Staffordshire County Council

Local Members Interest
N/A

Health and Care Overview and Scrutiny Committee Monday 03 October 2022

Clinical Policy Alignment (formerly Difficult Decisions)

Recommendation(s)

I recommend that:

a. The committee receives the Clinical Policy Alignment report relating to the involvement activities, options appraisal process and approved proposals from the Integrated Care Board.

b. The committee supports the implementation of the approved proposals from the Integrated Care Board and receives a report in 6 months that provides an update on the policy implementation and the development of an interim aligned assisted conception policy.

Report of Staffordshire and Stoke-on-Trent Integrated Care Board (ICB)

Summary

What is the Overview and Scrutiny Committee being asked to do and why?

In January 2020, the former Staffordshire and Stoke-on-Trent Clinical Commissioning Groups (CCGs) launched the Clinical Policy Alignment (formerly known as Difficult Decisions) involvement process regarding five areas of care. These are:

i. Assisted Conception
ii. Hearing Loss in Adults
iii. Male and Female Sterilisation
iv. Breast Augmentation and Reconstruction
v. Removal of excess skin following significant weight loss

It was recognised public, patient, and stakeholder involvement was required to shape proposals that will inform the future commissioning policy therefore significant involvement has taken place when reviewing this intervention.

This has included public surveys and face to face events prior to the COVID-19 pandemic for interested parties to share their views.

During the options appraisal process the former CCGs held several technical events to develop and review the proposals and two virtual public events to review and score the proposals.

This report provides assurance on the process undertaken when developing the recommended proposals which has included both clinical and public facing involvement throughout the entire process.

The Overview and Scrutiny Committee is asked to receive the update regarding this area of work and support the implementation of the proposals approved by the ICB.

Report

1. Background

1.1. Introducing excluded or restricted criteria for any intervention are difficult decisions to make, which is why the Integrated Care Board (ICB) has a clinically led prioritisation process.

1.2. Inevitably, as some interventions/services score below the threshold for investment, difficult decisions have to be made; however, using a clinically led prioritisation process based on review of available scientific evidence of effectiveness ensures that where interventions are excluded from commissioning or where appropriate, restrictive criteria are used to ensure that these interventions are reserved for those most likely to benefit.

1.3. The ICB has a process for prioritising the use of the resources available to commission healthcare across Staffordshire and Stoke-on-Trent. This is set out in the Policy on the Prioritisation of Healthcare Resources[1].

1.4. The ICB has a group known as the Clinical Priorities Advisory Group (CPAG), which is a subcommittee of the Finance and Performance Committee. The membership consists of Clinicians, Medicines

[1] The Policy on the Prioritisation of Healthcare Resources can be found on the IBC webpage Contents (icb.nhs.uk)

Optimisations Representatives and Consultant(s) in Public Health (the full terms of reference can be found in the Policy on the Prioritisation of Healthcare Resources). The group considers interventions and services which are referred from the commissioning team. This may be because there is a recognised unmet need and the ICB wishes to identify the best interventions to invest in or, as is the reason in this case, because there is a view that services need to be reviewed.

1.5. CPAG undertakes the ranking of healthcare interventions using a scoring system of criteria based on the Portsmouth Scorecard. Interventions are scored by the group against eight criteria that include:

i. Strength and quality of evidence - how well does this treatment or service work?
ii. Magnitude of health improvement benefit for the patient group or population - to what extent does this intervention increase the health gain or life expectancy for the patients/population? Appraise outcome measures e.g. improvement in functionality or of clinical markers for the condition, Quality of Life (QoL), increase in health expectancy
iii. Does the intervention prevent a condition or detect a condition which is not yet known (i.e. screening)?
iv. Supporting people with existing conditions - Does this intervention prevent or reduce complications in people with ongoing conditions?
v. How cost effective is the intervention – how much health gain compared to the cost?
vi. Does it address health inequalities?
vii. Does it deliver national and/or local requirements/targets?

1.6. CPAG does not make decisions on whether a service should or should not be commissioned. The group makes recommendations which are reviewed by the commissioning teams and taken to the ICB Board meeting for discussion and approval.

1.7. As the policy explains there is a threshold score, and interventions scoring below the threshold will not be considered by the ICB for

new investment and where already commissioned, current eligibility criteria will be subject to review.

1.8. This is particularly important given the ICB's challenged financial position and the need to balance the services that are commissioned against their statutory responsibilities to ensure that they operate within their defined budgets and achieve financial balance.

1.9. In 2018, the former six Staffordshire and Stoke-on-Trent CCGs reviewed eligibility criteria for a range of interventions/procedures with the overarching aim of aligning criteria where there were differences across the CCGs and to review any outstanding recommendations from the CCGs' CPAG. A timeline of key dates is provided in Table 1 below.

1.9.1. Table 1: Timeline of key dates

Milestone	**Date**
Six separate CCGs came together under a single management structure. We began to review policies and procedures.	July 2018
Differences in policies for procedures discovered that meant patients received different levels of access depending on where they lived ('postcode lottery').	July - December 2018
Development of case for change – including possible solutions for making policies the same across Staffordshire and Stoke-on-Trent in five clinical areas.	March 2019
Paper presented to Health and Care Overview and Scrutiny Committee outlining the planned activities within this area of work.	March 2019
Patient and public involvement about views or experiences of the five procedures. This feedback was used when developing our proposals.	January - March 2020
Briefing shared with Leek Health Overview and Scrutiny Panel outlining the planned activities within this area of work.	February 2020
Programme paused due to COVID-19 pandemic.	March 2020

Paper presented to Health and Care Overview and Scrutiny Committee specific to North Staffordshire Hearing Aid policy.	September 2020
Involvement findings from start of 2020 published.	November 2020
Stakeholder briefing shared with Health and Care Overview and Scrutiny Committee regarding changes to the eligibility criteria for moderate hearing loss within the North Staffordshire Hearing Aid policy.	February 2021
Paper presented to Health and Care Overview and Scrutiny Committee to provide an update on the involvement process.	September 2021
Involvement conversation restarted – to sense check if anything had changed due to the impact of COVID-19. Patients, public and other stakeholders were surveyed.	September 2021
Two internal technical events with clinicians, which produced a revised number of proposals.	October - December 2021
Further involvement events to confirm the desirable criteria ('impact on overall health and wellbeing' and 'clinical benefit') and their weighting; and to score proposals against desirable criteria.	March 2022
Third technical event to review the outcomes of the involvement phase. This was used to move to a final set of proposals.	May 2022
Equality Impact Assessments (EIAs) and Quality Impact Assessments) QIAs finalised for each proposal to inform governance process.	May 2022 – July 2022
Present recommendations to Finance and Performance meeting (6 September).	September 2022
Present recommendations to Quality and Safety Committee (14 September).	September 2022
Present recommendations to ICB Board meeting (22 September).	September 2022
Present recommendations to Health and Overview and Scrutiny Committees (Staffordshire and Stoke-on-Trent).	October 2022

2. Summary of the process

2.1. The Commissioning teams have previously reviewed policies and procedures to identify differences in eligibility criteria and ensure any eligibility criteria is in line with recommendations from the former CCGs' Clinical Priorities Advisory Group).

2.2. The differences were collated and reviewed on a line by-line basis with clinical leads. A large proportion of amendments were not expected to have a material impact on patient access, referral processes or treatment pathways therefore these were approved in line with the former CCGs' governance process and implemented either within the Excluded and Restricted Procedures policy or within separate commissioning policies.

2.3. For the areas identified within this work programme, the former CCGs noted that further work was required to understand any potential impact on patients prior to aligning these policies and therefore it was agreed that public, patient, and stakeholder involvement would be undertaken to shape proposals that will inform the future commissioning policy in line with the Integrated Care Board's Duty to Involve[2].

[2] The ICB has a statutory duty to involve patients and the public in the planning, development and delivery of local health services. The aim is to ensure the public receives meaningful information to make informed decisions and provide them with the mechanisms to get involved in the commissioning of local health services and influence ICB decisions at the level of participation they choose.

The public sector Equality Duty (2011) means that public bodies have to consider all individuals when carrying out their day-to-day work – in shaping policy, in delivering services and in relation to their own employees. It also requires that public bodies have due regard to the need to:

- Eliminate discrimination
- Advance equality of opportunity
- Foster good relations between different people when carrying out their activities

2.4. In January 2020 the former Staffordshire and Stoke-on-Trent CCGs began the involvement and options appraisal process for this programme of work. An overview of the phases is detailed below:

2.4.1. *Phase 1* - Winter 2019/2020 Listening exercise

2.4.2. *Phase 2a* - Autumn 2021 Public involvement refresh/sense check

2.4.3. *Phase 2b* - Winter 2021 Development of proposals

2.4.4. *Phase 2c* - Winter 2021/Spring 2022 Options appraisal

2.4.5. *Phase 3* - Summer 2022 Governance process

2.5. Phase 1 - This took place between January and March 2020, the objective was to understand service users and patient views and experiences of the interventions under consideration.

2.5.1. The feedback came back via survey and at seven deliberative events that were held in the localities. These were structured as an interactive event - *'be a commissioner'* workshops. These allowed the former CCGs to understand how patients felt services should be prioritised.

2.5.2. Two additional events were held at the request of organisations representing people who were suffering from hearing loss. The feedback from these events was considered when developing the proposals.

2.5.3. The report of findings can be found here Difficult decisions - Staffordshire and Stoke-on-Trent, Integrated Care Board (icb.nhs.uk)

2.5.4. Plans for further involvement were placed on hold when all local health services focused on managing the COVID-19 pandemic. Notification was sent to all stakeholders explaining the rationale for pausing the involvement.

2.6. Phase 2a - COVID-19 meant the NHS had to adapt and support new ways of working. Sense check involvement was undertaken with patients, stakeholders and the public in Autumn 2021 to understand any new experiences and considerations.

2.6.1. A survey was shared to understand if any new feedback needed to be considered since the pandemic. Feedback was gathered via online surveys; emails were sent to participants and community groups were contacted via social media and phone calls to encourage uptake. A phone number was provided

to enable people to respond to the survey if they did not have access to the internet.

2.6.2. The feedback was included with the feedback from the listening exercise to develop the proposals.

2.6.3. The report of findings can be found here Difficult decisions - Staffordshire and Stoke-on-Trent, Integrated Care Board (icb.nhs.uk)

2.7. Phase 2b – Autumn 2021 to Winter 2022 – Involvement to develop potential solutions for each of the clinical areas. Clinicians, Quality Leads and Locality Leads were involved with developing and evaluating the potential solutions. This included reviewing the clinical evidence base, taking the involvement feedback into consideration and oversight of finance and activity/demand.

2.7.1. On 19 October 2021, the former CCGs convened a technical event, with clinicians, quality leads, project managers and the executive leads to develop and critique each of the proposals.

2.7.2. A second technical event was held on 14 December 2021 to confirm the proposals for each of the interventions.

2.8. Phase 2c - Spring 2022 – Involvement to evaluate the potential solutions for each of the clinical areas.

2.8.1. Interested stakeholders, patients and members of the public were invited to an interactive workshop to inform the desirable criteria and weighting that should be applied against each proposal.

2.8.2. During a second workshop the public, patients and wider stakeholders worked together to evaluate each of the proposals against the desirable criteria through a scoring process.

2.8.3. The report of findings can be found here Difficult decisions - Staffordshire and Stoke-on-Trent, Integrated Care Board (icb.nhs.uk)

2.9. Phase 3 – Spring 2022 – Receive the report of findings from the workshops and determine any further involvement that is required.

2.9.1. A third technical event was held on 17 May 2022 to share the feedback from the workshops (phase 2c) and provide an update on any quality and equality impacts identified.

2.9.2. The group were asked to review the proposals in light of the information presented and provide input on whether any of the proposals may need amending or removing from the short-list.

2.9.3. Following discussion at the technical group, a number of unviable proposals were removed from the shortlist which resulted in proposal per clinical area. These are summarised in section 3.

2.10. We have worked closely with the Consultation Institute, as experts in consultation and involvement activity, throughout this process to ensure a robust and transparent process.

2.11. Both quality and equality impact assessments have been completed for each of the proposals. These recognised the positive impact of aligning criteria across the country. Where any negative impact was noted, adequate mitigations were identified and all assessments were approved. Further detail on the individual impact assessments can be found in Appendices A-E.

2.12. No material workforce impact was highlighted during the options appraisal process or within either the quality or equality impact assessments

3. Summary of approved proposals

3.1. The proposals for each of the interventions were refined through the technical events and options appraisal process. One proposal for each clinical intervention was presented the ICB Board meeting and approved.

3.2. Table 2 outlines the proposals and the impact on each of the geographical areas across Staffordshire and Stoke-on-Trent.

3.2.1. Table 2: Proposals for the interventions

Procedure / Proposal	Impact
Hearing loss in adults: *To commission hearing aids with no eligibility criteria.*	• Removal of current restrictions for mild hearing loss in North Staffordshire. • 343 (estimated) additional hearing aid fittings in North

	Staffordshire. No change in other areas.
Removal of excess skin following significant weight loss: *Abdominoplasty (tummy tucks)/ apronectomy (excess skin removal in lower abdomen) and body contouring (removing excess fat and skin) will not be commissioned.*	• A reduced offer for Stoke-on-Trent, South East Staffordshire and Seisdon Peninsular, Cannock Chase, Stafford and Surrounds, and East Staffordshire geographical areas where abdominoplasty/apronectomy is currently commissioned against criteria • A reduced offer within Stoke-on-Trent where body contouring is currently commissioned against criteria. Based on 2018/19 data the following numbers of patients could be impacted; -3 East Staffordshire, -2 South East Staffordshire and Seisdon Peninsular, -3 Stafford and Surrounds, -5 Stoke-on-Trent
Breast augmentation (enlargement) and reconstruction: *Will be routinely funded following mastectomies (breast removal) carried out due to suspected or proven cancer OR following double mastectomies for cancer prevention in high-risk cases.*	• An improvement on the policy within South East Staffordshire and Seisdon Peninsular, Cannock Chase, Stafford and Surrounds, and East Staffordshire where post-mastectomy reconstruction is only offered in the affected breast. • A reduced offer within North Staffordshire and Stoke-on-Trent where reconstruction due to burns is currently offered as well as for post-mastectomy. A reduced offer in Stoke-on-Trent where breast augmentation for

	developmental failure and significant asymmetry is currently commissioned against criteria. Reduction of approximately 14 non-cancer breast augmentations per annum in Stoke-on-Trent.
Male and female sterilisation: *Female sterilisation will be routinely funded for contraception when unable to tolerate other contraceptives OR absolute clinical contraindication (not suitable) to pregnancy.* *No amendment to male sterilisation is proposed.*	• Equal impact across Staffordshire and Stoke-on-Trent as currently no criteria in place. Potential reduction in activity. • **Note:** Vasectomies (male sterilisation) in an acute (hospital) setting will not be undertaken unless there is a clear clinical indication. Potential small decrease in surgical sterilisations (female) however this cannot be quantified based on available data
Assisted conception: *Develop an interim aligned policy*	• Following the publication of the national Women's Health Strategy on 20 July 2022, an aligned commissioning policy will be developed whilst the ICB awaits further guidance. Impact on activity unknown at this stage.

3.3. Further detail on each of the clinical areas is provided below in Appendices A-E.

4. Activity Implications

4.1. A review of previous activity was undertaken to understand the implications of the proposals.

4.2. Table 3 below provides an outline of the potential impact on activity within an acute (hospital) setting.

4.2.1.Table 3: Acute activity implications

	17/18 activity	18/19 activity	19/20 activity
Abdominoplasty	-8	-9	-13
Body Contouring	0	-4	0
Breast Augmentation and Reconstruction	-11	-11	-20

4.3. The above table outlines the reductions in activity within the ICB as a result of the approved proposals in these areas.

4.4. Table 4 below provides an outline of the impact on activity for the hearing loss in adults proposal.

4.4.1.Table 4: activity implications – hearing loss in adults

	Feb 2021 – Jan 2022 activity
Hearing Loss	343

4.5. The impact identified for hearing loss is based on the number of patients who did not qualify for hearing aids following assessment during the period February 2021 - January 2022 within North Staffordshire (data received through provider reports).

4.6. No impact is identified within Stoke-on-Trent, Cannock Chase, East Staffordshire, South East Staffordshire and Seisdon Peninsula and Stafford and Surrounds as these areas currently commission hearing aids in line with the approved proposal.

4.7. Table 5 below provides an outline of female sterilisations that are undertaken for contraceptive purposes.

4.7.1.Table 5: Female sterilisations activity

	17/18 Activity	18/19 Activity	19/20 Activity
Female Sterilisations: Acute	119	159	122

4.8. The introduction of eligibility criteria for female sterilisations may reduce activity however the level of reduction cannot be quantified from the data that is available.

4.9. Due to the publication of the Women's Health Strategy and the potential for further guidance on assisted conception services, an interim aligned commissioning policy within this area will be developed in this area. As a result, the activity implications are currently unknown within this area but will be taken through the ICBs governance process once the policy is developed.

5. Governance

5.1. An update on the work completed to date with the recommended proposals was presented to the ICB's Finance and Performance Committee on 6 September 2022. The committee was assured that a robust process had been followed through the work programme and approved the recommendations within the paper.

5.2. An update on the work completed to date with the recommended proposals presented to the ICB's System Quality and Safety Committee on 14 September 2022. The committee was assured that a robust process had been followed through the work programme and approved the recommendations within the paper.

5.3. An update on the work completed to date with the recommended proposals was presented to the Integrated Care Board Meeting in public on 22 September 2022. The Board was assured that a robust process had been followed through the work programme and approved the recommended proposals for implementation.

6. Implementation

6.1. There is some variation in the implementation of the proposals for each clinical area due to the differences in contractual arrangements. These are outlined in Table 6 below:

6.1.1. Table 6: Implementation by clinical area

Clinical Area	Implementation Plan
Assisted Conception	Develop an interim aligned commissioning policy. Timelines specific to this area is included in Appendix A, Table A3

Hearing Loss in Adults	Removal of North Staffordshire hearing aid policy. Implementation following one month notice to providers.
Male and Female sterilisation	Eligibility criteria to be included within the ICB Excluded and Restricted Procedures Policy. Implementation following one month notice to providers.
Breast augmentation and Reconstruction	Eligibility criteria to be included within the ICB Excluded and Restricted Procedures Policy. Implementation following one month notice to providers.
Removal of excess skin following significant weight loss	Eligibility criteria to be included within the ICB Excluded and Restricted Procedures Policy. Implementation following one month notice to providers.

6.2. The ICB recognises that there may be patients on a waiting list who meet the current eligibility criteria that is in place. The ICB will honour treatment for patients who have been added to a waiting list prior to the implementation of revised eligibility criteria.

6.3. Changes to policy will be clearly communicated to providers of services at all tiers of care (e.g. Primary, Community, Acute).

6.4. Updated policies will be uploaded to the ICB webpage, accessible to all, following implementation.

6.5. Patient advice on eligibility criteria can be accessed via the ICB's Patient Advice and Liaison Service.

Link to Strategic Plan

On 1 July 2022, Integrated Care Boards (ICBs) replaced clinical commissioning groups (CCGs), becoming the statutory organisations that bring the NHS together locally to improve population health and establish shared strategic priorities within the NHS, connecting to partnerships across the Integrated Care System (ICS).

Working with partners in Staffordshire and Stoke-on-Trent, the ICS has agreed on an ambitious vision which is 'working with you to make Staffordshire and Stoke-on-Trent the healthiest place to live and work.' Their purpose is as follows:

• If you live in Staffordshire or Stoke-on-Trent, your children will have the best possible start in life and will start school ready to learn
• Through local services, we will help you to live independently and stay well for longer Page 12
• When you need help, you will receive joined-up, timely and accessible care, which will be the best that we can provide.

Link to Other Overview and Scrutiny Activity

Since 2018, the ICB has attended committee meetings to update on progress against the transformation programme. Today's meeting is a continuation of this ongoing conversation.

Previous updates were under the programme name of Difficult Decisions, however within the ICB this work is now known as Clinical Policy Alignment. A list of key dates when updates were shared with the committee is provided below:

Paper presented to Health and Care Overview and Scrutiny Committee - 19 March 2019.

Briefing shared with Leek Health Overview and Scrutiny Panel – February 2020.

Paper presented to Health and Care Overview and Scrutiny Committee 14 September 2020 (specific to North Staffordshire Hearing Aid policy)

Stakeholder briefing shared with Health and Care Overview and Scrutiny Committee – February 2021 (specific to North Staffordshire Hearing Aid policy)

Paper presented to Health and Care Overview and Scrutiny Committee 20 September 2021

Community Impact

A quality impact assessment (QIA) has been completed for each of the recommended and approved proposals. Overall, the panel recognised the positive impact of aligning criteria and eliminating variation across the

county. The panel noted the potential mental health impact on some patients if they are no longer able to access certain procedures. Risk scores were increased to to reflect the comments from the panel regarding the mental health impact, adequate mitigations were identified, and all assessments were approved by the QIA panel on 29 June 2022. Further detail on the individual impact assessments can be found in Appendices A-E.

An equality impact assessment (EIA) was completed for each of the recommended and approved proposals. The assessments recognised the positive impact of aligning criteria across the county. Where any negative impact was noted, adequate mitigations were identified and all assessments were approved. Further detail on the individual impact assessments can be found in Appendices A-E

No material workforce impact was highlighted during the options appraisal process or within either the quality or equality impact assessments for the recommended and approved proposals.

List of Background Documents/Appendices:

Appendix A: Assisted Conception
Appendix B: Hearing Loss in Adults
Appendix C: Male and Female Sterilisation
Appendix D: Breast Augmentation and Reconstruction
Appendix E: Removal of excess skin following significant weight loss

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Appendix A: Assisted Conception

1. Rationale for review

1.1. There are different policies in place across Staffordshire and Stoke-on-Trent meaning patients have varying access to elective treatments/procedures depending on where they live. Table A1 below provides a high-level summary of the differences in policy.

1.1.1. Table A1: Differences in assisted conception services eligibility criteria

	North Staffordshire	Cannock Chase, East Staffordshire, South East Staffordshire and Seisdon Peninsula and Stafford and Surrounds	Stoke-on-Trent
Number of cycles	1 cycle consisting of 1 fresh embryo transfer only	1 Cycle and 1 fresh OR frozen embryo transfer	2 Cycles to include one fresh transfer and up to 3 frozen transfers per cycle
Age	Women aged 23-35 Male under 55	Women aged 23-39 No upper age limit for men	Women aged 23-39 No upper age limit for men
IUI	IUI Commissioned	IUI Not commissioned	IUI Not Commissioned
Investigations	Investigations not commissioned if patients do not meet eligibility criteria for IVF	No restrictions on investigations	No restrictions on investigations

Minimum ovarian reserve	No Criteria	It is proposed that a threshold of AMH >3 will be applied to all women 35 years or over for access to IVF treatment.	No Criteria
Donor Eggs	Not funded	Donor eggs commissioned if Premature ovarian failure, Gonadal dysgenesis including Turner syndrome, Bilateral oophorecto my, Ovarian failure following chemotherapy or radiotherapy	Not funded

1.2. Assisted conception was reviewed by the former CCGs CPAG where it scored below the threshold for commissioning. This means that if the ICB did not currently commission this, it would not be recommended for investment.

1.3. While the number of patients accessing assisted conception services is relatively low, we know that infertility is an area of considerable concern to the people affected. Table A2 below provides previous years activity.

1.3.1. Table A2: Assisted conception activity across Staffordshire and Stoke-on-Trent

	2018/19	2019/20
Activity (cycles)	216	169
Total cost	£875,952	£710,162

1.4. Assisted conception services are provided by specialist fertility providers with set fees per cycles which may include ovulation stimulation, egg retrieval, fertilisation and embryo transfer dependent on the individuals' clinical requirements.

1.5. Total activity and spend for 2018/19 and 2019/20 is included in the table above. Data for 2020/21 and 2021/22 has been excluded for evaluation purposes as COVID-19 led to restrictions in appointments that artificially suppressed activity.

2. Themes from involvement activities

2.1. Respondents raised concerns about the lack of access to treatment and the cost of self-funding.

2.2. The negative impact of infertility and unsuccessful treatment on patients' mental health, wellbeing and relationships were also highlighted.

2.3. Respondents tended to be in support of funding this service, but there were also suggestions to restrict the number of cycles (e.g. two or three) and who is eligible (e.g. prioritise those without children).

2.4. The Royal British Legion highlighted that Armed Forces couples' entitlement to three rounds of IVF should not be diminished.

3. Women's Health Strategy

3.1. Whilst developing the proposals for assisted conception services, the Women's Health Strategy was published which has indicated that a review of fertility provision across the UK will be undertaken

3.2. The strategy does not give an indication of whether ICBs will be expected to implement mandated access criteria however it is clear that the intention is to review geographic variation, address inequities of provision and remove any non-clinical criteria that is currently in place (for example, that people must not have children from previous relationships)

3.3. The strategy does not provide an estimated timeline for any policy mandates however a review of current NICE guidance has been initiated with expected publication in 2024.

3.4. In light of the publication of the strategy, a meeting was convened to consider the impact of this on the proposals for assisted

conception and whether this should be separated from the wider clinical policy alignment programme whilst awaiting further guidance.

3.5. The meeting was chaired by the Chief Medical Officer and included the following attendees:
3.5.1. ICB Clinical Lead Partnerships and Engagement
3.5.2. ICB Medical Director
3.5.3. Head of Transformation
3.5.4. Director of Communications and Corporate Services
3.5.5. Director of Corporate Governance
3.5.6. Senior IFR/Improvement Lead
3.5.7. IFR/Commissioning Support Manager

3.6. The meeting agreed that the ICB could not continue with proposals to reduce to zero cycles of IVF at this time and assisted conception should be separated from the wider clinical policy alignment programme.

3.7. The meeting highlighted that assisted conception policies are currently not aligned and this would need to be addressed to ensure there is a single policy across the ICB whilst waiting for further guidance.

3.8. The meeting recognised that, due to the differences in current policies, an aligned policy would inevitably result in levelling down in some areas of provision and a levelling up in other areas of provision.

4. Approved Proposal

4.1. Separate assisted conception from the wider clinical policy alignment programme and pause further work on proposals until further guidance is released.

4.2. Instruct the Chief Medical Officer to ensure that an interim aligned assisted conception policy is developed for implementation whilst the ICB awaits further directives following the national review of service provision.

4.3. Table A3 below outlines the process that will be undertaken to develop and interim aligned policy with indicative timescales.

4.3.1. Table A3: Assisted Conception policy alignment

Activity	Date
Clinical and technical working group(s) to review policy differences and recommend aligned criteria	September – October 2022
Draft aligned policy	October – November 2022
Complete quality and equality impact assessments	December 2022 – January 2023
Present aligned policy to F&P for approval	February 2023
Present aligned policy to ICB Board meeting for approval	February 2023
Present policy to Staffordshire and Stok-on-Trent HOSCs	March 2023
1 month notice of policy change to providers	April 2023
Policy implementation (if further public involvement is not required)	May 2023

4.4. To note, these are indicative timelines that may change if further public involvement is required.

Appendix B: Hearing Loss in Adults

1. Rationale for review

1.1. There are different policies in place across Staffordshire and Stoke-on-Trent meaning patients have varying access to this intervention depending on where they live. Table B1 below outlines the policy differences.

1.1.1. Table B1: Difference in hearing aid eligibility criteria.

North Staffordshire	Cannock Chase, East Staffordshire, South East Staffordshire and Seisdon Peninsula, Stafford and Surrounds and Stoke-on-Trent
Not routinely funded for patients diagnosed with 'mild' hearing loss, unless the patient: • is aged under 18 or has had hearing loss since childhood • has a confirmed diagnosis of dementia, a learning disability, an auditory processing disorder or a severe multiple sensory disability • has tinnitus • has sudden onset hearing loss • has multiple severe physical disabilities.	Commissioned for all patients with a hearing loss greater than 25 decibels (diagnosed through an audiogram or by an audiologist).

1.2. Hearing aids for mild hearing loss was reviewed by the former CCGs CPAG. This did not score below the threshold but in line with current commissioning margins in the policy, the recommendation was to commission with criteria. This means that if the ICB did not

currently commission this, the implementation would include clinical eligibility criteria.

1.3. We know people have different communication needs and that their hearing loss may not affect them in the same way as it affects someone else

1.4. The NICE guidance is clear – communication difficulties should not be judged by measuring only hearing thresholds (such as an audiogram)

1.5. Around 1 in 6 adults in England have some form of hearing loss, and as the number of older people increases, demand for hearing aids is expected to rise. Table B2 below shows previous years activity.

1.5.1. Table B2: Hearing aid activity across Staffordshire and Stoke-on-Trent

	2018/19	2019/20
Activity (hearing aid fittings)	13,502	12,400
Total cost	£3,412,847	£3,621,722

1.6. Hearing aids services are provided by community and acute providers through any qualified provider contracts with set tariffs which may include initial assessment, fitting, six-week review, aftercare and annual review.

1.7. Total activity and spend for 2018/19 and 2019/20 is included in the table above. Data for 2020/21 and 2021/22 has been excluded for evaluation purposes as COVID-19 led to restrictions in appointments that artificially suppressed activity.

2. Themes from involvement activities

2.1. The key themes raised tended to be in support of funding hearing aids for all patients.

2.2. Respondents noted the importance of hearing aids in improving hearing, patients' social life, wellbeing and quality of life including

the potential of untreated hearing loss resulting in adverse patient outcomes.

2.3. The need to improve follow-up care, such as access to batteries and checking patients are using their aids, was also highlighted.

2.4. Respondents also raised concerns over the lack of access to hearing aids.

3. Recommendations from the technical group

3.1. A technical event was held on 17 May 2022 to share the feedback from the deliberative events and provide an update on any quality and equality impacts identified.

3.2. The group were asked to review the proposals in light of the information presented and provide input on whether any of the proposals may need amending or removing from the short-list.

3.3. The group considered the proposal to commission this intervention with eligibility criteria.

3.4. The group stated that assessing the benefit of hearing aids in individuals is difficult to predict via a functional impact assessment in order to determine eligibility and the most effective way to assess benefit is once hearing aids are fitted and patients are supported to use them.

3.5. In addition, the group noted that the recommended functional impact assessment (HHIE-s) is a subjective tool that may be applied inconsistently and create inequalities amongst those who may benefit from hearing aids.

3.6. Whilst the group recognised the recommendation from CPAG to implement eligibility criteria, the consensus of the group was that the points noted above were sufficient to remove the proposal to commission in line with the CPAG recommendation and allow assessment of benefit to be undertaken during patients 6-week review following initial assessment and fitting of hearing aid(s)

3.7. The recommended proposal from the technical group was to commission hearing aids with no eligibility criteria and remove the current restrictions within North Staffordshire.

4. Impact assessments

4.1. A quality impact assessment (QIA) has been completed for the recommended and approved proposal. The assessment was presented to the QIA panel on 29 June 2022 and approved.

4.2. An Equality impact assessment has been completed for recommended and approved proposal which was approved on 20 July 2022.

4.3. Both assessments noted that the proposal improves access for patients with mild hearing loss within North Staffordshire. The proposal would also remove current inequities in access and improve patient experience.

4.4. No material workforce impact was highlighted during the options appraisal process or within either the quality or equality impact assessments

Appendix C: Male and Female Sterilisation

1. Rationale for review

1.1. There are no restrictions currently in place for these procedures other than the requirement to only undertake male sterilisations (vasectomies) within an acute setting if there is a clear clinical indication for doing so.

1.2. Male and Female sterilisation for contraceptive purposes was reviewed by the former CCGs CPAG where it scored below the threshold for commissioning. This means that if the ICB did not currently commission this, it would not be recommended for investment.

1.3. There are various forms of contraceptive available to patients, both surgical and non-surgical methods and it is estimated that in the UK 75% of women aged 16-49 use some form of contraceptive. Table C1 below provides previous years activity for sterilisation procedures.

1.3.1. Table C1: Male and Female sterilisation activity across Staffordshire and Stoke-on-Trent

	2018/19	2019/20
Female Sterilisation activity	370	354
Total Cost	£608,031	£693,433
Male sterilisation activity	1360	1309
Total cost	£294,976	£330,433

1.4. Female sterilisations are elective inpatient procedures undertaken by acute providers within block contracts. A small number of male sterilisations are undertaken in an acute setting but only where there is a clinical indication that means these cannot be undertaken within a community setting.

1.5. Male sterilisations are predominantly undertaken within a primary care or community setting with specialist clinicians through a service level agreement.

1.6. Total activity and spend for 2018/19 and 2019/20 is included in the table above. Data for 2020/21 and 2021/22 has been excluded for evaluation purposes as COVID-19 led to restrictions in appointments that artificially suppressed activity.

2. Themes from involvement activities

2.1. Respondents commented that these procedures should be available to anyone who wishes to be sterilised.

2.2. Respondents noted that not offering these procedures may have a financial impact on the NHS in the long-term e.g. maternity care and terminations.

2.3. Respondents also stated that there may be potential adverse impact of pregnancy on patients and this needs to be taken into consideration.

3. Recommendations from the technical group

3.1. A technical event was held on 17 May 2022 to share the feedback from the deliberative events and provide an update on any quality and equality impacts identified.

3.2. The group were asked to review the proposals in light of the information presented and provide input on whether any of the proposals may need amending or removing from the short-list.

3.3. The group considered the proposal to not commission these procedures for contraceptive purposes. As previously noted, sterilisations undertaken for medical purposes such as ectopic pregnancy were not within scope of discussions as this was outside of the CPAG review.

3.4. Under this proposal, patients are likely to access long-acting reversible contraceptives as an alternative. This will convert one off procedures into a requirement for ongoing and long-term GP appointments. This equates to an additional 5,661 appointments within year one and as the case load grows there is a potential for up to 34,846 appointments by year 5 resulting in a significant impact on Primary Care workforce and capacity.

3.5. It was also noted that as this removes a significant proportion of community vasectomy activity, providers may not be able to maintain their competency standards and this could lead to the cessation of these services.

3.6. In addition to the workforce impact the group also noted this proposal may create an inequity of choice for males who do not have an alternative choice of long-term contraception.

3.7. The group also discussed the proposal to introduce eligibility criteria for male and female sterilisations where patients may access these interventions if the female has an absolute contraindication to pregnancy or cannot tolerate other forms of long-acting reversible contraception.

3.8. The group recognised that whilst this proposal reduced the workforce impact when compared to the previous proposal, there may still be a large cohort of patients transferring to long-acting reversible contraceptives that impacts primary care capacity and potentially destabilises community-based vasectomy services.

3.9. The group also stated that this does not address the inequity impact and may create further inequities due to the proposal requiring patients to be in a relationship in order to access this intervention (i.e. vasectomies would only be undertaken if the patient's partner cannot tolerate alternative long-acting reversible contraceptives or has an absolute contraindication to pregnancy.)

3.10. Whilst the group recognised the recommendation from CPAG to implement eligibility criteria, the consensus of the group was that the points noted above were sufficient to remove previous proposals from the shortlist and an alternative proposal was discussed.

3.11. The recommended proposal from the technical group was to apply eligibility criteria to female sterilisations only. This ensures females can access sterilisation where there is no viable alternative whilst ensuring patients are fully counselled on their alternatives prior to undergoing invasive surgery. This also minimises the workforce impact and ensures equity of choice for males.

4. Impact assessments

4.1. A quality impact assessment (QIA) has been completed for the recommended and approved proposal. The assessment was presented to the QIA panel on 29 June 2022 and approved.

4.2. An Equality impact assessment has been completed for the recommended and approved proposal which was approved on 20 July 2022.

4.3. Both assessments noted the significant reduction in workforce and equity impact within this proposal. It was recognised that this proposal ensures invasive female sterilisations are only undertaken following full exploration of alternative methods of contraception and consideration of the risks associated with invasive surgery.

4.4. No material workforce impact was highlighted during the options appraisal process or within either the quality or equality impact assessments

Appendix D: Breast augmentation and Reconstruction

1. Rationale for review

1.1. There are different policies in place across Staffordshire and Stoke-on-Trent meaning patients have varying access to this intervention depending on where they live. Table D1 below outlines the policy differences.

1.1.1. Table D1: Difference in eligibility criteria for breast augmentation and reconstruction.

North Staffordshire	Cannock Chase, East Staffordshire, South East Staffordshire and Seisdon Peninsula and Stafford and Surrounds	Stoke-on-Trent
Commissioned following mastectomy, post burns or asymmetry following prophylactic bilateral mastectomy for cancer prevention in high-risk cases.	Not routinely commissioned for small breasts, congenital absence of breast or breast asymmetry. This procedure will ONLY be routinely commissioned in the following circumstances: - As reconstructive surgery following mastectomy for either suspected or proven malignancy *Treatment of the unaffected breast following cancer surgery shall not be routinely commissioned	Will be routinely funded under the following circumstances: - Developmental failure resulting in unilateral or bilateral absence of breast tissue/asymmetry (congenital amastia) OR - Significant degree of asymmetry of breast shape and/or volume at least a difference of 2 cup sizes as a result of: Previous mastectomy or excision breast

		surgery for cancer/lumpectomy or following prophylactic bilateral mastectomy for cancer prevention in high risk cases OR Trauma to the breast – post burns. Breast asymmetry, endocrine abnormalities, developmental asymmetry The following criteria must be met for surgery to be routinely funded: - Patient must have a BMI within the range of 18kg/m2 to 25kg/m2 AND - Minimum age for surgery is 18 of age and evidence that pubertal growth of breasts has ceased

1.2. Breast Reconstruction and Augmentation for cancer and non-cancer indications was reviewed by the former CCGs CPAG where it scored below the threshold for commissioning. This means that if the ICB

did not currently commission this, it would not be recommended for investment.

1.3. Although the number of people affected by a potential change in policy is relatively low, we know that this is an area of considerable concern to those people who are affected by it.

1.4. Breast cancer is diagnosed in approximately 55,000 patients in the UK every year. The incidence of breast cancer in western Europe is 89.7 per 100,000 women. Table D2 below provides previous years activity

1.4.1. Table D2: Breast reconstruction and augmentation activity across Staffordshire and Stoke-on-Trent

	2017/18	2018/19	2019/20
Activity	171	173	158
Total cost	£518,734	£540,674	£516,020

1.5. Within Stoke-on-Trent it is estimated that on average across the 3 years, 14 of the 30 procedures undertaken were for non- cancer indications.

1.6. Breast Augmentations and Reconstructions are elective inpatient procedures undertaken by acute providers within block contracts.

1.7. Total activity and spend for 2018/19 and 2019/20 is included in the table above. Data for 2020/21 and 2021/22 has been excluded for evaluation purposes as COVID-19 led to restrictions in appointments that artificially suppressed activity.

2. Themes from involvement activities

2.1. Service users highlighted the impact of the procedure on reducing discomfort and improving quality of life.

2.2. Key themes raised were that reconstructive surgery should be available for breast cancer or breast surgery patients. However, respondents were clear that the procedure should not be funded for cosmetic reasons.

2.3. The impact of this procedure on patient wellbeing, quality of life and relationships was also highlighted.

3. Recommendations from the technical group

3.1. A technical event was held on 17 May 2022 to share the feedback from the deliberative events and provide an update on any quality and equality impacts identified.

3.2. The group were asked to review the proposals in light of the information presented and provide input on whether any of the proposals may need amending or removing from the short-list.

3.3. The group considered the proposal to not routinely commission this intervention for any indication.

3.4. The group stated that this would have a significant impact on cancer patients as this proposal removes access to all post mastectomy breast reconstructions and could be seen as a disruption to the cancer pathway.

3.5. The group also stated that removing post cancer breast reconstructions would create inequity as other post cancer prosthetics are commissioned e.g. testicular prosthesis.

3.6. Non cancer indications for breast augmentation such as congenital absence of breast and significant asymmetry was discussed as these procedures are currently offered within Stoke-on-Trent.

3.7. Whilst the group recognised the potential mental health impact for those affected if this access is removed, it was noted that Stoke-on-Trent is currently an outlier with this criterion and no adverse impacts have been noted within the other geographical areas who currently do not offer breast reconstruction and augmentation for non-cancer indications.

3.8. Within North Staffordshire and Stoke-on-Trent breast reconstruction is offered post burns but not for other types of trauma. The group agreed that it was inequitable to offer treatment for one type of trauma and not others but there was insufficient evidence to consider expanding the criteria to all types of traumas. The group

did however note that in the case of significant trauma, this would be addressed within an emergency setting immediately following the trauma. The group also noted that no adverse impacts have been identified within the south of the country where this procedure is not offered post-burns.

3.9. Whilst the group recognised the recommendation from CPAG to not commission the procedures for any indication the consensus of the group was that the points noted above were sufficient to commission the intervention for cancer related indications but remove proposals relating to non-cancer indications.

3.10. The recommended proposal from the technical group was to commission breast reconstruction/augmentation following mastectomy following mastectomies carried out due to suspected or proven cancer OR following double mastectomies for cancer prevention in high-risk cases

4. Impact assessments

4.1. A quality impact assessment (QIA) has been completed for the recommended and approved proposal. The assessment was presented to the QIA panel on 29 June 2022 and approved.

4.2. An Equality impact assessment has been completed for recommended and approved proposal which was approved on 20 July 2022.

4.3. Both assessments noted the potential mental health impact on patients who were not able to access this procedure however it was recognised that there are mental health services in place to support these patients. Emphasis was placed on the importance of good communication when amending policy to confirm what is commissioned and ensure patient expectations are not raised during their clinical pathway. It was also noted signposting to relevant support services is essential where adverse impacts on mental health are identified.

4.4. No material workforce impact was highlighted during the options appraisal process or within either the quality or equality impact assessments

Appendix E: Removal of excess skin following significant weight loss

1. Rationale for review

1.1. There are different policies in place across Staffordshire and Stoke-on-Trent meaning patients have varying access to these procedures depending on where they live. Tables E1 and E2 below outlines the policy differences.

1.1.1. Table E1: Difference in eligibility criteria for abdominoplasty/apronectomy procedures

North Staffordshire	Cannock Chase, East Staffordshire, South East Staffordshire and Seisdon Peninsula and Stafford and Surrounds	Stoke-on-Trent
Not routinely commissioned	This procedure will ONLY be routinely commissioned in the following circumstances: - Weight loss of at least 10 points on BMI AND - An abdominoplasty /apronectomy has not already been performed AND - Presence of a large abdominal fold hanging below the level of the mons pubis AND - Documented evidence of clinical pathology due to the excess overlying skin e.g. recurrent infections, intertrigo which has led to ulceration requiring	Will be considered providing that ALL of the following criteria are met: - Documented evidence of clinical pathology due to the excess overlying skin e.g. recurrent infections, intertrigo which has led to ulceration requiring repeated courses of treatment for a minimum period of one year or disability resulting in severe restrictions in activities of daily living AND - The patients BMI before weight loss must have been no

	repeated courses of treatment with anti-fungal and other topical skin products for a minimum period of one year or disability resulting in severe restrictions in activities of daily living AND - The patients current BMI must be between 18kg/m2 and 25kg/m2 AND - The patients weight must have been stable and within this range for a minimum of 1 year as measured and formally recorded by an NHS service OR - If this weight range is not possible due to the weight of excess skin, the patient must have lost 50% of their excess weight and significant functional disturbance is also evident and the clinician must confirm that no further reduction in BMI will be possible without the removal of excess skin.	less than 40kg/m2 AND - The patients current BMI must be between 18kg/m2 and 25kg/m2 and has been within this range for a minimum of 1 year as measured and recorded by the NHS. If this is not possible due to the weight of excess skin, the patient must have lost 50% of their excess weight and the clinician must confirm that no further reduction in BMI will be possible without the removal of excess skin. AND - The patient's weight must have been stable and within this range for a minimum of 1 year as measured and recorded by the NHS AND - An abdominoplasty/ apronectomy has not already been performed

1.1.2. Table E2: Difference in eligibility criteria for body contouring procedures

North Staffordshire, Cannock Chase, East Staffordshire, South East Staffordshire and Seisdon Peninsula and Stafford and Surrounds	Stoke-on-Trent
Not routine commissioned	Will be commissioned where the criteria for abdominoplasty/apronectomy is met

1.2. Procedures to remove excess skin was reviewed by the former CCGs CPAG where it scored below the threshold for commissioning. This means that if the ICB did not currently commission this, it would not be recommended for investment.

1.3. While the number of patients receiving these surgeries is relatively low, obesity rates are rising, so demand for treatments like these is expected to rise**.** Table E3 below provides previous years activity.

1.3.1. Table E3: Excess skin removal activity across Staffordshire and Stoke-on-Trent

	2017/18	2018/19	2019/20
Activity	8	13	13
Total cost	£16,478	£23,615	£28,494

1.4. Surgeries to remove excess skin are elective inpatient procedures undertaken by acute providers within block contracts.

1.5. Total activity and spend for 2018/19 and 2019/20 is included in the table above. Data for 2020/21 and 2021/22 has been excluded for evaluation purposes as COVID-19 led to restrictions in appointments that artificially suppressed activity

2. Themes from involvement activities

2.1. There were mixed views on whether the removal of excess skin should be funded. Respondents stated that the excess skin does impact on patients' health and wellbeing such as sores, itching and may impact on patients' mental health.

2.2. Respondents commented that removal of excess skin should be funded to support patients who have made significant lifestyle changes.

2.3. Respondents also stated that restricting access to this procedure may discourage patients from losing weight. This, along with adverse impact in patients from not funding the treatment, may cost the NHS in the long-term.

3. Recommendations from the technical group

3.1. A technical event was held on 17 May 2022 to share the feedback from the deliberative events and provide an update on any quality and equality impacts identified.

3.2. The group were asked to review the proposals in light of the information presented and provide input on whether any of the proposals may need amending or removing from the short-list.

3.3. The group considered the proposal to not routinely commission these interventions.

3.4. Whilst the group recognised the potential mental health impact for those affected if this access is removed, patients would continue to access commissioned mental health services as required.

3.5. For some patients, there can be a functional impact of the excess skin, or example sores, rashes and potentially infections however the group noted conservative management would continue to be offered to support patients to manage their symptoms.

3.6. The group also noted that activity is minimal and no adverse impacts have been identified in areas where these procedures are not currently commissioned.

3.7. Following discussions the group agreed there was sufficient evidence to adopt the CPAG recommendation and remove proposals to commission these interventions.

3.8. The recommended proposal from the technical group was to not routinely commission abdominoplasty/apronectomy and body contouring procedures.

4. Impact assessments

4.1. A quality impact assessment (QIA) has been completed for the recommended and approved proposal. The assessment was presented to the QIA panel on 29 June 2022 and approved.

4.2. Equality impact assessments have been completed for the recommended and approved proposals for both abdominoplasty/apronectomy and body contouring procedures and these were approved on 01 August 2022.

4.3. Both assessments noted the potential mental health impact on patients who were not able to access this procedure however it was recognised that there are mental health services in place to support these patients. Emphasis was placed on the importance of good communication when amending policy to confirm what is commissioned and ensure patient expectations are not raised during their clinical pathway. It was also noted signposting to relevant support services is essential where adverse impacts on mental health are identified.

4.4. No material workforce impact was highlighted during the options appraisal process or within either the quality or equality impact assessments