**NHS Derby and Derbyshire Integrated Care Board**

**Ethical Framework for Decision‑Making**

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| **KEY POLICY MESSAGES** |
| 1. Has been developed to support corporate committees of the ICB in their decision-making processes. |
| 1. Specifies statutory duties for the ICB. |
| 1. Ensures due regard. |

**VERSION CONTROL**

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| **Target Audience:** | ICB approved policies apply to all employees, contractors, volunteers, and others working with the ICB in any capacity. Compliance with ICB policy is a formal contractual requirement and failure to comply with the policy, including any arrangements which are put in place under it, will be investigated and may lead to disciplinary action being taken. |

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1. Introduction
   1. NHS Derby and Derbyshire Integrated Care Board (the "ICB") is under a statutory duty to promote the health of the local community. They are also under a duty not to exceed their annual financial allocation. These legal requirements mean that, from time to time, difficult choices must be made.
   2. The Ethical Framework for Decision-Making (the "Ethical Framework") has been developed to support corporate committees of the ICB in their decision-making processes. For the purpose of this document, corporate committees of the ICB will be referred to as the "Committees".
2. Purpose of the Ethical Framework
   1. The purpose of this Ethical Framework is to support and underpin the decision-making processes of constituent organisations and their Committees to support consistent commissioning policy through:
      1. providing a coherent structure for the consideration of health care treatments and services to ensure that all important aspects are discussed;
      2. promoting fairness and consistency in decision-making, reducing the potential for inequity;
      3. providing a transparent means of expressing the reasons behind the decisions made to patients, families, carers, clinicians and the public;
      4. ensuring that the principles and legal requirements of the NHS Constitution, the Public Sector Equality Duty and the Legal Duty to Involve Patients, Carers and Public in decision making are adhered to consistently across all levels of commissioning from strategic planning through to individual funding requests;
      5. supporting and integrating with the development of the ICB commissioning plan; and
      6. reducing the risk of judicial review by implementation of robust decision-making processes that are based on evidence of clinical and cost effectiveness, and an ethical framework and adequately involve patients, carers and the public.
   2. Formulating policy recommendations regarding health care priorities involves the exercise of judgment and discretion and there will be room for disagreement both within and external to the Committees. Although there is no objective or infallible measure by which such decisions can be based, this Ethical Framework enables decisions to be made within a consistent setting which respects the needs of individuals and the community. The Committees recognise that their discretion may be affected by National Service Frameworks, National Institute for Health and Clinical Excellence (NICE) technology appraisal guidance and Secretary of State Directions to the NHS.
   3. The Ethical Framework builds upon the four 'prima facie' principles of:
      1. respect for autonomy;
      2. beneficence;
      3. non-maleficence; and
      4. justice.
3. Principles of the Ethical Framework

The following are the principles adopted by Committees during the decision-making process:

Standards of Business Conduct, Transparency and Accountability

* + 1. ICB Board members, employees, committee and sub-committee members of the ICB will at all times comply with the ICB Constitution and Standards of Business Conduct Policy and be aware of their responsibilities as outlined in it. They should:
       1. act in good faith and in the interests of the ICB;
       2. follow the Seven Principles of Public Life; set out by the Committee on Standards in Public Life (the Nolan Principles). These are:
          1. Selflessness: Holders of public office should act solely in terms of the public interest;
          2. Integrity: Holders of public office must avoid placing themselves under any obligation to people or organisations that might try inappropriately to influence them in their work. They should not act or take decisions in order to gain financial or other material benefits for themselves, their family, or their friends. They must declare and resolve any interests and relationships;
          3. Objectivity: Holders of public office must act and take decisions impartially, fairly and on merit, using the best evidence and without discrimination or bias;
          4. Accountability: Holders of public office are accountable to the public for their decisions and actions and must submit themselves to the scrutiny necessary to ensure this;
          5. Openness: Holders of public office should act and take decisions in an open and transparent manner. Information should not be withheld from the public unless there are clear and lawful reasons for so doing;
          6. Honesty: Holders of public office should be truthful;
          7. Leadership: Holders of public office should exhibit these principles in their own behaviour and treat others with respect. They should actively promote and robustly support the principles and challenge poor behaviour wherever it occurs.
    2. These principles should be applied at all times in decision-making and policy-setting environments. These will include decisions relating to clinical policy, staff policy, public policy, financial management and any other decision-making environments.

Consistency in demonstrating values and principles

The values and principles driving priority setting at all levels of decision-making must be consistent. The decision-making criteria and factors considered should be relevant to the goals and values of the affected stakeholders, such as patients, healthcare providers, and the community. These will be set by the ICB Board, in discussion and agreement with staff and other stakeholders.

Our approach to decision making

* + 1. The ICB will make our most significant decisions by ‘consensus’. We recognise that there will be reasonable disagreement about how we should allocate resources with a finite budget among those who are responsible for understanding the problem, want to find a just and fair solution and responsible for making a decision. The consensus of decisions made by the ICB must be mindful of not only meeting short term objectives but also long-term strategy, such as the Five-Year Plan and Joint Forward Plan. This framework will help us to treat disagreements respectfully so that those affected can sign up to decisions made by:
       1. finding solutions that everyone actively supports, or at least can live with. This is done by ensuring that all opinions, ideas and concerns are taken into account. The assumption is that every member of the group or committee has a voice worth hearing and that all concerns are reasonable, and this is crucial to making good decisions. If a proposal is deeply troubling to even one person, that concern is respected; if it is ignored, the group is likely to make a mistake;
       2. ensuring everyone in the group is committed to common goals that are clearly understood, and to be able to tell the difference between their personal preferences and what will help the group achieve its goals;
       3. ensuring decisions are reached by consensus and reflect the thoughts and feelings of the group as a whole, rather than just the majority. Effective consensus building results in decisions that have been thoughtfully considered and take into account diverse experience and views.
    2. A full consensus decision-making process may be most appropriate for:
       1. strategic decisions;
       2. decisions where “the stakes are high”;
       3. decisions for which a strong, united front is important.
    3. A full consensus-building approach may be unnecessary or less appropriate for:
       1. operational or tactical decisions; or
       2. decisions which have relatively minor impact, or which affect relatively few people.

Evidence of clinical and cost effectiveness

The Committees will seek to obtain the best available evidence of clinical and cost effectiveness using robust and reproducible methods. Methods to assess clinical and cost effectiveness are well established. The key success factors are the need to search effectively and systematically for relevant evidence, and then to extract, analyse, and present this in a consistent way to support the work of the Committees. Choice of appropriate clinically and patient-defined outcome needs are to be given careful consideration, and where possible the quality of life measures and cost utility analysis should be considered.

The Committees will promote treatments for which there is good evidence of clinical effectiveness in improving the health status of patients and will not normally recommend treatment that is shown to be ineffective. Issues such as safety and drug licensing will also be carefully considered. When assessing evidence of clinical effectiveness the outcome measures that will be given greatest importance are those considered important to patients’ health status. Patient satisfaction will not necessarily be taken as evidence of clinical effectiveness. Trials of longer duration and clinically relevant outcomes data may be considered more reliable than those of shorter duration with surrogate outcomes. Reliable evidence will often be available from good quality, rigorously appraised studies. Evidence may be available from other sources and this will also be considered. Patients’ evidence of significant clinical benefit is relevant and will be balanced against the strength of the available research.

* + 1. The committees will compare the cost of a new treatment to the existing care provided and will also compare the cost of the treatment to its overall benefit, both to the individual and the community. They will consider technical cost-benefit calculations (e.g. quality adjusted life years), but these will not by themselves be decisive. The Committees may use the ethical framework to guide context-specific judgements about the relative priority that should be given to each topic.

Equity

* + 1. The Committees believe that people should have access to health care on the basis of need. There may also be times when some categories of care are given priority in order to address health inequalities in the community. However, the Committees will not discriminate on grounds of personal characteristics, such as age, gender, sexual orientation, gender identity, race, religion, lifestyle, social position, family or financial status, intelligence, disability, physical or cognitive functioning (including employment status). However, in some circumstances, these factors may be relevant to the clinical effectiveness of an intervention and the capacity of an individual to benefit from the treatment. The committee will pay due regard to the Quality and Equality Impact Assessment process.
    2. The ICB will also ensure staff policies and procedures promote equity and equality.

Health care need[[1]](#footnote-1) and capacity to benefit

Health care should be allocated justly and fairly according to need and capacity to benefit, such that the health of the population is maximised within the resources available. The Committees will consider the health needs of people and populations according to their capacity to benefit from health care interventions. So far as possible, it will respect the wishes of patients to choose between different clinically and cost‑effective treatment options, subject to the support of the clinical evidence. This approach leads to three important principles:

in the absence of evidence of health need, treatment will not generally be given solely because a patient requests it;

a treatment of little benefit will not be provided simply because it is the only treatment available; and

treatment which effectively treat life-time or long-term chronic conditions will be considered equally to urgent and life prolonging treatments.

Cost of treatment and opportunity costs

Because each ICB is duty-bound not to exceed its budget, the cost of treatment must be considered. The cost of treatment is significant because investing in one area of health care inevitably diverts resources from other uses. This is known as opportunity costs and is defined as benefit foregone, or value of opportunities lost, that would accrue by investing the same resources in the best alternative way. The concept derives from the notion of scarcity of resources. A single episode of treatment may be very expensive, or the cost of treating a whole community may be high.

Needs of the Community

Public health is an important concern of the Committees, and they will seek to make decisions which promote the health of the entire community. Some of these decisions are promoted by the Department of Health and Social Care (such as the guidance from NICE and National Service Frameworks). Others are produced locally. The Committees also support effective policies to promote preventive medicine which help stop people becoming ill in the first place.

Sometimes the needs of the community may conflict with the needs of individuals. Decisions are difficult when expensive treatment produces very little clinical benefit. For example, it may do little to improve the patient’s condition, or to stop, or slow the progression of disease. Where it has been decided that a treatment has a low priority and cannot generally be supported, a patient’s doctor may still seek to persuade the ICB that there are exceptional circumstances which mean that the patient should receive the treatment. ([DDICB IFR Policy, 2019)](http://www.derbyshiremedicinesmanagement.nhs.uk/assets/Clinical-Policies/Goverance_Policies/IFR%20policy%20extented%20review%20April%202023.pdf)

Policy Driver/Strategic Fit

* + 1. The aim is to achieve the greatest possible improvement in health outcome for our population, within the resources that the ICB has available.

The Department of Health issues guidance and directions to NHS organisations which may give priority to some categories of patient or require treatment to be made available within a given period. These may affect the way in which health service resources are allocated by individual ICBs. The Committees operate with these factors in mind and recognise that their discretion may be affected by the following:

* + - 1. National Service Frameworks
      2. NICE technology appraisal guidance
      3. Secretary of State Directions to the NHS and performance and planning guidance
      4. how the service fits within the delivery of current national targets for the system
      5. how the service aligns with the STP/ICS strategi plan, Health and Wellbeing Board priorities

Locally, choices about the funding of health care treatments will be informed by the needs of each individual ICB and these will be described in their Commissioning Strategy (QIPP) and Operating Plans.

Exceptional Need

There will be no blanket bans on treatment since there may be cases in which a patient has special circumstances which present an exceptional need for treatment. Each case of this sort will be considered on its own merits in light of the clinical evidence. ICBs have procedures in place to consider such exceptional cases on their merits([DDICB IFR Policy, 2019)](http://www.derbyshiremedicinesmanagement.nhs.uk/assets/Clinical-Policies/Goverance_Policies/IFR%20policy%20extented%20review%20April%202023.pdf)

1. Equality Statement
   1. The ICB aims to design and implement policy documents that meet the diverse needs of our services, population and workforce, ensuring that none are placed at a disadvantage over others. It takes into account current UK legislative requirements, including the Equality Act 2010 and the Human Rights Act 1998, and promotes equal opportunities for all. This document has been designed to ensure that no one receives less favourable treatment due to their protected characteristics of their age, disability, sex (gender), gender reassignment, sexual orientation, marriage and civil partnership, race, religion or belief, pregnancy and maternity. Appropriate consideration has also been given to gender identity, socio-economic status, immigration status and the principles of the Human Rights Act.
   2. In carrying out its function, the ICB must have due regard to the Public Sector Equality Duty (PSED). This applies to all activities for which the ICB is responsible, including policy development, review and implementation.
2. Due Regard

This policy has been reviewed in relation to having due regard to the PSED of the Equality Act 2010 to eliminate discrimination; harassment; victimisation; to advance equality of opportunity; and foster good relations between the protected groups.

1. References/Supporting Documents

* NHSE Ethical Framework, Published 2013

<https://www.england.nhs.uk/wp-content/uploads/2013/04/cp-01.pdf>

* Thames Valley CCG Priorities Committee Ethical Framework – Published 2016

<http://www.fundingrequests.cscsu.nhs.uk/wp-content/uploads/2015/08/Ethical-Framework-March-2016-final.pdf>

* Portsmouth CCG – Ethical Framework for Decision-making <https://www.portsmouthccg.nhs.uk/publications-and-key-documents/ethical-framework-for-decision-making>
* Ethical dimensions of Covid-19 for Frontline Staff, Royal College of Physicians, February 2021 [Ethical guidance for publication\_8-2-21\_0.pdf](file:///C:\Users\Helen.moss\AppData\Local\Microsoft\Windows\INetCache\Content.Outlook\8O63VNB9\Ethical%20guidance%20for%20publication_8-2-21_0.pdf)
* NHS Derby & Derbyshire ICB Individual Funding Request Policy, published 2019, <http://www.derbyshiremedicinesmanagement.nhs.uk/assets/Clinical-Policies/Goverance_Policies/IFR%20policy%20extented%20review%20April%202023.pdf>
* Daniels N. Accountability for reasonableness. BMJ. 2000 Nov 25;321(7272):1300-1. doi: 10.1136/bmj.321.7272.1300. PMID: 11090498; PMCID: PMC1119050.

Appendix 1 – Additional Considerations

The following should be noted in addition to the ethical principles for decision-making:

1. Drug Trials

Patients participating in clinical trials are entitled to be informed about the outcome of the trial and the arrangements for continuation of treatment after the trial has ended by the party initiating and funding the trial and not the ICB, unless the ICB has either funded the trial itself or agreed in advance to fund aftercare for patients entering the trial.

1. Privately Funded Treatment

Unless the requested treatment is approved under existing policies of the ICB, except in exceptional circumstances, the ICB will not commission a continuation of privately funded treatment even if that treatment has been shown to have clinical benefit for the individual patients. **There may be some cases where a treatment is not available because there is limited evidence for how well it works or because it is very high cost and does not offer good value for money for taxpayers and the NHS.**

1. Rule of Rescue

The fact that a patient has exhausted all NHS treatment options available for a particular condition is unlikely, in itself, to be sufficient to demonstrate exceptional circumstances. Equally, the fact that the patient is refractory to existing treatments where a recognised proportion of patients with the same presenting medical condition at this stage are, to a greater or lesser extent, refractory to existing treatments is unlikely, of itself, to be sufficient to demonstrate exceptional circumstances

1. Health care need is a health problem which can be addressed by a known clinically effective intervention. Not all health problems can be addressed. [↑](#footnote-ref-1)