Item 9

Report to:	Integrated Care Board
Date of Meeting:	13th July 2022
Subject:	Clinical Policies
Director Sponsor:	Dr Nigel Wells, Executive Director of Clinical & Professional
Author:	Sarah Coltman-Lovell

STATUS OF THE REPORT:

Approve ☐ Discuss ☒ Assurance ☐ Information ☐ A Regulatory Requirement ☐

SUMMARY OF REPORT:

Whilst most service provision is commissioned through established service agreements there are occasions when services are excluded or not routinely available within the NHS.

The ICB is required to establish arrangements for taking decisions in these instances.

Decisions should be taken on the basis of the evidence base, cost effectiveness, improving health outcomes, reducing health inequalities, and value for money. Decision-making is supported by a series of clinical statements or policies which sit behind a robust operating model for managing Individual Funding Requests (IFR) on a case by case (individual patient) basis.

The purpose of this report is to inform the members of the Board of the work done to date, key considerations, and work plan to review and prepare both the IFR policy and clinical policies.

RECOMMENDATIONS:

Members are asked to:

i) Note/comment on the actions to be taken forward arising from discussions with the Ethics Panel.
ii) Note/comment on the action to consider how policies will be prepared in the context of developing organisational and system strategies.
iii) Note/comment on the actions to maintain, increase, and strengthen capacity to review and prepare policies and operating arrangements for IFRs.

ICB STRATEGIC OBJECTIVE	
Realising our vision	☐
Improving outcomes in population health and healthcare	☒

Supporting broader social and economic development	☐
Tackling inequalities in outcomes experience and access	☒
Delivering our operational plan 2022/23	☐
Developing our ICS	☒

IMPLICATIONS	
Finance	**Y** – there is a funding implication to all Individual Funding Requests and need to understand financial strategy in the broader context of decisions taken on occasions when services are excluded or not routinely available within the NHS.
Quality	**Y** - Decisions should be taken on the basis of evidence base, cost effectiveness, improving health outcomes, reducing health inequalities, and value for money.
HR	**Y** – It is a significant undertaking to align clinical policies across the Humber and North Yorkshire Places/Providers, and requires significant input from Clinical Leads, Public Health, and Managers with expertise in clinical commissioning, as well as input from finance, legal, contracting, engagement and quality experts.
Legal / Regulatory	**Y** – regarding processes for decision-making. The ICB has legal duties set out in the NHS Constitution (DH, March 2013) (Ref 12.3), which identifies patient rights specifically related to the availability of medicines and other treatments. The IFR Policy and process has been developed in response to these duties.
Data Protection / IG	**N/A –** the ICB will retain the Data Processing Agreements as part of the contract with NECS (a commissioning support provider) established with CCGs.
Health inequality / equality	**Y** – EQIAs will be completed, and reviews will incorporate health inequalities in relation to policy areas. Consideration will be given to the financial strategy for the new ICB organisation, in the context of levelling up and health inequalities.
Conflict of Interest Aspects	**N/A**
Sustainability	**N/A**

ASSESSED RISK:

125 clinical policies were risk assessed using an agreed methodology approved by the HNY Transition Group. The outcome was reported to ICB Transition Executive and CCG Governing Bodies in March 2022: 2 High Risk, 5 Medium Risk (11 new areas have been added brought about by new national Evidence Base interventions guidelines), 118 Low Risk.

Mitigations:

1. To complete policy review and preparations in two waves, in priority order of risk:
Wave 1: High and Medium Risk policies - aim to complete by March 2023
Wave 2: Low Risk policies – aim to complete by March 2024

2. To agree interim arrangements for IFRs and interim position statements and publish links ensuring alignment with ICB and CCG websites.

3. To have an approved IFR policy on 1 July 2022.
The IFR policy was assessed by the HNY Transition Group as high risk due to the ICB requiring a single process / position for individual funding decisions.

Plan for mitigations reported to the ICB Executive 21 June 2022:

1. Robust review process underway to prepare IFR policy for approval
2. Options appraisal undertaken for interim arrangements with ethical advice to assess relative risk of options.
3. Internal legal advice regarding interim arrangements and appeals process
4. Appeals process enables clinical policies to be re-categorised as high risk.
5. Implications for ICB capacity highlighted in terms of Clinical Lead, Public Health, and management time, and finance, legal, contracting, engagement and quality expert input.

MONITORING AND ASSURANCE:

The recommendations will be developed and implemented by members of the Clinical Policy Review Group.

The Clinical Policy Review Group reports to the Clinical and Professional Group, an Executive Committee of the ICB.

An annual report will be provided to the ICB Quality Committee outlining the cases referred and decisions taken through the IFR process which will include the number of IFRs received and the clinical areas being requested.

An internal audit of a selection of IFRs undertaken by an appointed independent clinician. This report will cover compliance, effectiveness, and outcomes of the policy, together with a summary of all the IFR Panel decisions for that financial year. This report will include adherence to clinical exceptionality and help to identify future training requirements.

ENGAGEMENT:
Clinical and professional engagement, internal and external to the HNY system has been a defining feature of the approach. Engagement with the ethics panel is in line with best practice.

Public involvement is not planned with regards to the IFR policy as the arrangement represents changes to the way commissioning operations are deployed as opposed to patient facing policies or pathways. Patient information is being developed to reflect the changes.

Public involvement will be a key part of the preparations for all clinical policies and will be comprehensively assessed using the ICB EQIA framework once the reviews have been undertaken. Patient insights are being gathered to support the review process. Engagement

plans will be developed by the Engagement lead member of the Clinical Policy Review Group and approval sought by the Clinical and Professional Group.

REPORT EXEMPT FROM PUBLIC DISCLOSURE	No ☒	Yes ☐
If yes, please detail the specific grounds for exemption		

REVIEW AND PREPARATION OF ICB INDIVIDUAL FUNDING REQUEST ARRANGEMENTS AND CLINICAL POLICIES

1. INTRODUCTION

1.1. ICB's have a statutory responsibility for commissioning services for the population within available resources by prioritising between competing demands.

1.2. Decisions should be taken on the basis of evidence base, cost effectiveness, improving health outcomes, reducing health inequalities, and value for money.

1.3. Whilst most of the service provision is commissioned through established service agreements with providers, there are occasions when services are excluded or not routinely available within the NHS.

1.4. Clinical statements or policies (the terms have been used interchangeably by commissioning organisations in the past) and the overarching Individual Funding Request (IFR) policy provide the means by which these decisions are taken, on a case by case (individual patient) basis.

1.5. A process of policy review and preparation is required. This is often referred to nationally as policy harmonisation and will be a feature of all ICB work plans, as new statutory organisations receive policies from CCGs with the introduction of the Health and Care Act 2022. This process must be robust, clinically effective, cost effective, fair, and equitable, reflecting the diverse populations we serve.

2. BACKGROUND

2.1. The HNY Transition Group identified Director-level support to establish and oversee the risk assessment of 125 clinical policies with IFR management and clinical leads across the six CCGs. The outcome and next steps were reported to the ICB Transition Executive and CCG Governing Bodies in March 2022.

2.2. A clinical policy review group was established on 29 April 2022 to review and prepare ICB policies for approval and oversee impact assessment and engagement processes. The group comprises leadership and expertise from clinical, nursing, public health, pharmacy, finance, legal, governance, and engagement. Continuity in Director-level oversight and IFR managerial leads will be essential to keep pace with the review requirements for each policy in Wave 1. The group includes GPs representing each local area, to lead the review of all clinical policies. Sub groups have been established to support the review work, led by a Clinical or Professional lead, and supported by a Managerial lead.

2.3. On 10 of June and 24 June advice form the Ethics Panel was sought on a number of key considerations arising from the initial work undertaken to review the first three policy areas: IFR and IVF/Access to Infertility Treatment (10 June) and Health Optimisation (24 June). The Panel advised on definition and application of Clinical Exceptionality in decision-making and recommended that training for IFR Panel

2.4. members include ethical training. The advice has strongly influenced the review phase, including options appraisals, and shaped interim positions for each policy area. Input from the Ethics Panel is next scheduled for the 22 July and will be a key contributor to the review phase of each policy.

2.5. On the 21 June the ICB Executive agreed pre-prepared position statements regarding interim arrangements as part of the plans for mitigation of risk. These statements provide IFR panel members with clarity and consistency to aid decision-making from July 2022 whilst the review and preparation work is undertaken.

2.6. On the 24 June 2022 the Clinical and Professional Group was asked to pre-approve the IFR Policy and interim arrangements, and also asked to comment on the work undertaken to date, key considerations, and next steps for the programme of work to review and prepare clinical policies. Pre-approvals and support were given with a recommendation to consider the financial strategy for the new ICB organisation, in the context of levelling up and health inequalities.

2.7. On the 1 July the Quality Committee approved the IFR Policy and associated panel arrangements, documents, processes, and terms of reference contained in the appendices. Operating arrangements are being implemented by the IFR managerial leads; this includes consolidating panels from five to three, refreshing training for members, and pooling clinical expertise for new appeals processes.

3. ASSESSMENT

3.1. Key considerations at this early stage of the review work are set out in this section of the report. Some have been discussed in the meetings outlined in section 2.2-2.5.

3.2. *Interim arrangements:* The Health and Care Act 2022 transferred policies from CCGs to ICBs on 1 July 2022. The act of transfer illuminates a variation in clinical policies across the geographic areas of Humber and North Yorkshire. The CCGs undertook significant and robust authorisation processes to develop local policies for local populations, and adopting a single policy is not always desirable or achievable quickly, for example due to differences in provision and local GP knowledge about service availability, and a statutory duty to engage on matters of proposed service change. For these reasons the ICB – through an appraisal of the options and discussion in the meetings outlined in section 2.2-2.5 – has adopted a CCG-based approach to IFRs, using patient GP post code aligned to the CCG boundary as it was on 30 June 2022.

3.3. *Review process:* The review process and consideration of any options will take ethical views into account, for the benefit of all populations served by Humber and North Yorkshire, recognising our responsibility as an ICB to allocate resources across an integrated health and care system in ways that move population health gains in the right direction. The review is engaging with national bodies and regional expert groups.

3.4. *Capacity: Review and Preparation:* The review and preparation of clinical policies is complex and lengthy. Dedicated clinical leadership, public health-led evidence-based review, and commissioning expertise is essential. The following excerpt documents the experience of a professional lead involved in this work following a CCG merger in the Midlands:

> "Clinical policy is a new area of work for me. I hadn't appreciated how much work was required to complete policy harmonisation until I was involved in it. We are working to a tight timeframe and have had to prioritise policies to harmonise first. Never underestimate the amount of work involved, even something that appears that it should be relatively straightforward can take longer to complete than anticipated so factor additional time in."
> *Harmonisation of Policies: National webinar 29 June 2022*.

The process from this Midlands example benefitted from dedicated managerial, clinical, and professional input, and bespoke external resource. The process of aligning 130 policies in this case took four years, partly because each policy review must take into account changing evidence-based guidance from national bodies and local service provision. The following learning points have been shared by the team:

Our policy harmonisation and development challenges

Timeframes can be tight – don't underestimate how long each process element will take

Bringing clinicians together – from different organisations and specialties

Planning engagement sessions – do this well in advance and keep patients at the heart

Access to public health teams – each policy needs a thorough evidence review

Scale and complexity – effective support from specialist partners is helpful.

These and other considerations arising from the learning shared by the Midlands team may form part of our ICB development, for example, the Midlands team recommend an ethical framework – consistent and evidence based – to support allocation and prioritisation decisions for all services, not just those which are not routinely commissioned.

3.5. *Capacity: Individual Funding Operating Arrangements:* The ICB is required to establish effective arrangements for taking decisions in instances where services are excluded or not routinely available within the NHS. The close down of CCG IFR arrangements and establishment of ICB arrangements has required additional managerial input over and above previous arrangements to establish and coordinate supporting infrastructure, for example, clinical membership to support three panels following changes to leadership, new appeals processes, new training for panel members, new systems for storage and monitoring adherence.

4. CONCLUSION

4.1. Experiences in policy harmonisation locally and nationally indicate that review and preparation of clinical policies is complex and lengthy.

4.2. The process in Humber and North Yorkshire has benefitted from Director-level leadership and extensive clinical and professional engagement from the outset, enabled by managerial and administrative support.

4.3. All policies have been risk assessed. Of the high-risk policies, one has already been approved (IFR) and is in the process of being implemented and the second (IVF/Access to Infertility Treatment) is in the process of review. Of the medium risk policies, three commenced late June 2022 and another three are due to start this month. Each review is expected to take between two and four months dependent upon the scope of the eligible population, evidence-base, and options under consideration, before recommendations can be formed to commence the preparation phase. A typical timeline is included for information:

Policy Review	
ICB Clinical Policy Review Group	22/06/2022
ICB Ethics Panel	24/06/2022
Clinical and Professional Leadership Group	Jul-22
Deputy Director of Finance Group	Jul-22
Population Health and Prevention Board	Aug-22
Policy preparation	
Task and Finish Group	Sep-22
3x Sub system Interface Groups	Oct-22
Place Partnerships (briefing / board paper)	Nov-22
ICB Ethics Panel	Oct-22
Clinical and Professional Leadership Group	Oct-22
ICB Clinical Policy Review (pre-approval)	Nov-22
ICB Quality Committee (approval)	Dec-22

4.4. Collaboration with the Ethics Panel has brought rigour to the process and enhanced the review process. Future collaboration is planned with primary, secondary, community, and mental health care provider leads to support the work to standardise clinical health pathways and reduce potential / unwarranted variation for patients. This provider collaboration is illustrated by the reference to '3 x sub system interface groups' shown in the above timeline.

4.5. Action will be taken to ensure all aspects of Clinical Effectiveness are appropriately resourced to address variation in access to health care, establish clinically robust and ethical policy foundations and system processes, and minimise the risk of legal challenge and its associated reputational and resource costs. This will include dedicated clinical and managerial resource for the development, implementation, and improvement of clinical policies and pathways, and a digital system capable of storing, augmenting, and monitoring adherence.

5. RECOMMENDATIONS

5.1 Members are asked to:

i) Note/comment on the actions to be taken forward arising from discussions with the Ethics Panel.
ii) Note/comment on the action to consider how policies will be prepared in the context of developing organisational and system strategies.

iii) Note/comment on the actions to maintain, increase, and strengthen capacity to review and prepare policies and IFR operating arrangements.