerns about the ability to respond.

- In 2020 the critical care unit at MDGH was extremely small by modern standards with capacity for just 6 Level III patients (normally hosts a mixture of Level II and Level III patients).

- Medical staffing to the unit was provided by a small anaesthetics department which consisted of just 8 consultants and 12 juniors (mixture of SAS, and trainees). 6 of the 8 consultants provided dedicated daytime weekday cover to the ICU; all other times were covered by the on-call consultant anaesthetist. Anaesthetic cover to the critical care unit was provided by a 24/7 resident SAS anaesthetist who also simultaneously provided anaesthetic cover to the labour ward.

It rapidly became apparent that the major limiting factor to the trust's ability to increase critical care capacity was the anaesthetic workforce and that it would not be possible to increase critical care capacity if 24/7 anaesthetic cover to the labour ward and emergency caesarean section cover was also required.

ECT liaised with partners across the NHS – including neighbouring maternity units and the NHSE Regional Team. All fully understood and appreciated the rationale for ceasing births and gave the proposal their unanimous support. The ECT Board took the decision to close the unit from 25th March 2020.

In 2021, and in response to concerns raised by the anaesthetic team regarding the return of Maternity services, ECT invited the Royal College of Anaesthetists (RCoA) to conduct a review of the anaesthesia service in relation to provision of maternity care and to provide independent and expert advice with regard to reinstating maternity services at the hospital. The RCoA report has helped to provide a framework for managing and implementing change linked to the full return of consultant delivered maternity care.

The RCoA review recommended that two tiers of middle-grade anaesthetists would be required on the on-call rota to ensure sustainability – one to support maternity and the other the critical care unit – and that significant consultant expansion was required. The review was accepted by the ECT Board and supported by the Cheshire and Merseyside ICB. The service has subsequently recruited an additional four consultant anaesthetists and eight specialty doctors, which has enabled a dedicated obstetric anaesthetic rota and robust consultant coverage of the labour ward.

2.3 Service provision during suspension (April 2020 - June 2023)

Inpatient intrapartum maternity services were suspended at Macclesfield DGH for slightly more than three-years, with most registered women delivering at neighbouring 'host' hospitals in Stockport, Wythenshawe and Crewe.

Whilst the service has been suspended, all inpatient intrapartum activity has been provided by host Trusts - Stockport NHS Foundation Trust (SFT) at Stepping Hill Hospital, Manchester University NHS Foundation Trust (MFT) at Wythenshawe Hospital and Mid Cheshire NHS Foundation Trust (MCFT) at Leighton Hospital. Women were given the option to choose which host site they want to attend by the time they were 20 weeks pregnant.

Delivery Provider	20/21	21/22	22/23
Mid Cheshire FT	330	261	290
Stockport FT	474	337	370
MFT (Wythenshawe)	407	563	443
Royal Stoke	107	41	13
Home births	14	41	17
Others	41	37	23
Total ECT registered births	1373	1320	1156

Most antenatal and postnatal care, including scans, tests and support for home births, continued to be provided throughout the suspension by ECT on site at MDGH and in the community across eastern Cheshire. Some women may have had their care transferred if considered high risk or complex.

2.4 Governance and Decision Making

The initial suspension of inpatient services was for a period of up to six months arising from the limited anaesthetic capacity in the Trust to deal with the COVID pandemic. The suspension was extended on three occasions following assessment against Board approved recovery criteria.

At its March 2022 Board meeting, the Board agreed that intra-partum services should be returned to the Macclesfield site when safe to do so with an initial goal of doing so by April 2023. Key to ensuring safety was the response to a Royal College of Anaesthetists invited review of obstetric anaesthesia provision and the final report of the Ockenden maternity review into another NHS Trust.

3

Preparation for the Return of Service

- 3.1 In September 2022, a detailed paper was considered by the ECT Board which set out options for how the service could be re-instated safely. These had been developed through significant work over the spring / summer, involving staff, partners, stakeholders, and patients including 3 workshops attended by 68 people many of who attended more than one workshop. The workshops brought people together to identify and consider the important issues in returning the service, and how it could be safely re-instated.

In order to return the agreed model (i.e., a full consultant led obstetric unit with an Alongside Midwife Led Unit and Special Care Baby Unit (SCBU)), and in light of the output from the workshops, the Board confirmed that a supportive partnership model should be established with a neighbouring trust.

Two reports were critical to the Board's considerations:

- The Findings, Conclusions and Essential Actions from the Independent Review of Maternity services at the Shrewsbury and Telford Hospital NHS Trust ('The Ockenden Report, March 2022).
- The Royal College of Anaesthetists invited review of the anaesthesia service in relation to provision of maternity care at East Cheshire NHS Trust (February 2022) (attached).

- 3.2 To oversee this, the Board established a regular cycle of meetings of two groups:
- Maternity Oversight Group provided senior trust and partners organisation oversight of the plans to repatriate maternity services, it was chaired by ECT CEO, attended by representatives of Cheshire and Merseyside ICB; Cheshire East ICB Place Team; Cheshire East Council; and Greater Manchester and East Cheshire Local Maternity and Neonatal Network

- Maternity Implementation Group co-ordinated the delivery of the programme of work required to return maternity services, it was chaired by the ECT Medical Director, attended by ECT representatives plus the Maternity Voices Partnership.

Key risks to the safe re-instatement of the service were agreed as:

- a) The need to develop robust arrangements to deliver high quality, safe and sustainable intrapartum services with a supporting partner,
- b) The need to secure support from NHS England the Cheshire & Merseyside ICB for the proposals,
- c) ECT's ability to recruit, retain and train sufficient staff to sustainably deliver the service,
- d) The need to reduce the requirement for escalation beds, allowing Ward 6 to return to its previous function as the maternity ward.

3.3 Criteria to confirm the decision to return the service were reviewed and amended and agreed by ECT Trust Board in November 2022:

Local Level

1. *National modelling indicates that further C19 surge is unlikely and local capacity to meet clinical need would be manageable within enhanced workforce and environment.*
2. *Robust arrangements are in place to deliver high quality, safe intrapartum services with a supporting partner; this includes support for the ongoing training and development of staff.*
3. *Workforce recruitment, attendance and resilience is at a level sufficient to maintain safe staffing levels in obstetrics, midwifery, neonatal, anaesthetic and theatre services:*
 1. *Obstetrics – full establishment required.*
 2. *Midwifery – 90% establishment seen as safe.*
 3. *Neo-natal – 87% establishment seen as safe.*
 4. *Anaesthetics – please see note below.*
 5. *Theatres – service can accommodate 1.27 ODP vacancy.*
4. *Capacity for patients (including any COVID 19 positive patients, any linked to seasonal pressures and any with no criteria to reside) can be accommodated to core wards without the requirement to utilise additional estate and facilities in maternity.*
5. *The Trust has robust plans in place to guarantee access to emergency theatres when necessary.*

System Level

6. *Local Maternity Systems in Cheshire & Mersey and Greater Manchester are safely resilient to the impact of the ECT recovery plan.*
7. *Support is received from commissioners and regulators for proposals to return intrapartum services.*

3.4 Assessment of readiness against these criteria were considered by the ECT Board each month. In March 2023, the ECT Trust Board assessed that they were confident that all criteria would be met by June 2023 and that it would therefore be safe to reinstate the service. The Trust continued to monitor readiness against the criteria which is illustrated on the dashboard below.

DASHBOARD

UPDATED 21/06/2023 - FOR BOARD APPROVAL

Maternity Return Criteria Review		Nov 22	Dec 22	Jan 23	Feb 23	Mar 23	Apr 23	May 23	June 23
Local Criteria									
	1. National modelling on C19 surge								
	2. Robust arrangements with a supporting partner								
3. Safe staffing levels									
	Obstetrics								
	Midwifery								
	Anaesthetic Consultants								
	Anaesthetic SAS Doctors								
	Theatres								
	Neonates								
	4. Bed Capacity								
	5. Emergency Theatres								
System Criteria									
	6. Host resilience								
	7. Regulator and commissioner support								
Blue		Green		Amber		Red			
Criteria Met		Solution identified – on track		Solution not yet confirmed		Solution not identified			

4

Pathway to 'Go Live'

- 4.1 A detailed project plan to 'go live' was developed and proactively managed, which captured over 400 tasks required to be completed before the service could return. This plan was overseen by both the Maternity Implementation Group (chaired by the ECT Medical Director) and Maternity Oversight Group (chaired by ECT Chief Executive). Five key strands of this plan included:
- Staffing training and re-orientation**
Plans for all necessary staff to be re-trained to be competent and confident to deliver a safe service from early summer. Ongoing training may be required, for which arrangements are in place.
 - Estates & facilities**
Work took place to convert Ward 6 back into the Maternity ward, including aesthetic improvements to improve patient experience, upgrading IT equipment and installation of a new baby tagging system.
 - Equipment**
New equipment was purchased, including major items such as Labour Ward Beds and Phototherapy Units and other equipment serviced.
 - Communications & patient engagement**
A robust Communications Plan was created, including open days for pregnant women and families as well as work with Maternity Voices Partnership (MVP). MVP and service users were invited to take part in a 15 Step Assessment to review the new unit from a patient perspective.
 - Transfer of care**
Robust plans were in place to care for women booked with ECT to deliver from early summer. Women were advised of the date of reinstatement and be expected to attend ECT from that date this should minimise the requirement of the host sites providing care without ECT staff. Beyond the re-start date, host sites were only required to care for women who were in active labour or recently given birth. A small amount of the babies requiring neonatal care may require care by the neonatal unit at the host site, and an individual assessment was to be undertaken for any baby that does to see if they could be transferred to ECT.



Engagement session.



Maternity recruitment event.

- 4.2** ECT Executives and Operational teams worked closely with a range of external partners on issues of assurance:
- ECT Executives met regularly with senior colleagues from Cheshire & Merseyside ICB, Cheshire East Place, NHS England North West and Greater Manchester & East Cheshire Local Maternity and Neonatal System (LMNS) to appraise them of progress and deal with any issues and concerns.
 - The Maternity Service was in close contact with the Regional Chief Midwife and Regional Chief Obstetrician to provide ongoing assurance and responded to several clinical and operational queries.
 - The service worked closely with the ECT Planning team to ensure plans for 2023/24 are in line with Operational Planning Guidance.

- A new GMEC LMNS safety progress and performance meeting was created to monitor all trusts against the national standard 3 year delivery plan for Maternity and Neonatal services (2022) at which the trust will present and update on a quarterly basis to the board.

5 The return of The Service

- 5.1 On Monday 26th June 2023 staff celebrated the re-opening of intrapartum services under the headline "Macc is Back!"



Later that day, the first baby to be born at Macclesfield DGH was a little boy called Oakley, born via caesarean section at 38 weeks weighing 7.3lb. Mother, Stacey and Dad, Lewis were delighted to deliver their second baby at Macclesfield as their first son was born one week after the unit closed in April 2020 at Stepping Hill following an emergency caesarean section.



The first babies born on the unit were each given personalised baby grows and hampers.



- 5.2** In the first three months since the service reopened there were 270 births at Macclesfield maternity (up to end of September 2023). This is in line with predictions for the service (approx. 2 to 3 babies each day).

Activity has grown each month, again, in line with predictions. In September 2023 there were 86 births:

	June (from 26/06/23)	July	August	September
Bookings	103	124	136	115
Births	15	89	80	86
Vaginal births	9 (60%)	53 (59.5%)	48 (60%)	47 (54.7%)
Elective Caesarean sections	3 (20%)	12 (13.5%)	14 (17.5%)	18 (20.9%)
Emergency Caesarean sections	3 (20%)	24 (27%)	18 (22.5%)	21 (24.4%)

Of the 270 births there has been:

- 1 stillbirth
- 157 had vaginal births (58%)
- 37 had Elective Caesarean sections (13.7%) (regional comparison 17.7%)

- 66 had Emergency Caesarean sections (24.4%) (regional comparison 25.8%)
- 4 had post-partum haemorrhage >1500mls (0 > 2500mls)
- 3 had 3rd degree tears
- 15 admissions to the Special Care Baby Unit
- 10 babies received transitional care on the maternity ward

With no diverts, deflects or closure of the unit.

6 Post Implementation Review

- 6.1 ECT is committed to learning from the experience of the suspension and return of intrapartum maternity services and has conducted a post implementation review. In doing so we hope to capture good practice from this successful project as well as learn any lessons that may be useful in the future.

The review has taken place three months after the return of services. Board members, staff, partners, key stakeholders, and patient representatives who were involved in the project were all invited to take part in this process, and feedback has been received through a combination of surveys, one-to-one discussions, and small workshops.

- 6.2 Views have been sought on a range of component parts of the project to return services including workshops held in 2022 to identify future models for delivering services, the return criteria used by the trust to assess our readiness to return the service, governance arrangements, risk management, communications and engagement as well as identifying any unforeseen issues that were not predicted as part of the planning process.
- 6.3 Given the nature of the feedback received and the number of internal and external stakeholders involved in this review, the report is primarily qualitative, seeking to identify and explain any good practice or lessons for the future.

7 Findings

7.1 2022 Workshops:

A series of workshops were held between April and June 2022 to engage stakeholders from clinical, commissioning and lived experience groups. The purpose of the workshops was set out by NHS England/Improvement (NHSEI) and Cheshire & Merseyside ICB to fully explore the potential to return consultant led obstetric services to Macclesfield and to understand the preferred options to do this safely.

Over the three workshops participants helped to create criteria for success, develop a long list of 14 potential service model options, refine this to a short list of nine and ultimately agree a set of three preferred options for further consideration by ECT.

The workshops took place in community venues across eastern Cheshire and were attended by representatives from ECT (including midwifery, obstetric, theatre, anaesthetic and paediatric clinicians and managers) plus external representatives from host sites, Greater Manchester & East Cheshire Local Maternity & Neonatal System, NHS England, Royal College of Midwives, Cheshire Clinical Commissioning Group and Macclesfield Maternity Voice Partnership.

Following the workshops, the ECT Board received a detailed report at its private meeting in September 2022 and fully endorsed the model of care which was scored highest by the workshop (which was a full consultant led obstetric unit with an Alongside Midwife Led Unit and Special Care Baby Unit (SCBU)).

Some materials from the workshops are included in the appendices. Full details of the workshops and the tools used throughout are available upon request from the Strategy Team at ECT.

Feedback:

All participants in the workshops were invited to take part in a survey, in addition a meeting with heads of Midwifery also discussed the workshops.

Feedback has been very positive.

- All survey respondents thought the workshops format was either “very appropriate” or “somewhat appropriate” in helping to design future services.
- Most people thought that the format and invite list for the workshops was right, and that adequate time and focus was given to the discussions.
- Some made comments about possible improvements – for example,
 - allowing people to participate online,
 - having more clinicians in attendance (this included more ECT clinicians, plus clinicians from NHSE, the ICB and NWAS), and
 - allowing more ‘shopfloor’ representation.
- One person said that they didn’t find the process for shortlisting and selecting a preferred model to be helpful, saying that all models should have still been considered.

7.2 Return Criteria

The initial suspension of inpatient services was for a period of up to six months. The suspension had been extended on three occasions following assessment against recovery criteria that had initially been agreed by the Board at ECT shortly after the original suspension.

In September 2022 the ECT Board received a detailed report into the 2022 workshops and agreed that the original 2020 recovery criteria should be reviewed. In November 2022, Board agreed a revised set of recovery criteria (featured above in section 3.3) this revised criteria included a blend of the original criteria, some updated criteria plus some new criteria.

Assessment against these criteria was regularly reported to Board having been thoroughly considered by Maternity Implementation Group (MIG) and Maternity Oversight Group (MOG). Progress towards meeting the criteria could easily be seen via the BRAG dashboard (featured above in section 3.4).

Feedback:

Board members, members of MIG and MOG as well as ECT clinicians and service managers were asked for their views on the return criteria.

- There has been broad support for the return criteria with no suggestions made for additional criteria that may have been useful.
 - A potential refinement was suggested, questioning whether the continued focus on C19 preparedness was right and whether it could have been broadened to cover any pandemic response.
- Widespread support from all for the BRAG assessments and dashboard;
 - these are seen to have helped to keep the project focussed,
 - seen as useful to review detail as the project progressed, including discussion on levels, and ability to be self-critical against what level was being achieved,
 - good visual tool and method of recording a snapshot on progress and progress over time,
 - It was noted the BRAG was not regularly reviewed at the MPG and that this could have been beneficial in terms of oversight, progress, and motivation for MPG members.

7.3 Governance arrangements:

To support the programme of work to return services, the Trust established a number of time limited working groups, these were:

- Maternity Oversight Group (MOG): chaired by ECT Chief executive, attended by representatives of Cheshire East ICB Place Team; Cheshire East Council; and Greater Manchester and East Cheshire Local Maternity and Neonatal Network as well as key ECT clinical leads.
- Maternity Implementation Group (MIG): chaired by the ECT Medical Director, attended by ECT clinical and managerial representatives plus the Maternity Voices Partnership.
- Maternity Project Group (MPG): chaired by the Director of Operations and attended by key internal project leads including the Head of Midwifery, anaesthetic lead, theatre lead, HR, IT and Estates.

Monthly meetings were scheduled for these groups with MPG feeding into MIG, MIG feeding into MOG and MOG providing updates to Board on a regular basis.

Feedback:

Members of the ECT Board, MIG, MOG and MPG were asked for their views on the governance arrangements.

- Having three separate but connected meetings was seen as helpful;
 - It provided a clear escalation process,
 - Helped to capture and consolidate progress,
 - Allowed a wide range of people to be involved,
 - Allowed focussed time to discuss blockages to the project,
 - Provided a good rhythm to the project.
- Involvement of external stakeholders (in MIG and MOG) was seen as useful;
 - It allowed for robust check and challenge,
 - It allowed external representatives to understand the complexity of the issue and the relationships between competing factors,
 - External representatives were also able to have more informed discussions within their own organisation,
 - It enabled longer term discussions to take place as well as a focus on the immediate task in hand – this has put Place arrangements in a stronger position as a result.
- The membership and Terms of Reference for the groups are seen to have been fit for purpose;
 - One potential oversight was not including the Deputy Director of Operations (who chaired MPG) as a member of MOG.
- Overall, Board members felt that they were provided with enough information in regular board updates to provide them with sufficient assurance in the whole process and allow them to make informed decisions.
 - One anonymous board member, a relatively new member on the Board, said that they didn't feel they knew enough of the background to the project. This is potentially a lesson for the future in terms of the induction of new board members.

7.4 Risk Management

The project, working through MPG, MIG and MOG, created a risk log to identify and manage risks. This was kept under constant review through the project. The risk log used a standard trust template to capture risks, gaps and mitigations. The log identified 12 risks, however four were identified as “principal” risks and were reviewed in greater detail.

Feedback:

Members of MIG, MOG and MPG were asked for their views on the approach to risk management.

- Survey responses showed support for the way that risks were identified and managed, and that sufficient emphasis was given to each one and that they supported decision making.
- MIG and MOG members found the process helpful.

- Having a long list of all risks as well as a shortlist of principle risks allowed sufficient focus on those principal risks (such as anaesthetic recruitment),
- Members were confident that sufficient mitigations were in place to appropriately manage risks,
- Members thought that it may have been more helpful to have risk discussions at the end of MIG and MOG agendas to allow more informed discussion.

7.5 Project Plan and plan to 'go live'

The trust's Strategy team established a detailed project plan that led up to the final 'go live' date. This was proactively managed through one-to-one discussions and discussions primarily at MPG, with any concerns escalated to MIG or MOG as appropriate. Each task on the plan had an owner, a target date to complete and progress notes. Broad areas covered by the plan also had leads who took responsibility for any actions that were overdue or facing barriers.

Feedback:

Survey responses show support for the project plan and the approach taken by the project, with no suggestions made for improvements.

Members of MPG and MIG felt the structure of the project plan was clear on responsibilities and useful in helping to drive work forward, hold people to account and reduce delays.

- MPG felt that the fact that so few actions had to be escalated to MIG showed how well the plan worked,
- The detail in the project plan was helpful in reassuring external partners how well-thought-out the plans to reinstate services were, and gave reassurance on progress being made towards the target date to re-open services,
- Executive members said that they had confidence in the process. They trusted action owners and MPG to manage actions and trusted that issues would be escalated where appropriate.

7.6 Decision-making

In addition to internal decision-making structures (individual managers, MPG, MIG, MOG and Board) the project also had to operate within a changing external decision-making landscape brought about by the implementation of the Health and Care Act of 2022. This included the abolition of statutory bodies such as Clinical Commissioning Groups and the establishment new Integrated Care Systems and Integrated Care Boards. These changes coincided with the period when plans for the reinstatement of maternity service were being implemented and it meant that part way through the programme there were significant changes in terms of organisational responsibilities and of the individuals involved in the programme.

Feedback:

Members of MIG and MOG as well as external stakeholders were asked for their views on the decision-making process associated with the project.

- Clearly the timing of the project and the changes brought about by the Health and Care Act caused some confusion.
- New organisations, teams and individuals were brought into the programme part way through, which added some delay into the programme as new relationships and arrangements needed to be formed, and new roles and responsibilities needed to be understood.
- This was further complicated by the fact that the project needed to look towards ICB arrangements in Cheshire and Merseyside as well as towards Local Maternity and Neonatal arrangements in Greater Manchester.

- Engagement with system partners was seen to be good – with positive feedback received from external attendees of the Checkpoint meetings with NHS England, ICB, CEP and LMNS.
- Given the heightened national focus on Maternity safety issues (such as the Ockenden and Kirkup reviews with their separate requirements) a high level of system interest was to be expected. Other future services might not face such levels of interest.

7.7 Communications and Engagement

Throughout the suspension, and then in preparation for the return, the trust aimed to keep staff, stakeholders and patients informed on progress; this has been achieved through a combination of briefings, press releases, meetings and in the case of patients, through work with Maternity Voice Partnership.

Feedback:

Whilst the focus of the review is the period running up to the return of services, some comments have been received relating to the overall suspension, these include:

- Recognising it was difficult to keep people fully updated and dealing with the uncertainty of the long suspension,
- Focus was given to keeping midwifery teams fully informed, including regular briefings with the trust Chief Executive and Director of Nursing, and this is seen to have worked well, however some other teams did not feel so well informed,
- Often these briefings were verbal, with nothing shared for those unable to attend,
- Communication and engagement improved throughout the suspension, particularly in the last 12-18 months as the service prepared for return.

In terms of the period of the project focussed on the return of the service, the review considered communications and engagement for staff, stakeholders and patients.

7.7.1 Staff engagement:

- Regular meetings of the project group helped support a consistent message across departments that could be fed back to staff. These meetings also improved relationships between group members that improved working outside of the meetings.
- It was easier to liaise with staff on site. More difficult to liaise with staff off site particularly where work was moving at pace.
- The workshops in 2022 were very valuable to midwives to allow them to be part of the process, understand the work, and build trust with the Executive team and wider project team. It is believed that this helped to minimise some of the conflict that may have developed.
- There was no one-size-fits-all approach to keeping staff informed – especially midwifery staff. A combination of briefings, newsletters, team meetings and WhatsApp were all seen to have helped to keep staff informed.
- Not all interested staff groups felt as involved as the midwifery teams. It was not always possible for clinical staff to be released from clinical activity to take part. The role of clinical leads in cascading information could have been better understood and explained.
- A mix of informal and formal communications are seen to have been successful – examples include attending staff meetings as well as circulating emails.
- It may have been helpful to include ‘key messages’ as a standard agenda item for MIG and MOG – agreeing what information could and should be shared.

7.7.2 Stakeholder engagement:

Heads of Midwifery from host sites and members of the NHS England checkpoint meetings have confirmed they were happy with the way they were engaged and communicated with.

- A regular Heads of Midwifery meeting was established at the start of the suspension. The good relationships built up over the whole period are seen to have helped with understanding and joint working in the lead up to the return of the service.
- NHS England established a regular 'Checkpoint' meeting for external partners to receive regular updates. Members of this group have confirmed they were happy with their engagement and thought that the group was a useful opportunity to raise issues, discuss risks and develop plans.

7.7.3 Patient Engagement:

The project aimed to provide a 10-week window to share information with pregnant women and the wider public on the return of the service, however, the complexity of the decision making and associated delays in announcements meant that this was not possible.

Feedback from MPG, MIG and host sites shows that maternity teams worked hard to make sure that pregnant women were kept informed as best as they could be of the planned changes and how they may affect plans for delivery. At all times patient safety was prioritised and expectant women with imminent due dates were provided with information on host sites (including key phone numbers) as well as the Macclesfield service.

This period of delay:

- is thought to have reduced trust in what the maternity teams were saying to expectant mothers. The lack of ability to give clear communication to women due to give birth close to their due date was not supportive and fell short of what the project aspired to. could have caused mixed messages that could have posed a risk.
- led to a lack of communication through official trust social media or the web site which is seen to have given a negative impression to patients.

Maintaining a good working relationship with Maternity Voices Partnership (MVP) is seen to have been crucial – MVP is a trusted partner for many pregnant women and their families as well as for statutory agencies. MVP were actively involved throughout the project to return the service (indeed, throughout the suspension) including the 2022 workshops, being members of MIG and supporting patient communications and engagement.

7.8 'Snagging issues'

Everyone involved in the project was asked to identify any snagging issues in the hope that the trust, and any future projects, may be able to learn from them.

Feedback:

Snagging issues identified can be grouped into 3 broad areas:

- **Staffing:**
 - Short notification of a change of guidelines linked to the second scrub in theatre meant that there was little time to re-arrange rotas and shift patterns. This was a potential 'showstopper' which required bank and permanent staff to work flexibly to cover.
 - There have been difficulties in signing off job plans part way through the year as would normally be done prior to April. This has been compounded with in-year recruitment.
- **Digital & Telephony:**
 - An NHSE site visit two weeks before re-opening advised the need for centralised cardiotocographs. This required additional data points, licences and support from IT. Such short notice changes are challenging in terms of cost and lead times – this needs to be considered for any future re-fit or relocation across the trust.
 - There was an interface issue with the IT systems which meant that many babies were being allocated two hospital numbers rather than one, this led to delays to tests for blood and radiology. Additional admin support was required to work around this issue until it was resolved.

- **Estates:**
 - Prior to re-opening, plans were made for the renovation of the maternity ward. These plans were later changed without the full involvement of the maternity team which led to delays. These plans should have had oversight by the maternity team to ensure that the plans were appropriate.
 - Some minor estates work was incomplete at time of opening,
 - Due to the delays in the estates work, the cleaning team had issues gaining access to the unit to undertake a deep clean. This meant that the Maternity staff came into the unit to clean the unit the weekend before the re-opening.
- **Equipment and stock:**
 - Not all of the equipment or stock was available initially. Although it is worth noting that all essential items were in place,
 - Five new resuscitaires were purchased and in place at the time of the reinstatement, it was soon realised they connected to the medical air and oxygen supply differently and that cylinders were emptying quicker than expected. With support from the EBME the manufacturers quickly created adaptors for the equipment.

7.9 Unintended consequences

Similar to snagging issues, any large project such as the return of a major service is likely to have unintended consequences – these are often difficult to recognise or predict. It is hoped that by identifying any unintended consequences connected to this project it may support future projects.

Feedback:

Feedback has helped to identify a number of positive as well as negative unintended consequences.

Positive:

- ✓ **Investment** continues to flow to East Cheshire Trust and people want to work here
- ✓ **Better opportunities** for paediatric medical staff, focus on up skilling
- ✓ **Heightened confidence** in MDGH for the future
- ✓ **Anaesthetics** were able to increase their establishment.
- ✓ Better **continuity of care** for pregnant women
- ✓ Seeing patients on the children's ward who have already been seen on neonates - **better follow through of care.**

Neutral

- the number of **staff changes** leading to change in leadership, management and ownership.

Negative:

- × Acute **medical beds that were gained during the suspension were lost which in turn has impacted on Paediatric beds and flow through the organisation**
- × **Operating Department Practitioner (ODP) structure.** Model of Care is managed in line with policy, however fallout from minority of team increased demand on the service
- × Loss of theatre capacity and in particular **elective gynaecology operative lists** to accommodate the elective caesarean section lists and its impact on gynaecology waiting lists and skill maintenance in clinicians. This will have a detrimental financial impact and exacerbate long waits for elective operations.
- × Without significant increase in births, **Unit likely to remain sub-scale** and questions over future sustainability will remain.
- × Will contribute significantly to trust's financial deficit as **loss making service.**

Lessons & Recommendations

- 8.1 The return of intrapartum maternity services to Macclesfield DGH after a significant suspension is great news for current and future expectant women and their families, and should be celebrated. Everyone involved in this project are to be thanked and congratulated for their hard work and determination.

Feedback from this review has been broadly positive and there are lessons to be learned from the maternity experience that could be useful for future projects.

The lessons from this review can be grouped under the following headings:

8.2 The importance of ongoing engagement

For maternity this included wider participation workshops, a number of working groups, plus regular formal and informal briefings. Not all projects would need to follow the exact same approach, however, the lessons from maternity would stress the importance of:

- Clinical engagement and the role of clinical leadership. Not just the teams and services that are immediately impacted by a project but interconnected services as well (in this case, not only maternity, but paediatrics, anaesthetics, and theatres). Clinical leads can play a vital role in ensuring wider teams are aware of and involved in change programmes.
- Clear and regular communication processes with staff members affected by the changes and to listen to understand their perspectives.
- Ensuring all staff members affected by the changes are actively involved in taking forward the service change.
- Regular and timely messages to patients and the community. Each project will need to consider how best to keep patients and the community informed. Clinical teams could be one of the strongest assets to any similar project. They are trusted by patients, their direct communication with patients is probably more important than any official press release or post on social media. Any future project needs to harness these assets.
- Coproduction – patient voice is central to the service change having the support and active engagement in design and implementation plans of the local MVP ensured that the opening of the maternity unit took into consideration the needs of the local population and ensured strong relationships were developed with the clinical teams.

Stakeholder Mapping:

From 2020 onwards, it was crucial for the maternity project to understand the needs of various internal and external stakeholders including patients, clinicians, regulators and local politicians.

Future projects should take time to map out all the wider stakeholders affected by the changes, their drivers, and motivations, and ensure that they are appropriately engaged in the development and implementation of plans.

8.3 Establishing appropriate governance arrangements.

For maternity this involved three internal groups, plus regular updates for Board and external partners, escalation processes and decision making processes were clearly set out in terms of reference.

It is not the case that this approach should be replicated for future programmes, rather that each project needs to develop its own approach and be appropriately managed and controlled. Potential future projects need to consider their own needs; the approach taken needs to be proportionate to the scale and complexity of the task.

External involvement in governance has been shown to work in this project and should always be considered, including involvement of patients or patient representatives via an appropriate VCSE organisation.

8.4 **Project management approach.**

All major projects need some form of project management and this needs to be proportionate to the project. Key elements of the approach to maternity are likely to be needed for all projects such as a project plan, risk management, action logs with escalations where appropriate to ensure projects remain on target and any barriers are overcome.

For maternity a clear set of return criteria helped the project to focus on an end goal. Such criteria may not be suitable for all projects; however, a clearly articulated set of objectives, goals and milestones is necessary for any major project.

8.5 **Decision making**

Having appropriate governance arrangements in place, being clear on your purpose and having robust project management arrangements will all aid good internal decision making. However, external factors can also affect project decision making.

It is important for any major project to understand any external decision-making factors, to understand the critical dependencies to secure the service change and any new arrangements and involve them in the development and implementation of plans as part of a coherent overarching programme.

It is essential that there is clarity regarding decision making across statutory bodies which have an interest in the service change, and that all relevant decision makers are appropriately and effectively engaged.

This could be straightforward for example where a local or even national commissioner needs to approve a proposal or business case, but this could also be more complicated, for example where several regulators or statutory bodies have partial responsibilities in any area.

8.6 **Leadership**

The maternity project had significant Executive input, from the Chief Executive and several key Executives including Chief Nurse, Medical Director and Chief Operating Officer, in recognition of the strategic importance of the project and the complexity of returning such a major service.

Project management resources were identified to support the work, ensuring clarity of actions required and a proactive approach to achieving them.

Not all projects will require such Exec level input (although some may be required), but projects do need leadership, and it is common to see large projects at the Trust have designated Senior Responsible Officers (SRO) and Clinical Lead roles. These roles often play formal governance roles in decision making and reporting arrangements, they also play less formal roles in negotiations, setting direction and overcoming any obstacles, as such, the SRO and Clinical Lead will need to be decision makers with appropriate levels of authority within the Trust.

Similarly, not all projects will require dedicated project management support, however, all projects should adopt appropriate project management approaches commensurate with the size and complexity of the project.

8.7 **Snagging issues and unintended consequences should be expected and where possible anticipated.**

The maternity project has experienced snagging that can be grouped into categories such as estates, digital and staffing issues, unintended consequences included a mix of positive and negative issues – future projects could consider these themes and try to anticipate potential issues before they arise.

Appendices

1. Agenda – Workshop 1
2. Agenda – Workshop 2
3. Agenda – Workshop 3
4. Criteria for Success – Updated post-Workshop 2
5. Scoring Outcomes
6. Return criteria
7. Terms of Reference – Maternity Implementation Group
8. Terms of Reference – Maternity Oversight Group
9. Dashboard of Maternity Return Criteria
10. Project Plan – Example for Host Provider actions
11. Maternity Project Group – Project Progress Report
12. Maternity Implementation Group – Project Progress Report
13. Risk Register
14. Public Board Paper – March 2023

Workshop 1 – Agenda

Time	Item	Presenter
13:00-13:10	1. Welcome & Introductions	Kate Daly-Brown
13:10-13:20	2. Background <ul style="list-style-type: none"> Where are we now in East Cheshire? What is the current situation? 	KDB/FW
13:20-13:30	3. The national context	NB/JA
13:30-13:40	4. The patient perspective	JN
13:40-14:20	5. The task for today <ul style="list-style-type: none"> Group work What criteria is important to ensure a safe and successful maternity service for women and families? Write each criterion on a piece of A4 paper 	KSh/FW/NB
14:20-14:40	6. Coffee break and theming of the feedback	
14:40-15:00	7. Review and understanding the criteria/themes <ul style="list-style-type: none"> What would that give us? What are the challenges in meeting this? 	FW/NB
15:00-15:15	8. Weighting of criteria – Group discussion and share thoughts	Facilitators
15:15-15:30	9. Weighting of criteria individually	KSh
15:30-15:45	10. Reflections on the scoring	NB/JA
15:45-15:55	11. Next steps – outline for the next workshop	FW
15:55-16:00	12. Close	

Workshop 2: Friday 23rd May 22

Workshop 2 – Agenda

Purpose: Review and confirm criteria for success and develop service model options (long list).

Time	Item	Presenter
13:00-13:10	1. Welcome & Introductions <ul style="list-style-type: none"> ○ Purpose of today 	Kate Daly-Brown John Hunter
13:10-13:30	2. Why are we here? <ul style="list-style-type: none"> ○ Suspension of services ○ Recent considerations ○ Importance of work 	Kate Daly-Brown John Hunter Eileen Stringer
13:30-14:15	3. Follow up from Workshop 1: Developing Criteria for Success <ul style="list-style-type: none"> ○ Summary of criteria developed last meeting 10 mins ○ Table discussion on criteria: What does good look like? 20 mins ○ Wider group feedback 10 mins ○ Summarise changes and key points from discussion 5 mins 	Katherine Sheerin Groupwork All Katherine Sheerin
14.15-14.30 Break		
14:30-15:55	4. Developing the long list of options to deliver the service: <ul style="list-style-type: none"> ○ Introduction 5 mins ○ Table discussions – Creating the long list 15 mins ○ Wider group feedback of options 10 mins ○ Review of the options – SWOT analysis of each options 55mins 	Nicky Biggar & Jyotsna Acharya Groupwork Katherine Sheerin Groupwork
15:55-16.00	5. Reflections and Close	Kate Daly-Brown
Workshop 3: Friday 24 th June 22		

Workshop 3 – Agenda

Purpose: Review options against the criteria to create a list of preferred options

Time	Item	Presenter
09:00	1. Welcome & Introductions <ul style="list-style-type: none">○ The process so far○ Purpose of today○ Context setting	Kate Daly-Brown
09:20	2. Confirming the process <ul style="list-style-type: none">○ Criteria	Kathrine Sheerin
09:30	3. What have we learned? <ul style="list-style-type: none">○ Feedback from the various clinical groups○ Long list to short list○ Pre-scoring	Alex Vincent Dave Nunns Nicky Biggar
09:45	4. Clinical Standards <ul style="list-style-type: none">○ Ockenden standards○ Anaesthetics & Theatres○ Neonates	Nicky Biggar John Hunter
10:00	5. Scoring of the remaining options using the criteria <ul style="list-style-type: none">○ Definitions	Dave Nunns Groupwork
Break		
11:30	6. Feedback and discussion of scoring	Groupwork
12:30	7. Clarification of outcomes, preferred options and next steps	Kate Daly-Brown
13:00	8. Close	

Criteria for Success – updated version

Agreed criteria:	Dots	%
1. Meets quality standards including safe staffing	231	30
2. Staff health and wellbeing	83	11
3. Good patient experience	81	10
4. MDT working and training	66	9
5. Accessibility	66	9
6. Promotes Choice	60	8
7. Enables effective partnership working	55	7
8. Sustainable and implementable	54	7
9. Equipment and estates	39	5
10. Cost	37	5

There was a vote to ask feedback on whether the criteria should be grouped into themes or kept as 10.

Vote to Group Criteria:

Grouped: 7 Keep as ten: 22

There was an agreement in the room that the criteria should be kept as a list of 10 and this is what will be used to score the models.

Scoring outcomes

		Weighting	Meets quality standards including safe staffing	Staff health and wellbeing	Good patient experience	MDT working and training	Accessibility	Promotes Choice	Enables effective partnership working	Sustainable and implementable	Equipment and estates	Cost	Individual Option Weighted Totals	OVERALL OPTION TOTAL
Option	Group	Score	Score	Score	Score	Score	Score	Score	Score	Score	Score	Score		
Full Obstetric Unit with Alongside Midwifery Led Unit (AMLU) & SCBU provided by ECT	Group 1	3	4	4	3	4	4	2	2	4	3	3.32	3.265	
	Group 2	3	3.5	4	2.5	4	4	2	1.5	4	3	3.185		
	Group 3	3	4	4	3	4	4	3	2	4	3	3.39		
	Group 5	3	4	4	2	4	4	2	2	3	3	3.18		
	Group 6	2.5	4	4	3	4	4	3	2.5	4	2.5	3.25		
Full Obstetric Unit with AMLU & SCBU delivered as a managed clinical service	Group 1	3	2	2.5	4	4	4	2	2	2	4	2.99	3.303	
	Group 2	3	3	4	3.5	4	4	3	3	4	3.5	3.42		
	Group 3	3	3	4	4	4	4	4	2	4	3	3.44		
	Group 5	4	3	4	3	4	4	4	3	4	3	3.72		
	Group 6	2.5	1	3	4	4	4	3	3	4	2.5	2.945		
Full Obstetric Unit with AMLU & SCBU delivered as a shared service	Group 1	3	3	2.5	3.5	4	4	3	2	3	3	3.125	3.473	
	Group 2	3	3.5	4	3.5	4	4	3	2.5	4	3	3.415		
	Group 3	3	3	4	4	4	4	4	2	4	3	3.44		
	Group 5	4	3	4	3	4	4	4	3	4	3	3.72		
	Group 6	4	2.5	3	4	4	4	4	3.5	4	2.5	3.665		
Freestanding MLU with 24/7 staffing delivered by ECT	Group 1	2	3	2	2	2	2	2	2	4	2	2.23	2.368	
	Group 2	3	2.5	2.5	3	2	2	2.5	1.5	4	1	2.565		
	Group 3	2	3	2	2	2	3	2	2	4	2	2.31		
Freestanding MLU with 24/7 staffing delivered as a managed service	Group 1	2	2	2	2.5	2	2	2.5	1.5	2	2.5	2.09	2.388	
	Group 2	3	2	2.5	3	2	2	3	2	4	1.5	2.605		
	Group 3	2	3	2	3	2	3	3	2	4	2	2.47		
Freestanding MLU with 24/7 staffing delivered as a shared service	Group 1	2	2	2	2.5	2	2	2.5	1.5	3	2	2.115	2.388	
	Group 2	3	2	2.5	3	2	2	3	2	4	1	2.58		
	Group 3	2	3	2	3	2	3	3	2	4	2	2.47		
Freestanding MLU with on-call staffing delivered by ECT	Group 3	2	1	2	1	2	3	2	2	3	2	1.95	1.473	
	Group 5	1	1	1	1	1	1	1	1	2	1	1.06		
	Group 6	2	1	1.5	1	1	1	1	1	2	1	1.41		
Freestanding MLU with on-call staffing delivered as a managed service	Group 3	2	1	2	2	2	3	3	2	3	2	2.11	1.45	
	Group 5	1	1	1	1	1	1	2	1	2	1	1.13		
	Group 6	1	1	1.5	1	1	1	1	1	2	1	1.11		
Freestanding MLU with on-call staffing delivered as a shared service	Group 3	2	1	2	2	2	3	3	2	3	2	2.11	1.45	
	Group 5	1	1	1	1	1	1	2	1	2	1	1.13		
	Group 6	1	1	1.5	1	1	1	1	1	2	1	1.11		

Maternity Return Criteria

Local Level

1. *National modelling indicates that further C19 surge is unlikely and local capacity to meet clinical need would be manageable within enhanced workforce and environment.*
2. *Robust arrangements are in place to deliver high quality, safe intrapartum services with a supporting partner; this includes support for the ongoing training and development of staff.*
3. *Workforce recruitment, attendance and resilience is at a level sufficient to maintain safe staffing levels in obstetrics, midwifery, neonatal, anaesthetic and theatre services:*
 1. *Obstetrics – full establishment required.*
 2. *Midwifery – 90% establishment seen as safe*
 3. *Neo-natal – 87% establishment seen as safe*
 4. *Anaesthetics – please see note below*
 5. *Theatres – service can accommodate 1.27 ODP vacancy*
4. *Capacity for patients (including any COVID 19 positive patients, any linked to seasonal pressures and any with no criteria to reside) can be accommodated to core wards without the requirement to utilise additional estate and facilities in maternity.*
5. *The Trust has robust plans in place to guarantee access to emergency theatres when necessary.*

System Level

6. *Local Maternity Systems in Cheshire & Mersey and Greater Manchester are safely resilient to the impact of the ECT recovery plan.*
7. *Support is received from commissioners and regulators for proposals to return intrapartum services.*

Title: Maternity Implementation Group		EAST CHESHIRE NHS TRUST
Authors Name: Associate Director of Strategy		
Scope: East Cheshire NHS Trust		Classification: Trust Organisation Structure and Minutes
Replaces: Not Applicable		
To be read in conjunction with the following documents:		
Unique Identifier:	Review Date: March 2023 This document is no longer authorised for use after this date	
Issue Status: Confirmed	Issue No: 1	Issue Date: August 2022
Authorised by: Maternity Oversight Group		Authorisation Date: TBC
Document for Public Display: No		
After this document is withdrawn from use it must be kept in an archive for 6 years.		
Archive:		Date added to Archive:
Officer responsible for archive:		

1. Purpose

The Maternity Implementation Group has been established as a sub-group of the Maternity Oversight Group and coordinates the delivery of the programme of work required to return intra-partum (in-patient birthing) maternity services to Macclesfield District General Hospital by April 2023.

2. Duties

The group will:

- Produce a project plan, action plan, and timeline for the return of intrapartum care to Macclesfield Hospital based on the clinical model agreed by ECT's Trust Board
- Review and identify the inter-dependencies and implications for other service areas at the trust e.g., theatres, paediatrics, anaesthetics
- Determine the requirements for the midwifery and medical workforce availability and capability and monitor progress against plan, including staff orientation to site, statutory & mandatory training and role specific simulation training.

- To ensure that the physical estates/ premises are fit for purpose to support the return of services and that appropriate equipment/ medical devices are available.
- To identify operational challenges and associated clinical and non-clinical risks associated with the return of the service
- Ensure appropriate consideration is made for the continuity of care and service for the current host sites ensuring an appropriate plan is in place for a phased return of service to reduce to risk to host site services
- To ensure communication and engagement supports effective on-boarding of new staff, deployment back of staff from host sites and ensures interdependent services are fully briefed and prepared.

3. Chairmanship

The Chair of the group will be the Medical Director and vice chair the Director of Nursing Quality.

4. Membership

The membership will include:

- Medical Director (Chair)
- Director of Nursing and Quality (Vice Chair)
- Chief Operating Officer
- Director of Transformation & Partnerships
- Deputy Director of Operations for Planned Care, Women & Children, Allied Health, and Clinical Support Services
- Head of Midwifery
- Clinical Lead for Obstetrics & Gynaecology
- Clinical Lead for Anaesthetics
- Clinical Lead for Paediatrics
- Associate Director of Estates
- Chair, Macclesfield Maternity Voices
- Associate Director of Strategy
- Acting Head of Financial Management, Income and Costing
- Strategic Workforce Lead
- Media and Communications Manager

5. Quorum

The quorum shall be at least three members, one of which shall be the chair or vice-chair.

6. Frequency and Attendance

75% attendance standard will be required, and this will be monitored by the meeting chair with appropriate action taken to address persistent attendance issues.

Members of the Committee should make every effort to attend meetings in person via Microsoft teams. If members are on annual or sick leave, deputies who have the appropriate level of authority, should attend. The Chair should be notified of members wishing to join by telephone, and the attendance of deputies, at least 24 hours in advance of the meeting.

Other specialists and clinical leads may be co-opted to discuss specific items on the agenda.

7. Minutes

Abridged minutes of the meeting, with key decisions and actions, will be produced and presented for agreement at the ensuing meeting.

8. Authority

Decisions will be made by members in line with East Cheshire NHS Trust's Scheme of Reservation and Delegation and that of delegated authority of partner organisation's representatives.

Members will be asked to declare any interests in agenda items at the start of each meeting. Any trust member conflicts, that are not already recorded on the trusts register, will be noted along with any partner organisation representatives' conflicts. The chair of the group, with advice from the Director of Corporate Affairs and Governance, will determine measures to be taken to mitigate any potential impact of declared conflicts.

9. Conduct of Meetings

Agendas will normally be prepared and circulated 5 working days in advance. Any member or attendee may request an item for the agenda through the Chair.

10. Reporting

The group will provide monthly assurance reports to the Maternity Oversight Group on the progress of the repatriation work programme, escalate key risks or concerns with proposed mitigating actions.

11. Review of the Group

The establishment of this group is time-limited and will extend until the service is repatriated safely and assurance that all milestones have been reached. The disestablishment of the group will be determined by the Maternity Oversight Group.

12. Terms of Reference

The terms of reference will be reviewed initially after three months.

Title: Terms of Reference for Maternity Oversight Meeting		East Cheshire NHS Trust
Authors Name: Lorraine Jackman, Director of Corporate Affairs and Governance		
Scope: Trust Wide		Classification: Trust Organisation Structure and Minutes
Replaces: Not applicable		
To be read in conjunction with the following documents: Corporate Governance Manual		
Unique Identifier:	Review Date: April 2023 This document is no longer authorised for use after this date	
Issue Status: Confirmed	Issue No:	Issue Date: June 2022
Authorised by: Chief Executive		Authorisation Date: 11/08/2022
Document for Public Display: No		
After this document is withdrawn from use it must be kept in an archive for 6 years.		
Archive:		Date added to Archive:
Officer responsible for archive: Executive PA to the Director of Nursing and Quality		

1. Purpose

The Maternity Oversight Group is a sub-group of the Clinical Leadership Board and provides senior trust and partner organisation oversight of the repatriation plan for intra-partum (in-patient birthing) maternity services. As such, it is time-limited until members agree that the service has been safely repatriated and business as usual resumes.

2. Duties

To receive assurance reports in relation to the implementation of the programme of work to return services by April 2023, including the following;

- Midwifery and medical workforce – availability and capability
- Operational issues, impact and mitigations
- Estates infrastructure
- Equipment and medical devices

- Communication – clinical and corporate
- Service compliance with regulations and clinical standards

To receive assurances on the management of risks relating to service repatriation, including how gaps in control will be mitigated and managed.

To establish a Maternity Implementation Sub-group to lead on the operationalisation of the programme of work.

3. **Membership**

Chief Executive -ECT
 Medical Director (Deputy Chief Executive) - ECT
 Director of Nursing and Quality – ECT
 Director of Corporate Affairs and Governance – ECT
 Chief Operating Officer – ECT
 Director Transformation and Partnership - ECT
 Head of Midwifery – ECT
 Clinical Lead for Obstetrics and Gynaecology - ECT
 Cheshire East Place Director – Cheshire and Merseyside ICB
 Cheshire East Council Representative

Open invitation to the Non- Executive Director - Maternity Safety Champion to attend

4 **Quorum**

Chief Executive or Medical Director in their absence – chair
 Two Executive Directors
 Head of Midwifery or their deputy

5. **Attendance**

75% attendance standard will be required, and this will be monitored by the meeting chair with appropriate action taken to address persistent attendance issues.

Members of the Committee should make every effort to attend meetings in person via Microsoft teams. If members are on annual or sick leave, deputies who have the appropriate level of authority, should attend. The Chair should be notified of members wishing to join by telephone, and the attendance of deputies, at least 24 hours in advance of the meeting.

Other specialists and clinical leads may be co-opted to discuss specific items on the agenda.

6. **Meeting Chairing**

The Chief Executive will act as the meeting chair and in their absence the Medical Director (Deputy Chief Executive)

7. **Minutes**

Abridged minutes of the meeting, with key decisions and actions, will be produced and presented for agreement at the ensuing meeting.

8. **Frequency of Meetings**

The group shall meet monthly with extra-ordinary meetings convened at the discretion of the chair.

9. Authority

Decisions will be made by members in line with East Cheshire NHS Trust's Scheme of Reservation and Delegation and that of delegated authority of partner organisation's representatives.

Members will be asked to declare any interests in agenda items at the start of each meeting. Any trust member conflicts, that are not already recorded on the trusts register, will be noted along with any partner organisation representatives' conflicts. The chair of the group, with advice from the Director of Corporate Affairs and Governance, will determine measures to be taken to mitigate any potential impact of declared conflicts.

11. Conduct of Meetings

Agendas will normally be prepared and circulated 5 working days in advance. Any member or attendee may request an item for the agenda through the Chair.

12. Reporting

Board assurance on the progress against the repatriation milestone plan and associated risks to delivery will be via the Chief Executive's report to Board.

Clinical Leadership Board will receive risk oversight via monthly project highlight report with quarterly high level risk reporting via the Board Assurance Framework and Corporate Risk Register Report.

Assurance on safety, quality and standards will be via the Safety Quality and Standards Committee of the Board (e.g. spotlights, assurance reports) and via the quarterly Board Assurance Framework and Corporate Risk Register Report.

13. Review of the Group

The establishment of this group is time-limited and will extend until the service is repatriated safely and assurance that all milestones have been reached. A self-assessment of the effectiveness of the group will be undertaken prior to dissolution and reported to Clinical Leadership Board.

15. Terms of Reference

The Terms of Reference will be subject to gateway reviewed after three months and at April 2023. Changes to the terms of reference must be authorised by the Chief Executive.

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DASHBOARD

UPDATED 21/06/2023 - FOR BOARD APPROVAL 06/07/2023

Maternity Return Criteria Review				Nov 22	Dec 22	Jan 23	Feb 23	Mar 23	Apr 23	May 23	June 23
Local Criteria											
	1. National modelling on C19 surge										
	2. Robust arrangements with a supporting partner										
3. Safe staffing levels											
		Obstetrics									
		Midwifery									
		Anaesthetic Consultants									
		Anaesthetic SAS Doctors									
		Theatres									
		Neonates									
	4. Bed Capacity										
	5. Emergency Theatres										
System Criteria											
	6. Host resilience										
	7. Regulator and commissioner support										
Blue		Green		Amber			Red				
Criteria Met		Solution identified – on track		Solution not yet confirmed			Solution not identified				

ID	Workstream	Workstream lead	Key activities/outputs	Notes	Owner	Start Date	End Date	Status
RMCHFT1	Host providers - MCHFT	N Biggar	Provide 6 weeks formal notice for return of service		N Biggar	Decision Date	6 weeks before opening	In progress
RMCHFT10	Host providers - MCHFT	N Biggar	Closure of governance items - Incidents	Depends on severity	N Biggar / E Boland	In progress	2 weeks after opening	In progress
RMCHFT11	Host providers - MCHFT	N Biggar	Plan for preceptorship going forwards		N Biggar	In progress	Ongoing	In progress
RMCHFT12	Host providers - MCHFT	N Biggar	Return of handheld records to ECT	Ongoing	N Biggar	30/11/22	1 month after opening	Planned/Not started
RMCHFT13	Host providers - MCHFT	N Biggar	Confirmation of activity done by staff in [Month before opening] for payroll / enhancements - Maternity	BAU - Staff confirm shifts via E-Roster every month	N Biggar	Decision Date	1 week after opening	In progress
RMCHFT14	Host providers - MCHFT	N Biggar	Confirmation of activity done by staff in [Month before opening] for payroll / enhancements - Neonates	BAU - Staff confirm shifts via E-Roster every month	N Biggar	Decision Date	1 week after opening	In progress
RMCHFT15	Host providers - MCHFT	N Biggar	Remove staff from MCHT roster and access to Roster - Maternity	Have discussions prior	J Butters	Decision Date	1 week after opening	Planned/Not started
RMCHFT16	Host providers - MCHFT	N Biggar	Remove staff from MCHT roster and access to Roster - Neonates	Have discussions prior	J Butters	Decision Date	1 week after opening	Planned/Not started
RMCHFT17	Host providers - MCHFT	N Biggar	Return equipment that belongs to ECT	CTG Equipment - Could be closer to return but needs a plan	J Butters	01/03/23	1 month before opening	Planned/Not started
RMCHFT18	Host providers - MCHFT	N Biggar	Review patients which are booked for elective sections	Taken to HoM (April)	J Butters	19/12/22	03/04/2023	In progress
RMCHFT19	Host providers - MCHFT	N Biggar	Review patients which are booked for inductions	Taken to HoM (April)	J Butters	19/12/22	03/04/2023	In progress
RMCHFT2	Host providers - MCHFT	N Biggar	Agree approach to return of babies - Neonates	Approach has been agreed with the ODN, and Partners will be advised of their recommendation at the Partners meeting 26th October	N Biggar	30/11/22	1 month before opening	Planned/Not started
RMCHFT3	Host providers - MCHFT	N Biggar	Finalise return of babies - Neonates		N Biggar	01/03/23	1 week before opening	Planned/Not started
RMCHFT4	Host providers - MCHFT	N Biggar	Inform all patients service is returning - Maternity	Awaiting NHSE Confirmation	N Biggar / JA	Decision Date	17/04/23	Planned/Not started
RMCHFT5	Host providers - MCHFT	N Biggar	Inform all parents service is returning - Neonates		N Biggar / JA	30/11/22	1 month before opening	Planned/Not started
RMCHFT7	Host providers - MCHFT	N Biggar	Get assurance from IG regarding closure of information sharing agreements		C Hepplestone	30/11/22	1 month before opening	Planned/Not started
RMCHFT8	Host providers - MCHFT	N Biggar	Closure of governance items - risks	Depends on severity	N Biggar / E Boland	30/11/22	2 weeks after opening	Planned/Not started
RMCHFT9	Host providers - MCHFT	N Biggar	Provide assurance to LMS and project group of activity versus staffing		N Biggar	In progress	31/12/22	Completed

Maternity recovery - Project Progress Report

Author		Nicky Biggar		Period		26/04/2023 to 22/05/2023													
Progress in the past week – key achievements				Focus for following month – key milestones															
<p>Progress as of 12pm, Tuesday 24th #May</p> <ul style="list-style-type: none">Estates works are underway to revert the ward back to Maternity. The target completion date is the end of the month, with Estates providing assurance weekly.Implementation project plan is underway, planned for the next 5 weeks. Workstream leads are engaged weekly at MPG to ensure actions are completed.Heads of Midwifery meetings are underway to ensure smooth transition of staff, women and babies. These meetings have stepped up in frequency to continue providing assurance to host sites.Work has progressed on gaining feedback from staff who have rotated to Stepping Hill, with the feedback being recording on the master training document.All midwives at host sites have had their rosters confirmed to finish on 25/06/23, ready for the new roster to begin at ECT on 26/06/23.The current status of the project plan is as follows: <table><tr><th>In progress</th><th>Overdue</th><th>Complete</th><th>Planned/ Not started</th><th>Retired</th><th>Total</th></tr><tr><td>97</td><td>0</td><td>182</td><td>51</td><td>37</td><td>375</td></tr></table>				In progress	Overdue	Complete	Planned/ Not started	Retired	Total	97	0	182	51	37	375	<ul style="list-style-type: none">Training at SHH to continue as noted in the training plan.Progress with equipment ordered.Progress with ward renovations.To continue to advertise for any vacancies for all staff groups, with particular focus on locum anaesthetic shift gaps and theatre staffing recruitment.Pulling together an assurance document relating to staff training / competency.Meeting with Digital/Telephony staff to complete actions.Neonatal review of safe staffing for an agreed allocation of cots.Continue to meet action plan deadlines.			
In progress	Overdue	Complete	Planned/ Not started	Retired	Total														
97	0	182	51	37	375														
Challenges – what themes are emerging? Suggested course of action?				Lessons Learned															
<ul style="list-style-type: none">Offered temporary appointment to anaesthetic locums to cover gaps in shifts until anaesthetic consultants start. Awaiting full confirmation.																			
Escalation – any issues requiring escalation?				New Risks Identified – to be scored and recorded on risk log															
<ul style="list-style-type: none">‘Go public’ date (KDB)Bed capacity for medical patients (SG)																			

Maternity recovery - Project Progress Report

Author	Charlotte Danford					Period	20/09/2022 to 04/10/2022													
Progress this week – key achievements						Focus for following fortnight – key milestones														
<ul style="list-style-type: none">Progress as of 12pm, Tuesday 4th October:Initial meeting taken place with all but 1 workstream lead.Updates were given and dates assigned.Further meetings were put in the diary – majority of these started in January where appropriate.Status update of actions in project plan: <table><tr><th>In progress</th><th>Overdue</th><th>Complete</th><th>Planned/not started</th><th>Retired</th><th>Total</th></tr><tr><td>57</td><td>1</td><td>8</td><td>286</td><td>12</td><td>364</td></tr></table>						In progress	Overdue	Complete	Planned/not started	Retired	Total	57	1	8	286	12	364	<ul style="list-style-type: none">Meet with remaining Workstream lead to supply dates and current action status.Meet with Nicky and Emma regarding their actions and start dates.Prepare to give an update at the next Maternity Implementation Group (13/10/22)Final check that estates timeline does not affect the dates in other sectionsContinuing to meet action plan deadlines, including:<ul style="list-style-type: none">Continue focus on recruitment across Maternity, Anaesthetics and TheatresDeveloping Comms planBeginning stock and equipment actionsTheatre consultation paper – 21st OctoberCascade competency plan with medical staff		
In progress	Overdue	Complete	Planned/not started	Retired	Total															
57	1	8	286	12	364															
Challenges – what themes are emerging? Suggested course of action?						Lessons Learned														
<ul style="list-style-type: none">Input from Paeds is awaited, in order to populate the action plan for these areasConfirmation of the Anaesthetic clinical lead for Maternity																				
Escalation – any issues requiring escalation?						New Risks Identified – to be scored and recorded on risk log														
<ul style="list-style-type: none">Some actions raised further questions:<ul style="list-style-type: none">Training updates and closure of incident information from host sites not being received back by ECT;Maternity theatre refurb and requirement for separate elective theatre.																				

Project Risk Register (Updated 21/06/2023)

Project: Maternity Oversight Group

Lead: Ged Murphy

Ref	Status	Date added	Datix Ref	Risk category	Principle risk description	Initial Likelihood	Initial Impact	Initial Rating	Key controls established	Current Likelihood	Current Impact	Current Rating	Gaps in controls	Actions to reduce the risk if current controls are insufficient	Final Likelihood	Final Impact	Final Rating	Assurances	Gaps in assurance	Actions to mitigate gaps in assurance	Adequacy of controls	Risk owner
1	Closed	15/09/2022		Wider System	PRINCIPLE RISK: If an agreeable partner organisation cannot be sourced as part of a shared service model, this may have an adverse impact patient safety and experience as a result of the inability to implement the preferred option of a shared service.	3 Possible	5 Catastrophic	15	<ul style="list-style-type: none"> Monthly MOG & MIG established. CEO written to all host Trusts. 2 have responded positively. Board agreed shared model - September 2022. Board agreed preferred partner organisation. A draft MOG was written and supported by both Heads of Midwifery. This was then changed to a letter of confirmed support from SFT, which was received in May 2023. 	1 Rare	5 Catastrophic	5	<ul style="list-style-type: none"> MOU is not yet in place with preferred partner. Currently no partner representation at the MOG and MIG meetings. 	<ul style="list-style-type: none"> MOU under development with preferred partner. Partner representation at MOG, B-MIG to be defined and implemented. 	1 Rare	5 Catastrophic	5	Assurance and update reporting provided to the Trust Board via the Clinical Leadership Board.	None identified	Not applicable	Further action required	K Sheerin / D Nunn
2	Closed	15/09/2022		Wider System	PRINCIPLE RISK: If the trust does not receive adequate financial support from the Integrated Care Board this may have an adverse impact on patient experience as a result of further delays to the return of the intrapartum service.	3 Possible	5 Catastrophic	15	<ul style="list-style-type: none"> CEP Place Director is a member of MOG. Monthly maternity checkpoint meetings in place with NHSE (NW) and C&M ICB. ECT CEO Chair of MOG. Indicative budgets were included in the November 2022 ICB paper Update paper presented to ICB Board 23/02/23. ICB has confirmed support for return of full service. 	1 Rare	5 Catastrophic	5			1 Rare	5 Catastrophic	5	Assurance and update reporting provided to the Trust Board via the Clinical Leadership Board. DoF sighted on issues via EMT reporting/discussion.	None identified	Not applicable	Further action required	K Sheerin
3	In progress	15/09/2022		Workforce	PRINCIPLE RISK: If ECT (and any potential partners) are unable to recruit sufficient staff to run the new service this may have an adverse impact on patient safety due to the lack of suitably trained staff.	4 Likely	5 Catastrophic	20	<ul style="list-style-type: none"> Newly recruited Anaesthetic middle grade, midwifery staff, obstetrics & gynaecology consultant staff to commence in post from November 2022 onwards. Weekly anaesthetic updates provided to CEO. Monthly update reporting on recruitment to MOG and MIG meetings. Dedicated governance team with maternity to review risks and incidents. Monthly governance meetings to monitor incidents. Board approved recruitment and investment strategy Maternity recruitment day completed with successful hires Anaesthetic consultant adverts adapted to feature joint roles with SFT, daytime-only working, RRP and ability to build own job plan. Strategy development for recruitment of anaesthetists 8 Anaesthetic SAS doctors are in post. 9 international midwives successfully recruited. Safe levels achieved for all staff groups predicted to now be fully met. Midwifery has achieved 50% staffing in June 2023 (Safe staffing level), with 100% projected by September 2023. This is based on an estimate of 1500 births. Midwifery bank staff have also been recruited to cover potential spikes in births at ECT following reinstatement of services. 4 substantiated Anaesthetic consultants have been recruited and are due to start before September 2023. Locums have been recruited to cover shift gaps between reinstatement and September. 	2 unlikely	5 Catastrophic	10	<ul style="list-style-type: none"> Vacancies remain in midwifery (DCC safe level achieved; recruitment underway to achieve a full establishment) and Anaesthetics. 2 more Anaesthetic SAS doctors are not yet in post due to start before May 23. 	<ul style="list-style-type: none"> Ongoing recruitment campaign for midwifery. Ongoing Escalated activity to attract and recruit anaesthetic consultants. Interview dates are scheduled for both Anaesthetic Consultants and SAS doctors, with candidates available for each. 	2 unlikely	5 Catastrophic	10	Assurance and update reporting provided to the Trust Board via the Clinical Leadership Board. Incident monitoring via Datix. All incidents reporting directly to DNQ	None identified	Not applicable	Further action required	J Acharya A Gorman N Biggar S Dean
4	Closed	31/08/2022	3817	Wider System	PRINCIPLE RISK: If the number of patients with no criteria to reside continues at current levels or increases there is a risk that Ward 6 escalation capacity of 32 beds will not be able to be released to allow maternity services to return to Macclesfield Hospital site.	5 Almost Certain	4 Major	20	<ul style="list-style-type: none"> Winter Planning preparation established ICB winter planning meetings established ECT winter planning meetings established Winter planning schemes submission Investment into winter schemes within ECT financial plan Urgent and Emergency Care Action Plan in place COST (NHSE Emergency care intensive support team) Support for Frailty and Wards - Test of Change events throughout October and November Maternity Operational Group established Spot purchase capacity Weekly system wide KIT meeting re winter planning and community capacity National funding of £500m confirmed for winter pressures Cheshire East Place allocation of national funding confirmed - £2.5m £1.1m in December 2022, £1.4m in January 2023 On 9.12.22, there were 107 patients with No Criteria To Reside. A weekly update on these numbers will be received Community Bed Capacity Modelling requirement commenced by ICB. A robust action plan relating to the national discharge fund has been developed and implemented. Discharges are monitored via the daily Reablement/Care Delays MOT Weekly Operational Leads meetings increased to three times weekly (09.12.22). Progress will be reported to the weekly Monday KIT meeting, and updates to the Monthly Operational Resilience Group meeting and to the Operational Delivery Group Meeting. Ward 6 successfully de-escalated on 13/02/23. Estates works began on 14/03/23 to reinstate the maternity ward. Capacity and community places are coming online funded by the National Discharge Fund 	2 unlikely	5 Catastrophic	10	<ul style="list-style-type: none"> Community bed deficit 60 Local Authority Domiciliary Care Capacity core gaps in service 		3 Possible	4 Major	12	Winter Planning Submission monitored at Winter planning meeting UEC action plan monitored Urgent and Emergency care group OTG and UEC monitoring actions, highlight reports and test of change presentations Governance and Oversight Ward 6 Initiative established 09.12.22.	None identified.	None identified.	Managed	J Young
5	In progress	15/09/2022		Patient	If patients do not have sufficient confidence in the returned service they may continue to choose to book and give birth with host Trusts.	3 Possible	3 Moderate	9	<ul style="list-style-type: none"> Patient engagement to date has shown high levels of support for the return of services to MDGH. Women continue to book with ECT in similar numbers to pre-suspension. All women scheduled to birth around the reinstatement date have been contacted by letter to assure them of the key information regarding reinstatement. 	2 unlikely	Minor 3	6	<ul style="list-style-type: none"> Any further delays could further remove confidence in the returned service. Updates with the public are limited in the suspension phase due to project uncertainty. 	<ul style="list-style-type: none"> We are committed to working with Maternity Voices Partnership to understand the views of pregnant women and their families and will work with them to promote any new services. Communications and Engagement plan will feature key initiatives to boost patient engagement, such as opportunities to visit the site and facilities. 	1 Rare	3 Minor	3		None identified	Not applicable		N Biggar
6	Closed	15/09/2022		Finance	If the costs of any proposed model are higher than the pre-suspension service, this may have an adverse effect on the ability to return the service (either Trust or System).	3 Possible	4 major	12	<ul style="list-style-type: none"> MOG will be appraised of all known financial implications of any proposed service. Monthly MOG & MIG established. Board agreed shared model - September 2022. Board agreed preferred partner organisation. ICB board responded favourably to paper September '22 detailing need for extra costs. Modelling of the potential options includes a financial assessment, presented to ICB in November '22. ICB has confirmed support for return of full service. 	2 unlikely	4 major	8			2 unlikely	4 Major	8	Assurance and update reporting provided to the Trust Board via the Clinical Leadership Board.	None identified	Not applicable	Further action required	S Johnson

	In progress	15/09/2022		Clinical	If the Trust is unable to safely run both elective and emergency maternity theatres, which is a requirement set by the Regional Chief Midwife and Regional Clinical Lead of Obstetrics, there is both a risk to patient safety and to the likelihood of regulators supporting the return of the service.	3 Possible	4 major	12	<ul style="list-style-type: none">Guidance obtained from Regional Chief Midwife in October 2022Elective and emergency theatre proposal submitted on 8 September 2022, with work done by theatre staff.SBAR of theatre lists suitable to be dropped and replaced with elective section lists confirmed and supported at Project Group.The impact on existing elective activity has been discussed and agreed with services affected.Theatre paper discussing dropped lists approved at MIG on 16/02/23 and MOG on 23/02/23.	2 unlikely	4 major	8		<ul style="list-style-type: none">Ongoing management of theatre lists to mitigate worst case scenario outlined in SBAR.	1 Bare	4 major	4	Assurance and update reporting provided to the Trust Board via the Clinical Leadership Board. Representative from GM LMS present at MOG	None identified	Not applicable	Further action required	F Walton
8	In progress			Project	If the Maternity Recovery criteria are not fully met by March 2023, there is a risk that the trust will not meet the target date for reinstatement of maternity inpatient services by the end of June 2023.	3 Possible	4 major	12	<ul style="list-style-type: none">A detailed Project Plan monitored by the Maternity Implementation Group. Where necessary issues will be escalated to the SRO and/or Maternity Oversight GroupExceptions to meeting criteria are escalated to the Trust Board monthly.Monthly assurance reporting from host sites on the impact of repatriated service provision is given.Recovery criteria were reviewed and finalised in November '22.Recovery criteria are reviewed internally and externally (via MIG and MOG) on a monthly basis.Board approved recovery criteria on 16/03/23 as all criteria are met or on target. <p>» The reinstatement date of 26/06/23 was confirmed by Executives in March '23. The project actions are scheduled to be completed and the service reinstated by that date.</p>	2 unlikely	4 major	8		<ul style="list-style-type: none">ECT Board remain committed to return maternity services when safe to do so, and review readiness against the recovery criteria at monthly board meetings.	2 unlikely	4 major	8	Assurance and update reporting provided to the Trust Board via the Clinical Leadership Board. Reporting of project actions are cascaded upwards from Maternity Project Group, Maternity Implementation Group and Maternity Oversight Group.	None identified	Not applicable	Further action required	N Biggar
9	Closed			Wider System	If the current NHS Specialist Commissioners review of neonatal provision in the North West determines that the region has an over supply of neonatal (including Special Care Baby Unit) cots, there is a risk that it will not be possible to maintain a SCBU on the MDGH site.	3 Possible	4 Major	12	<ul style="list-style-type: none">ECT have already made contact with NHS Spec Com and will keep apprised of the review.GM LMS is part of MOG and continued liaison will take place.	3 Possible	4 Major	12	<ul style="list-style-type: none">There is a need to fully understand the planned timescales and process of the NHS Spec Com review.The review may take many years to conclude, and may only impact services at some stage in the future.	<ul style="list-style-type: none">Continued liaison with GM LMS will be required leading up to and beyond reopening the service	2 unlikely	4 Major	8	Assurance and update reporting provided to the Trust Board via the Clinical Leadership Board.	None identified	Not applicable	Further action required	N Biggar / F Walton (to be escalated to K Daly Brown with a score of 15)

Update on the return of inpatient intrapartum services

The purpose of this paper is to update the Board regarding the state of readiness to safely return full intra-partum care to Macclesfield District General Hospital (DGH).

1 INTRODUCTION

Intrapartum maternity services remain suspended at Macclesfield DGH.

- 1.1 Inpatient intrapartum maternity services have been suspended at Macclesfield DGH since March 2020, with most registered women delivering at neighbouring 'host' hospitals in Leighton, Stockport and Wythenshawe.
- 1.2 The initial suspension of inpatient services was for a period of up to six months arising from the limited anaesthetic capacity in the Trust to respond to the Covid-19 pandemic. The suspension has been extended on three occasions following assessment against Board approved recovery criteria (which have changed over the period). The most recent extension (March 2022) set out the Board's commitment to return the services by April 2023 when safe to do so.

2 BACKGROUND

Significant work has been undertaken since the suspension to ensure services can be safely returned.

- 2.1 In September 2022, a detailed paper was considered by the Trust Board in private, which set out a number of appraised options for how the service could be re-instated safely. These had been developed through significant work over the spring / summer, involving staff, partners, stakeholders and patients.
- 2.2 Two reports were critical to the Trust Board's considerations: -
 - The Findings, Conclusions and Essential Actions from the Independent Review of Maternity services at the Shrewsbury and Telford Hospital NHS Trust ('The Ockenden Report', March 2022).
 - The Royal College of Anaesthetists invited review of the anaesthesia service in relation to provision of maternity care at East Cheshire NHS Trust (February 2022).

- 2.3 The board concluded that, in order to meet the requirements of these reports and in line with the options appraisal, a supportive partnership model should be established. This would allow for rotation of staff to ensure that skills are appropriately retained to meet the needs of service delivery.
- 2.4 The paper also set out the four key areas of risk to securing full service restoration at that time as follows: -
 - The need to develop robust arrangements to deliver high quality, safe intrapartum services with a supporting partner.
 - The need to secure support for the proposals, including financial, from NHS England and NHS Cheshire and Merseyside – Integrated Care Board.
 - The trust’s ability to recruit, retain and train sufficient staff to sustainably deliver the service.
 - The need to reduce the requirement for escalation beds, allowing Ward 6 to return to being used for maternity patients.
- 2.5 Robust governance arrangements are in place (both internally and with partners) to oversee the safe return of services.
- 2.6 NHSE and NHS Cheshire and Merseyside are fully appraised of progress through monthly oversight meetings and reports to the NHS Cheshire and Merseyside Board.

3 RETURN CRITERIA

Revised return criteria were agreed by the Trust Board in November 2022.

- 3.1 The revised return criteria agreed by East Cheshire NHS Trust Board in November 2022 are as follows: -

Local Level

1. National modelling indicates that further a Covid-19 surge is unlikely and local capacity to meet clinical need would be manageable within enhanced workforce and environment.
2. Robust arrangements are in place to deliver high quality, safe intrapartum services with a supporting partner; this includes support for the ongoing training and development of staff.
3. Workforce recruitment, attendance and resilience is at a level sufficient to maintain safe staffing levels in obstetrics, midwifery, neonatal, anaesthetic and theatre services.

4. Capacity for patients (including any Covid-19 positive patients, any linked to seasonal pressures and any with no criteria to reside) can be accommodated to core wards without the requirement to utilise additional estate and facilities in maternity.
5. The trust robust plans in place to guarantee access to emergency theatres when necessary.

System Level

6. Local Maternity Systems in Cheshire & Merseyside and Greater Manchester are sighted and safely resilient to the impact of the recovery plan.
7. Support (including funding) is received from commissioners and regulators for proposals to return intrapartum services.

4 READINESS TO RETURN

Significant progress has been made to secure the safe return of the service

- 4.1 Progress against the return criteria has been monitored each month by Maternity Oversight Group and Board, most recently at Public Board in February 2023
- 4.2 Significant progress has been made against all the return criteria such that they have all been met or have secure plans to be delivered imminently.
- 4.2 A summary of progress against the criteria is as follows:-

DASHBOARD

UPDATED 03/03/2023 - FOR BOARD APPROVAL 16/03/2023

Maternity Return Criteria Review		Nov 22	Dec 22	Jan 23	Feb 23	Mar 23
Local Criteria						
	1. National modelling on C19 surge					
	2. Robust arrangements with a supporting partner					
	3. Safe staffing levels					
	Obstetrics					
	Midwifery					
	Anaesthetic Consultants					
	Anaesthetic SAS Doctors					
	Theatres					
	Neonates					
	4. Bed Capacity					
	5. Emergency Theatres					
System Criteria						
	6. Host resilience					
	7. Regulator and commissioner support					
Blue		Green		Amber		Red
Criteria Met		Solution identified – on track		Solution not yet confirmed		Solution not identified

5 OUTSTANDING RISKS

5.1 The risks highlighted to the Board in September 2022 have been reassessed as follows:-

Of the four key risks highlighted to the Board in September 2022, all have been reduced to 10 or below.

Risk	Score Sep 2022 (L x I*)	Score Jan 2023 (L x I*)	Score Mar 2023 (L x I*)	Notes
Confirmation of a partner	(2 x 5) 10	(1 x 5) 5	(1 x 5) 5	SFT confirmed as supportive partner.
Support from ICB	(2 x 5) 10	(2 x 5) 10	(1 x 5) 5	ICB has indicated financial support for return of full service.
Recruitment of staff	(4 x 5) 20	(3 x 5) 15	(2 x 5) 10	Safe staffing numbers for all staff groups predicted to now be fully met.
Return of bed capacity	(5 x 4) 20	(5 x 4) 20	(2 x 5) 10	Ward 6 closed to admissions and estates work underway. Capacity in community now in place / coming on line funded through national Adult Social Care Discharge Fund.

*Likelihood v Impact

6 PATHWAY TO 'GO LIVE'

A detailed implementation plan to ensure safe 'go live' is in place; this has guided all the work to date.

Delivery of all the actions within the Implementation Plan will continue to be overseen by the Maternity Implementation Group (chaired by the Medical Director) and Maternity Oversight Group (chaired by the CEO).

6.1 Given that the criteria for safe return of the service have now been met or have a solution in place which is on track for delivery, and that the risks are under control, it is proposed that the service 'goes live' in early summer 2023.

6.2 There is a detailed implementation plan to support this, the key strands of which are as follows:-

6.3 **Staffing training and re-orientation**

Plans are in place for all necessary staff to be re-trained to be competent and confident to deliver a safe service from early summer. Ongoing training may be required, for which arrangements are in place.

6.4 **Estates & facilities**

Work is currently taking place to convert Ward 6 back into the Maternity ward, this includes aesthetic improvements to improve patient experience, upgrading IT equipment and installation of a new baby tagging system. Once completed, plans are in place to undertake soft facilities management actions including catering, laundry, cleaning etc..

6.5 **Equipment**

Equipment has already been already ordered. Some major items such as Labour Ward Beds and Phototherapy Units have already arrived. Minor IT tasks are planned along with PAT testing.

6.6 **Communications & patient engagement**

A robust Communications Plan is in place once a positive decision to confirm the date for reinstatement has been made. This includes planned open days for pregnant women and families as well as work with Maternity Voices Partnership (MVP). MVP and service users will be invited to take part in a 15 Step Assessment to review the new unit from a patient perspective.

6.7 **Transfer of care**

Robust plans are in place to care for women booked with ECT to deliver from early summer. Women will be advised of the date of

reinstatement and be expected to attend ECT from that date this should minimise the requirement of the host sites providing care without ECT staff. Beyond the re-start date, host sites should only be required to care for women who are in active labour or recently given birth. A small amount of the babies requiring neonatal care may require care by the neonatal unit at the host site, and an individual assessment will be undertaken for any baby that does to see if they can be transferred to ECT.

The Maternity Implementation Group and Maternity Oversight Group will continue until the service goes live, and then will be superseded by an enhanced internal assurance group.

6.8 ASSURANCE FOLLOWING RETURN OF THE SERVICE

6.8.1 Internal

The trust has well established internal assurance processes through committees of the Board up to the trust board. For maternity, this includes a Directorate Maternity Governance Group, which will report to the Safety, Quality and Standards Committee of the Board.

External

ECT Executives and Operational teams are working closely with a range of external partners on issues of assurance:

- ECT Executives meet regularly with senior colleagues from Cheshire & Merseyside ICB, NHS England North West and Greater Manchester & East Cheshire Local Maternity and Neonatal System (LMNS) to appraise them of progress and deal with any issues and concerns.
- The Maternity Service is in close contact with the Regional Chief Midwife and Regional Chief Obstetrician to provide ongoing assurance and have responded to a number of clinical and operational queries and will continue to do so.
- The service is working closely with the ECT Planning team to ensure plans for 2023/24 are in line with Operational Planning Guidance.
- A new GMEC LMNS safety progress and performance meeting has been created to monitor all trusts against the national standards (Ockenden and Kirkup) at which the trust will present and update on a quarterly basis.
- Further future external assurance arrangements will be agreed with commissioners and regulators (ICB, NHSE and CQC) in due course.

7 RECOMMENDATIONS

7.1 The Trust Board is asked:-

- To note the contents of this report and the significant progress made in order to safely return full intrapartum care to Macclesfield DGH.
- To note the plan for the safe return of the service with a revised reinstatement timescale of early summer 2023.

Name	Katherine Sheerin
Job Title	Director of Transformation & Partnerships



East Cheshire
NHS Trust

**Post Implementation Review of
East Cheshire Inpatient
Maternity Services**

12th December 2024

Nicola Biggar – Head of
Midwifery, Women's and
Children's Services

MATERNITY SERVICES CHANGES AT MACCLESFIELD HOSPITAL - MARCH 2020

Please note that in order to meet pressures relating to Covid-19, births are being temporarily relocated from Macclesfield Hospital to neighbouring maternity units as a safety measure.

The measure is necessary because East Cheshire NHS Trust, which runs the hospital, has a small number of anaesthetists who would be unable to provide cover both for maternity-related procedures such as emergency caesarian sections and an expected rise in patients being treated for Covid-19.

Any women due to give birth at the hospital from Wednesday, March 25th 2020 onwards will instead deliver at one of our partner trusts close to their home.

Women should have been contacted by their midwife but if anyone has not or has any urgent queries or concerns, including relating to the onset of labour please contact one of the following:

- For Stepping Hill Hospital Labour Ward: 0161 419 5551 / 3
- For Royal Stoke Hospital Labour Ward: 01782 672300
- For Leighton Hospital Labour Ward: 01270 612144 / 01270 273116
- For Wythenshawe Hospital Labour Ward: 0161 291 294

[Read more - Pregnancy and Coronavirus](#)

OFFICIAL

Service Provision During Suspension

- Most inpatient intrapartum activity was provided by ‘host’ Trusts at Stepping Hill, Wythenshawe and Leighton hospitals.
- Women were given the option to choose which host site they want to attend by the time they were 20 weeks pregnant.

Delivery Provider	20/21	21/22	22/23
Mid Cheshire FT	330	261	290
Stockport FT	474	337	370
MFT (Wythenshawe)	407	563	443
Royal Stoke	107	41	13
Home births	14	41	17
Others	41	37	23
Total ECT registered births	1373	1320	1156

DASHBOARD

UPDATED 21/06/2023 - FOR BOARD APPROVAL

Maternity Return Criteria Review		Nov 22	Dec 22	Jan 23	Feb 23	Mar 23	Apr 23	May 23	June 23
Local Criteria									
	1. National modelling on C19 surge								
	2. Robust arrangements with a supporting partner								
3. Safe staffing levels									
	Obstetrics								
	Midwifery								
	Anaesthetic Consultants								
	Anaesthetic SAS Doctors								
	Theatres								
	Neonates								
	4. Bed Capacity								
	5. Emergency Theatres								
System Criteria									
	6. Host resilience								
	7. Regulator and commissioner support								
Blue		Green		Amber		Red			
Criteria Met		Solution identified – on track		Solution not yet confirmed		Solution not identified			

Progress reviewed and reported monthly via

- Maternity Project Group,
- Maternity Implementation Group,
- Maternity Oversight Group,
- and Trust Board.

Progress reported to NHSE, LMNS and Council Overview Committee.

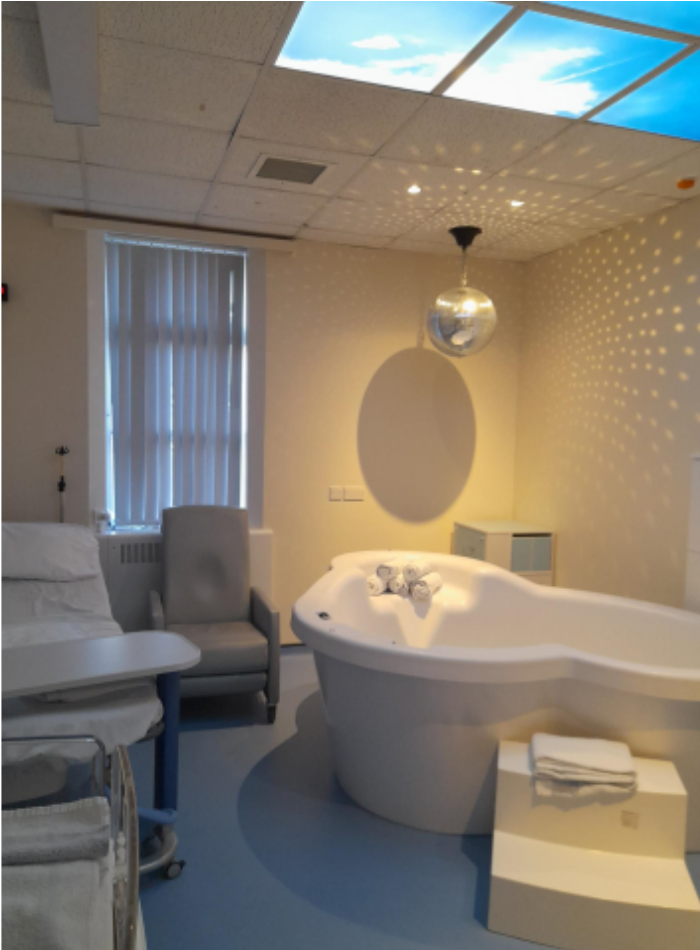
Pathway to 'Go Live'

- Staff training
 - Plans for all necessary staff to be re-trained to be competent and confident to deliver a safe service
 - Midwives and support workers

- HCA
- Obstetrics
- Neonatal
- Anaesthetics
- Paediatrics
- Theatres

SFT	DS - 4th April	DS - 11th April	DS - 17th April	DS - 27th April	DS - 4th May	DS - 9th May	DS - 16th May	DS - 23rd May		DS - 7th June
SFT	DS - 6th April		DS - 20th April	DS - 24th April	DS - 5th May			DS - 25th, 26th May		
MCHFT						DS - 11th May	DS - 19th May	DS - 22nd May		
SFT	DS - 3rd April	DS - 13th April	DS - 20th April	DS - 25th April	DS - 2nd May			DS - 24th May		
MCHFT	DS - 3rd April	DS - 14th April	DS - 17th April	DS - 24th April	DS - 3rd May			DS - 23rd May		
SFT							DS - 18th May	DS - 22nd May	DS - 30th May	DS - 5th + 6th June

- Ongoing training is required, for which arrangements are in place.





Macclesfield maternity unit shut in pandemic ready for births again

26 June



EAST CHESHIRE NHS TRUST

The trust said the team at the unit were delighted that "Macc is back"



Lessons for future projects

- Each project needs to establish **appropriate governance arrangements** that are proportionate to the scale and complexity of the task. Involving external partners in this governance should be considered for all projects.
- It is important for any major project to understand any **external decision-making factors**. To take time to understand any critical dependencies required to secure the service change and that all relevant decision makers are appropriately and effectively engaged.
- Project may need to appoint a **Senior Responsible Officer and Clinical Lead** to help lead any given project, these leaders need appropriate levels of authority and decision making to help drive the project.
- **Snagging** issues and unintended consequences should be expected and where possible anticipated.
- The importance **of ongoing engagement**:
 - With staff, including face to face, to listen to and understand their perspectives,
 - With clinical leadership, ensuring they play a role in feeding in to and out of a project,
 - With patients, ensuring patient voice is central to the service change, and wherever possible patients, or patients' groups are involved in co-producing service change.
- To take time to map out all the wider **stakeholders** affected by the changes, their drivers and motivations, and ensuring that they are fully engaged in the development and implementation of plans.

Activity since June 2024

	Jun 23	July 23	Aug 23	Sept 23	Oct 23	Nov 23	Dec 23	Jan 24	Feb 24	Mar 24	Apr 24	May 24	Jun 24	July	Aug	Sept	Oct	Total
Total births	18	88	80	86	125	97	102	102	93	119	97	114	110	117	87	121	110	1885

BIRTHRATE PLUS 2021 (Pre suspension data)

Macclesfield Hospital	% Cat I	% Cat II	% Cat III	% Cat IV	% Cat V
DS % Casemix	8.2%	14.8%	18.5%	27.2%	31.3%
	41.5%			58.5%	

BIRTHRATE PLUS 2024

Macclesfield Hospital	% Cat I	% Cat II	% Cat III	% Cat IV	% Cat V
DS % Casemix	2.3%	10.7%	24.5%	30.9%	32.6%
	37.7%			62.5%	

Ethnicity and Language

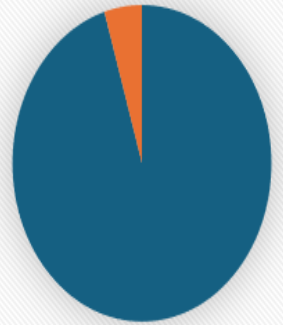
Ethnicity at Booking 2023/2024



■ White British ■ Non White British

Total WB = 83.8% (previously 87.8%)
Total non-WB = 16.2% (previously 12.3%)

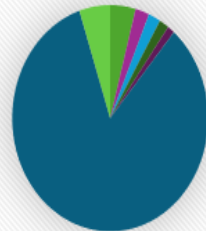
1st Language 2023/2024



■ English ■ Other

Any Other White Background = 4.2%
Asian or Asian British - Indian = 2.3%
Black or Black British – African = 2%
Any Other Ethnic Group = 1.6%
Any Other Mixed Background = 1.2%

Ethnicity breakdown 2023/2024



■ Any Other White Background ■ Asian or Asian British - Indian
■ Black or Black British – African ■ Any Other Ethnic Group
■ Any Other Mixed Background ■ White British
■ Other

English = 91.4%
Other = 8.6%
Polish = 14
Arabic = 9
Hindi = 9
Spanish = 9
Malayalam = 7

Reducing Health Inequalities

- ECT demographics have changed.
- We have:
 - 3.6% of women in the most deprived decile
 - 3.6% of women with complex social factors
 - 40% of women reported as having a mental health concern at booking
- The Trust has set out an anti-racism statement as a key step in the trusts journey towards becoming an intentionally anti-racist organisation
- Working with GMEC LMNS on the E & E action plan
- Birthchoice clinic and vulnerable families support women with information and choices individualised care plans(IPC)
- We have included ethnicity and social factors in the PSIRF paperwork to ensure they are considered on reviewing incidents

2023 staff survey reported that:

- 32% experienced harassment, bullying or abuse from patients, relatives, or the public (25% White staff).
- 26% experienced harassment, bullying or abuse from staff (20% White staff).
- 19% experienced discrimination at work from a manager, team leader, colleague (4% White staff).
- 44% believe the organisation provides equal opportunities for career progression (58% White staff).



FEAR LEARNING GROWTH

CQC Inspection December 2023

East Cheshire
NHS Trust

CQC Maternity Ratings	Overall	Safe	Effective	Caring	Well-Led	Responsive
	Good	Requires Improvement	Good	Good	Good	Good

Inspection findings:

- Staff felt respected and supported. They were focused on the needs of women and birthing people receiving care. The service generally had an open culture where women and birthing people, their families, and staff could raise concerns without fear.
- Leaders and staff engaged with women and birthing people, staff, the public and local organisations to plan and manage services. They collaborated with partner organisations to help improve services for women and birthing people.
- Leaders had the skills and abilities to run the service. They were visible and approachable in the service for staff.
- The design, maintenance and use of facilities, premises and equipment mostly kept people safe. Staff were trained to use them.
- The service generally had enough medical staff with the right qualifications, skills, training, and experience to keep
- Women and birthing people and babies safe from avoidable harm, and to provide the right care and treatment.
- Staffing levels did not always match the recommended numbers, potentially putting the safety of women and birthing people and babies at risk.
- Records were not always clear and easily available to all staff providing care.
- Governance and data collection processes were in their infancy due to the short time the service was operational, and needed to be embedded.
- **Actions – 6 Must Do's and 8 Should Do's**

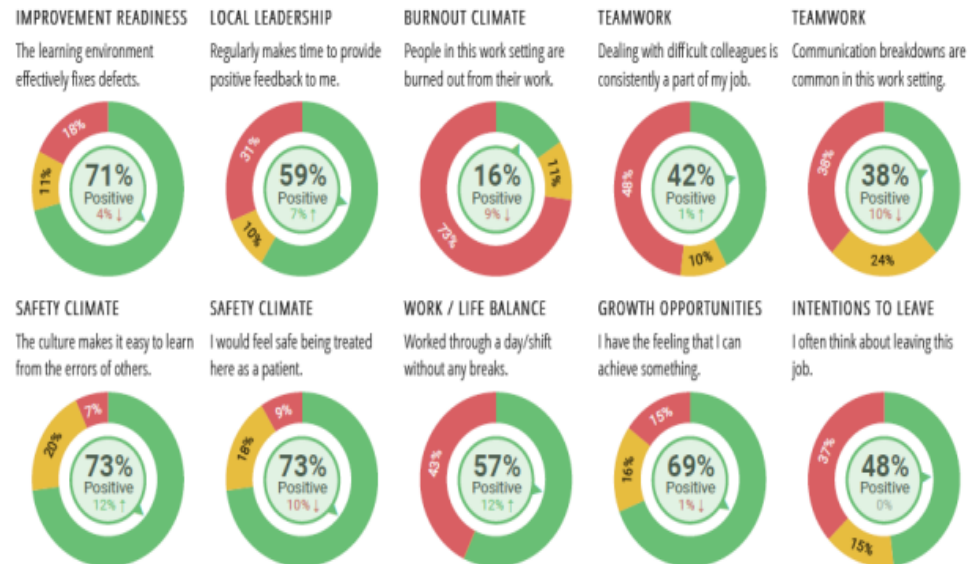
Workforce

- Birthrate Plus ® Midwifery Workforce Calculation undertaken for ECT. Report identified a deficit in the current funded establishment of 8.3wte
- Minimal vacancies and no issues recruiting to roles
- All locums have CVs checked for training compliance. Any long-term locums will be included in ECT training and have robust induction
- Work ongoing with the senior workforce information analysts to address the PWR data issue
- Maternity anaesthetic provision is stable and a priority staffing
- Pressures of a small team sharing lead roles to work against National Standards

Team Working

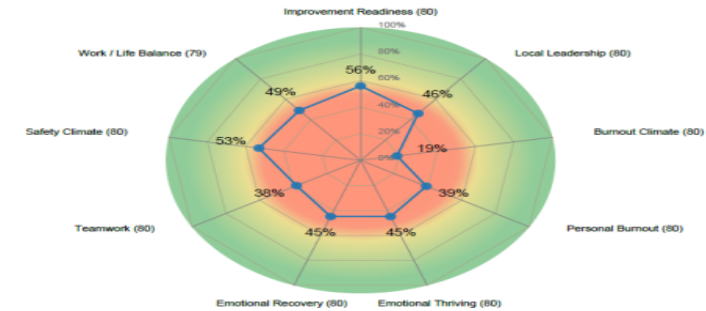
- The new Quad formed in October 2023 and commenced on the PCLP
- SCORE SURVEY undertaken in April 2024 – 61% response rate
- Meet Bi-monthly QUAD meetings
- Bi-monthly safety champion meetings
- Various involvement and attendance to monthly safety meetings, ATAIN, Maternity & Neonatal Clinical Governance, Performance meetings, Directorate & Trust SQS, bi - monthly Public board, Monthly Clinical Leadership board

Key Drivers of Culture & Engagement (Green is good)



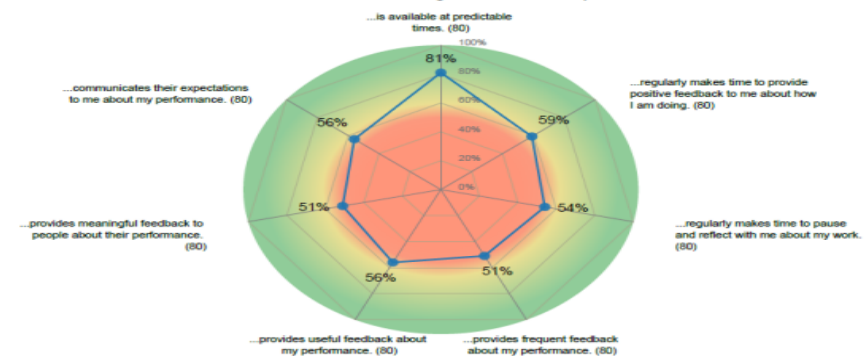
Source Data: Apr 2024
Institution: East Cheshire NHS Trust
Work Setting(s): All Work Settings
Position(s): All Positions

East Cheshire NHS Trust All Culture Domains



East Cheshire NHS Trust Local Leadership Domain

In this work setting, local leadership...



Source Data: Apr 2024
Institution: East Cheshire NHS Trust
Work Setting(s): All Work Settings
Position(s): All Positions

Percentage who Agreed slightly or Agreed strongly with each question or Disagreed slightly or Disagreed strongly if reversed.



Celebrations and Achievements

- SBL compliant
- Shortlisted for Parliamentary award
- Euroking issues – MSDS compliant and NPSA deadline met
- BFI stage 1 accreditation expected by March 2025
- SCORE survey good response rate and mostly positive results
- 100% PMRT reviews have external bodies involved
- Dedicated maternity emergency theatre and separate theatre for elective activity
- All ward rounds are face to face
- Minimal vacancies
- Social media engagement
- Learning from incidents – no blame culture

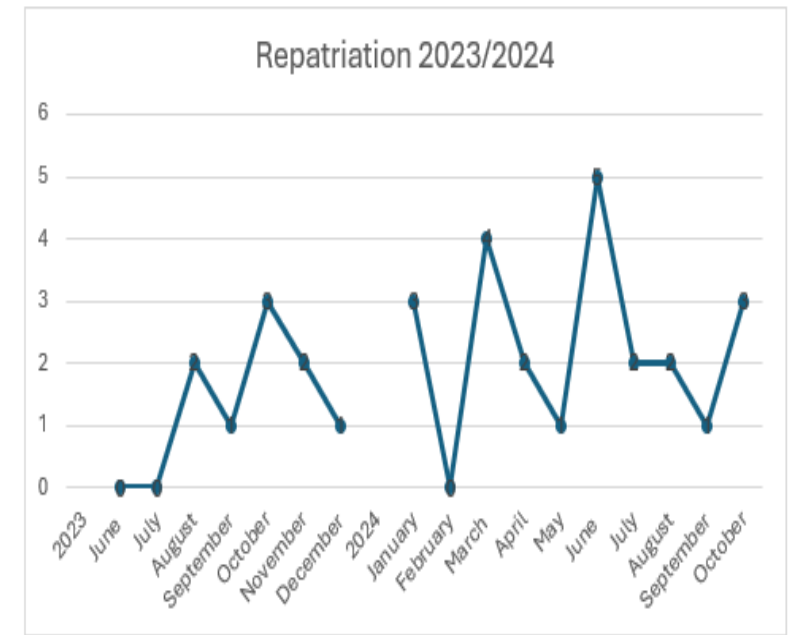
MNVP Engagement

Work Plan – key areas

- Adding in Neonatal – focus on setting up listening events alongside Neonatal staff and other agencies.
- Equity and Equality – want to use some of the additional funding to pay for VCSE stakeholder involvement (Pearls of Cheshire) – this will enable us to hear more voices.
- Bereavement – working on reviewing the documents is in progress.
- What information do you need/ did you need in pregnancy? Looking at reviewing website and other digital information. Also looking at Parent Education offering and what needs are of SUs and partners.
- Awaiting formal confirmation on formal funding – proposal was to increase to 72 hours per month (was 32 hours per month). Payment Via place to ECT and MNVP account but not an employed position unlike GM trusts.
- Active engagement from MNVP chair including:
 - Participation in the LMNS PSCP QI project
 - 15 steps assessment undertaken in June 2024
 - Digital review ongoing
 - Maternity Vision and Strategy
 - CQC action plan
- To be included in reviewing the complaints process and Safety Champion meetings in November 2024

Neonatal Care

- NWNODN undertook annual site visit on 31st July 2024 – report now received and working on recommendations
- Emergency Simulations run by ECT consultants to maintain skills
- Stabilisation training from NWNODN
- Had discussion with NWNODN re HD care for babies staying longer than 6 hours – improved the transfer time
- ATAIN – reducing term admissions for hypoglycaemia and RDS/TTN
- TC reviewed criteria has been amended and to be implemented once training provision resolved
- FiCare and the requirement to provide allied health services
- In SCBU in progress
- Repatriation rates improving



Focus & Priorities

- Aim for compliance against the 3-year single delivery plan
- CQC action plan & CQC survey action plan
- Cultural improvement work from PCLP – Themes:
 - Personal Burnout (but good emotional recovery)
 - Teamwork
 - Safety Culture
- Review SCBU activity and bed base including TC
- New digital strategy and system – improve efficiency, accurate data extraction, EPC
- MNVP role evolving – Requires adequate funding to enable this
- Staffing levels – Workforce paper to include BR+ findings, PAs, review impact of training requirements, retention and vacancy
- Increase birth numbers
- Aim to provide Maternity Continuity of Care including intrapartum care

Any questions?



East Cheshire NHS Trust Charitable Fund

[Fundraise for us](#)

[Donate](#)



Healthier
Futures

Cheshire East Council Scrutiny Committee meeting – 12th December

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Agenda Item 7

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UNCLASSIFIED

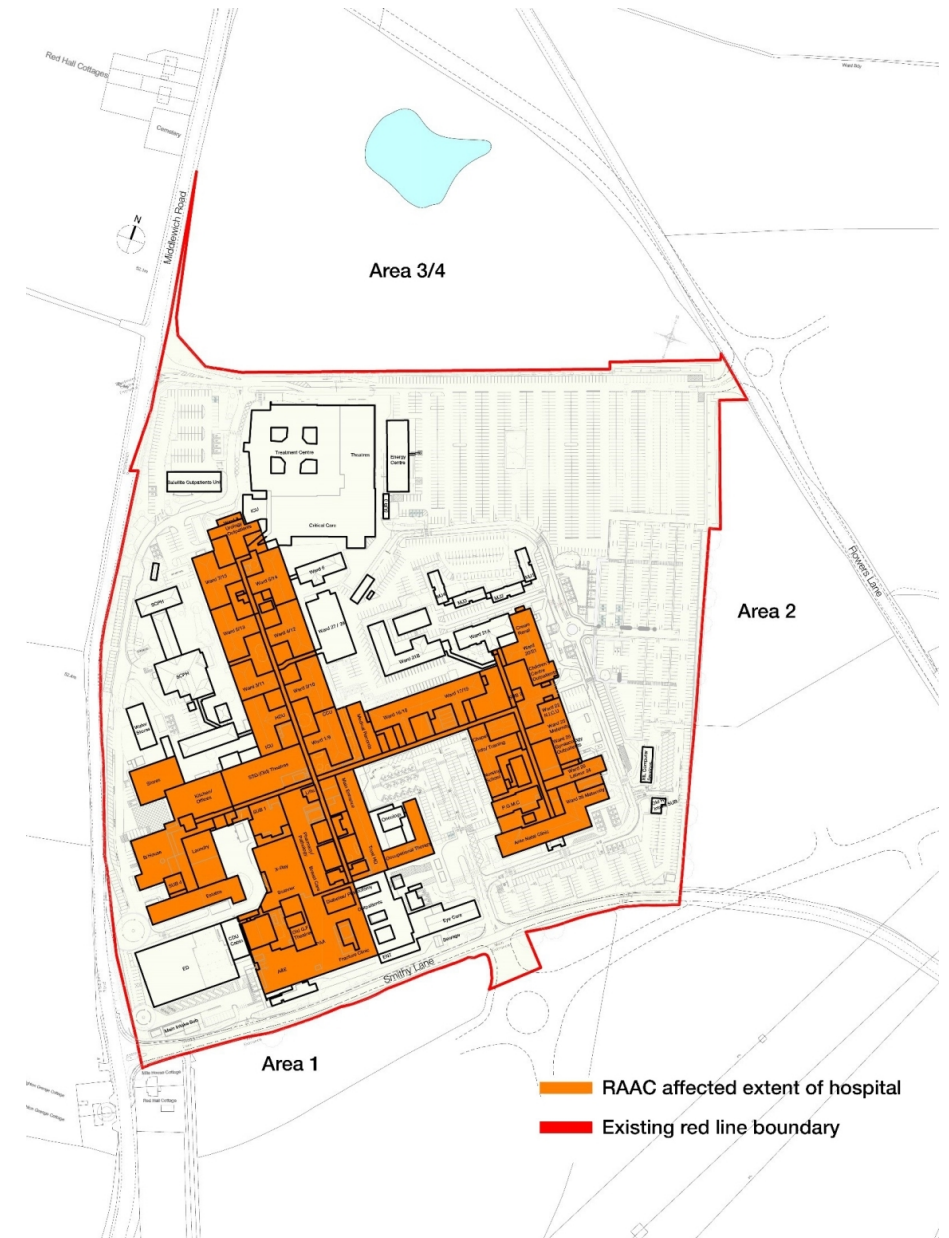
Leighton Hospital Context

- Built in the early 1970s
- Located in Mid Cheshire by Crewe
- Employs around 5,500 staff
- Serves a community of over 300,000 people
- 450,576 patients seen per year
- Has a number of infrastructure issues including RAAC and asbestos



Existing site

- 'Bubbly' lightweight form of reinforced concrete
- Shelf-life estimated to be about 30 years
- Committee of Structural Engineers (SCOSS) issued a notice in 2019 highlighting the significant risk of failure of these planks
- Mid Cheshire has over 16,000 roof and 100,000 wall planks. Over 80% of the hospital estate at Leighton affected by RAAC, including acute services
- NHSEI issued instructions requiring the removal of RAAC planks by 2030
- 7-year remediation programme initiated to install failsafe steel work



Existing Hospital and Site

- Large spread of footprint with excessive travel distances and disconnect between acute services
- Large amounts of accommodation does not meet HBN technical standards
- Inflexible environments with limited opportunity for future adaptability and future expansion
- Clinical and operational inefficiencies
- Poor aspect and daylighting impacts on patient, staff and visitor wellbeing and satisfaction
- Poor wayfinding externally and internally
- By end of current financial year circa £100m has been spent since 2020 on RAAC works



Preferred Way Forward

- Main new hospital build containing theatres, ED, women's & children's, inpatient wards, main outpatients etc
- Maximise retained estate where practical – ED converted to training and education and Darwin converted to a rehab bed model
- Optimised clinical and operational functionality, adjacencies, flows and travel distances
- Compact and efficient footprint provides the necessary access for blue light, service and public traffic, and a landscaping setting benefitting patient and user wellbeing
- Footprint pulled away from Flowers Lane / existing and consented development
- Fully net zero carbon compliant
- Fully digitally enabled hospital



Preferred Way Forward scheme at a glance



To inspire hope and provide unparalleled care for the people and communities of Cheshire, helping them to enjoy life to the fullest

We put you first

We strive for more

We respect you

We work together

Trust objectives

Improving health outcomes

to deliver the best care and experience centred on the patients needs

Working in partnership
to collaborate across place and wider boundaries to enhance patient care

Empowering our people
to be the best they can be

Building a better tomorrow
to deliver a sustainable and innovative infrastructure

Project objectives

Improving Health outcomes
Delivery of high quality, digitally enabled hospital estate and healthcare services to be delivered at supporting right time, right place delivery of healthcare and releasing staff time to care

Working in Partnership
Maximise the Trust's role as an anchor institution by working with partners to increase social mobility, improve access into community services and reduce health inequalities in our communities

Empowering our people
Deliver healthcare spaces that enhances the health and well being of our staff, reduces staff turnover and improves the ability of the Trust to attract and retain talented individuals

Building a better tomorrow
Provide a New Zero Carbon Hospital estate that can meet future clinical capacity and has eradicated RAAC by 2030

Efficient

Increase efficiency across service delivery and hospital estate to support financial sustainability for the trust and system

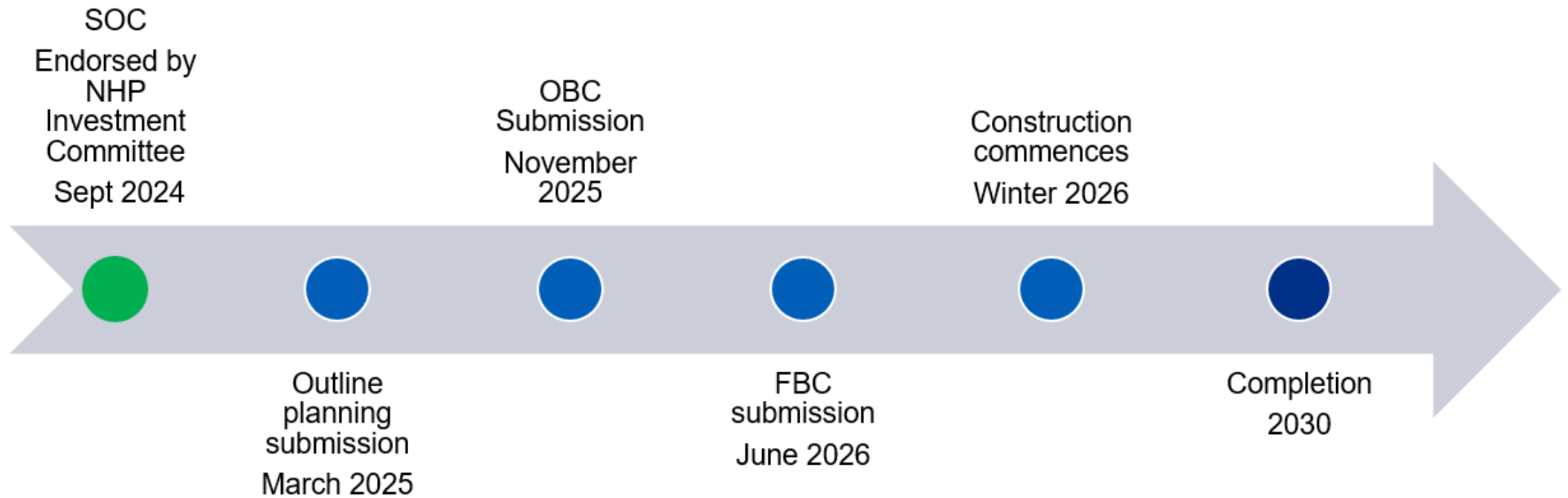


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Timetable

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Redevelopment – Target Dates



Next steps – Outline Business Case stage

Key deliverables during OBC

- RIBA stage 2 – December 2024
- Outline Planning application – April 2025
- Outline approval – September 2025
- ICB support – October 2025
- Trust Board approval – November 2025
- Submission – November 2025



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Clinical and Digital Transformation

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Clinical vision

In 2021, the Trust launched population segmentation work to gain a deeper understanding of the healthcare needs of the local population.

Key findings revealed an anticipated population growth of 5-8% over the next five years, with the highest growth among individuals aged 65 and above.

Additionally, 17% of children live in low-income families, and 11% of areas within the Trust's catchment area rank among the UK's 10% most deprived regions.

As the Trust aims to optimise care, it has created four models of care centred around these distinct needs.

These models of care underpin the transformation plans for a new Leighton



Transforming Care

- D&C modelling completed with transformation levers applied
- Transformation group to be established including system and PLACE partners
- Mapped existing Trust transformation plans against D&C transformation levers
- Total of 25 levers selected covering a number of areas such as;

Community falls prevention

ED attendance avoidance and frequent attenders

Care home response

Virtual wards (admission avoidance)

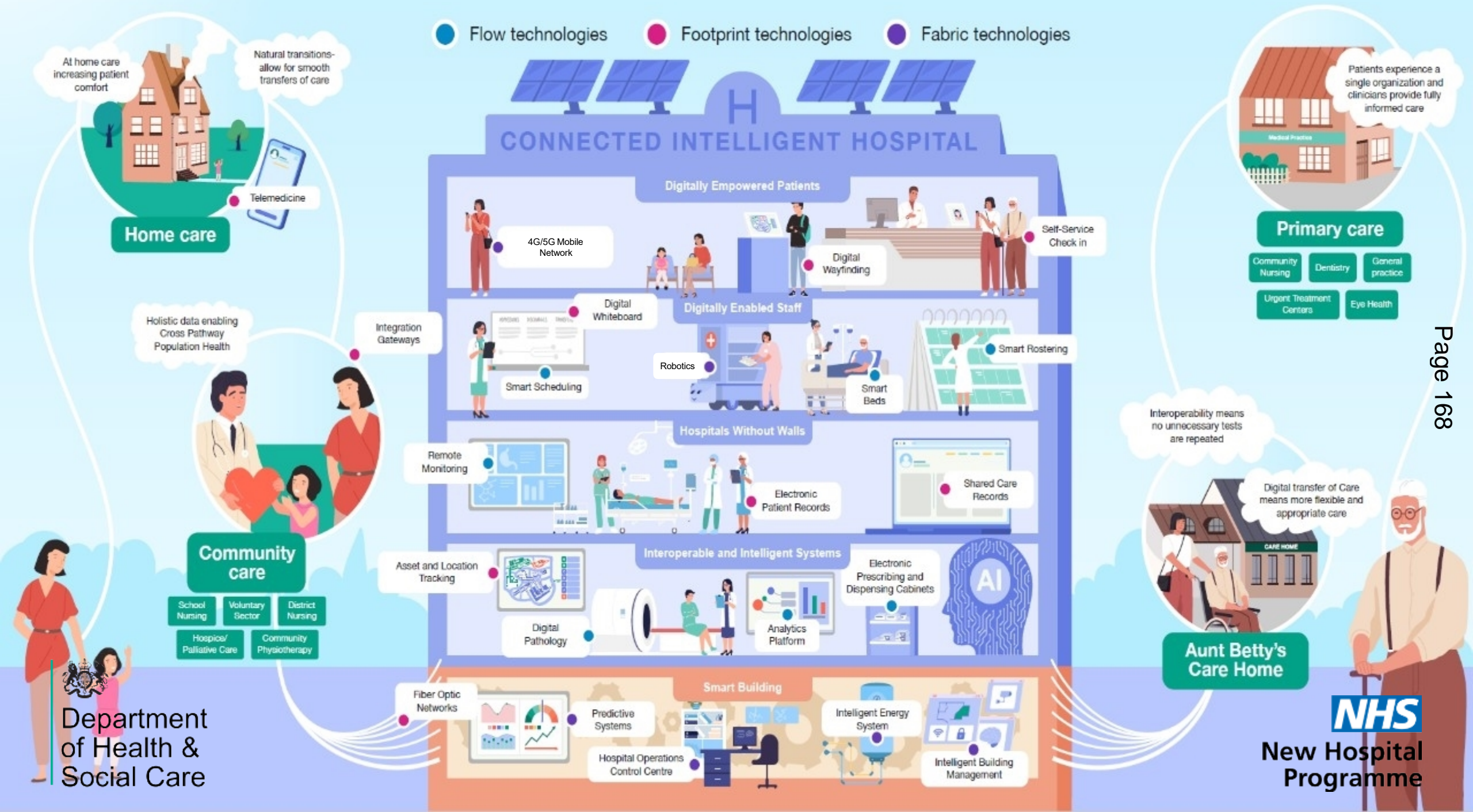
Patient Initiated Follow Up

Expansion of SDEC model

Provision of hot clinics

Early supported stroke discharge

● Flow technologies
 ● Footprint technologies
 ● Fabric technologies



Inpatients

New Leighton Hospital



Michael



Olive



Technologies

Patient
Persona

START HERE

Outpatients

New Leighton Hospital



Fiona



Sadha



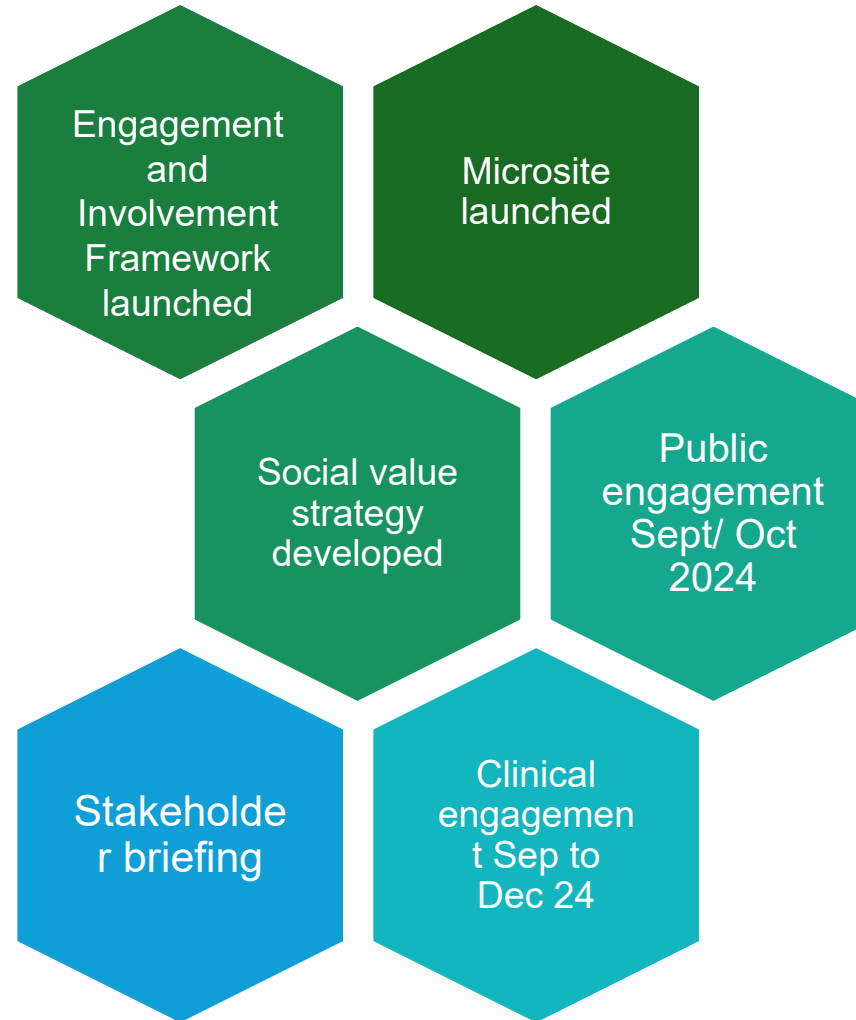
Malcolm



Wendy



Communications & engagement





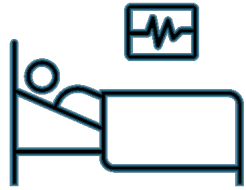
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The Design

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What is Hospital 2.0

Standardised repeatable design



- Consistent Design Across all New Hospital Construction
- Some Be-spoking for Site Specific issues example ground conditions
- Kit of Parts e.g. bathroom components, doors (27k to 700)
- Uses Modern Methods of Construction

Efficiencies

- Integrated whole systems approach enabling best-value procurement and construction
- Schedule and Time Savings as Design already Completed
- More cost certainty due to designs being re-used and less risk of design flaws.
- Allows more investment by private sector to innovate

Improvements in patient care

- Enables consistent approach to transformation across the NHS
- Encourages standard and tested patient flows due to standardised patient pathways
- Greater Staff familiarity when working out of multiple hospitals
- Allows more input from Staff, Patients and patient representative groups

Illustrative Visual of a Future Healthcare Campus





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Scrutiny Committee Work Programme 2024-25

Report Reference	Scrutiny Committee	Title	Purpose of Report	Corporate Plan Priority	Lead Officer	Exempt Item	Consultation	Equality Impact Assessment	Part of Budget and Policy Framework
December 2024									
SC/12/2023-24	12/12/24	Macclesfield District General Hospital Intrapartum Maternity Services: Post Implementation Review	To receive the findings of the post implementation review of the return of intrapartum maternity services to Macclesfield District General Hospital.	Open Fair	Director of Public Health	No	No	No	No
SC/09/24-25	12/12/24	Leighton Hospital Expansion Programme	To receive an update on the Leighton Hospital expansion programme	Open, Fair, Green	Director of Public Health	No	No	No	No
SC/13/24-25	12/12/24	Proposed changes to NHS funded gluten free prescribing	To consider whether proposals would constitute being a Substantial Development of Variation of Service (SDV) ICB Consultation underway to assess the current variation in the prescribing of gluten free products across Cheshire and Merseyside.	Open, Fair	Director of Public Health	No	No	No	No
SC/11/24-25	12/12/24	Northwest Ambulance Service	To receive an update from the NWAS in relation to response times, resource, staffing and new initiatives.	Open	Director of Public Health	No	No	No	No
March 2025									
SC/08/24-25	13/03/25	Flood Risk Management	To receive an update on flood risk management from partner agencies (LLFA, Fire Authority, UU and the Environment Agency).	Open, Green, Fair	Contract Operations Manager - Highways	No	No	No	No

Scrutiny Committee Work Programme 2024-25

Dates to be agreed									
SC/04/24-25	TBC	Review of Prevent and Channel Guidance	To receive an update on the implementation of the national Prevent and Channel Guidance.	Open, Fair	Director of Adult Social Care	No	No	No	No
SC/14/24-25	TBC	Right Care, Right Person	Following its implementation, review a year on, the impact it has had on residents and policing across the Cheshire East area.	Open, Fair	Director of Adult Social Care	No	No	No	No
SC/15/24-25	TBC	Early Release from Prison	To enable the committee to understand the impact on the Probation Service following the early release of two cohorts of Prisoners, and also the support being provided by Housing Partners and their commitment to residents in conjunction with Anti Social Behaviour.	Open, Fair	Director of Adult Social Care / Director of Public Health	No	No	No	No
SC/16/24-25	TBC	Cheshire & Merseyside Health Partnership	Following the setting of a number of objectives, how is the partnership meeting the 2 objectives of 'improving population health and health care', and 'tackling health inequalities', –have they been achieved, and what is being done to achieve them?	Open, Fair	Director Public Health	No	No	No	No
SC/17/24-25	TBC	Domestic Abuse Related Deaths and Inquests at Coroners Courts	The committee to scrutinise why it can take a significant amount of time for an inquest to be undertaken.	Open, Fair	Director of Adult Social Care	No	No	No	No

Scrutiny Committee Work Programme 2024-25

SC/10/24-25	Moved from December	Primary Care Estate Update	To receive an update on the future Primary Care Estates Programme and potential changes to services (following changes to Community Services in Poynton Sep 2023)	Open, Green, Fair	Director of Public Health	No	No	No	No
SC/06/23-24	Moved from December	Sustainable Hospital Services Programme - East Cheshire NHS Trust	To update the Committee on the proposed major service redesign at East Cheshire Trust. What services are being moved from Macclesfield what is the impact, will A&E stay open?	Open, Fair	Director of Public Health	No	No	No	No

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