



**Isle of Man
Government**

Reilitys Eilan Vannin



Commissioning Policy

Ethical Framework
for priority setting and resource allocation

Department of Health & Social Care

31 August 2016

Contents

Policy Statement	3
Equality Statement	3
1 Guidance Note	4
A. Core Principles	5
B. Factors taken into account when prioritising competing needs for healthcare	6
2. Core Principles	7
3 Key Factors	9
4 Documents which have informed this policy	11
5 Glossary	12

Policy Statement

This ethical framework should underpin and be applied to priority setting processes carried out by the direct commissioning arm of the Department of Health and Social Care (DHSC) and its associated committees with delegated authority. In particular it should be the basis for decision-making in:

- The development of strategic plans for individual services
- Making investment and disinvestment decisions during the annual commissioning cycle
- Making in-year decisions about service developments or disinvestments
- The management of individual funding requests

The purpose of setting out the principles and considerations to guide priority setting is to:

- Provide a coherent framework for decision making
- Promote fairness and consistency in decision making
- Ensure that the reasons behind decisions that have been taken are clear and comprehensive

Equality Statement

The DHSC recognises the Government's key priority to protect the vulnerable. This policy addresses that priority by seeking to reduce health inequalities in access to health services and health outcomes. The DHSC will seek to ensure equality of access and non-discrimination, irrespective of age, gender, disability (including learning disability), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex (gender) or sexual orientation. This applies to all activities for which the DHSC is responsible, including policy development, review and implementation.

1. Guidance Note

The DHSC receives a fixed budget from the Treasury with which to fund all the health and social care required for the residents of the Isle of Man. Under the National Health Service Act 2001 (Section 1), the DHSC has a duty to *'continue to promote in the Island a comprehensive health service designed to secure improvement in (a) the physical and mental health of the people of the Island and (b) the prevention, diagnosis and treatment of illness.'*

It is not possible to fund all types of health and social care which may be requested within a fixed budget. The National Health Service Act 2001 reflects the reality of budget constraints by conferring a duty to 'promote a comprehensive health service', that is a target or aspirational duty which the DHSC must continually work towards, rather than a duty to fund a comprehensive service at any given point in time. The duty to promote a comprehensive service must be balanced against the concurrent duty to meet reasonable requirements for care within the allocated budget.

Promoting a comprehensive service includes making decisions to invest in new treatments of proven clinical and cost effectiveness and disinvesting from existing services which are less clinically or cost effective. Investment and disinvestment decisions are informed by a range of DHSC processes. The DHSC, in conjunction with partner organisations, undertakes policy reviews, needs assessments and strategic planning which underpin the decisions made in its annual commissioning round. The DHSC seeks to base its decisions about which services to commission on a systematic approach which is centred on the needs of the population but which distributes services fairly across different patient groups. It can only do so if all decision-making is based on clearly defined and consistently applied evaluation criteria and follows clear ethical principles. These principles are set out in the ethical framework.

Given resource constraints, the DHSC cannot meet every healthcare need of all patients within its areas of responsibility. The DHSC may take a decision not to fund a service to meet a specific healthcare need, even though there may be evidence of clinical and cost effectiveness. Decisions not to fund due to resource constraints need to demonstrate why the particular treatment is considered to be of lower priority than other options for investment. Where such decisions are taken, the DHSC will set out clearly the reasons for them, in line with the ethical framework. Making a decision not to fund a treatment for which there is evidence of clinical or cost effectiveness does not, of itself, indicate that the DHSC is breaching its statutory obligations.

The ethical framework should underpin and be applied to priority setting processes carried out by the DHSC and its associated committees. In particular it should be the basis for decision-making in:

- The development of strategic plans for individual services
- Making investment and disinvestment decisions during the annual commissioning cycle
- Making in-year decisions about service developments or disinvestments
- The management of individual funding requests

The purpose of setting out the principles and considerations to guide priority setting is to:

- Provide a coherent framework for decision-making
- Promote fairness and consistency in decision-making
- Provide clear and comprehensive reasons behind decisions that have been taken

The ethical framework has two parts: Core Principles and Factors which are taken into account when prioritising competing needs for healthcare.

A. Core Principles

These are the principles that should guide all decision-making by the DHSC. As with all DHSC policies, this policy should be reviewed at regular intervals. However, these core principles should guide all decision-making unless and until the DHSC decides to amend this policy.

The core principles should be applied to all types of decision making from population level funding policies through to individual funding requests.

Five important themes can be found within the core principles.

- i) The first is that, as budget holder for a defined population and a range of clinical services, the DHSC and its committees should ensure that all decisions are framed and considered in such a way that all options for investment are considered. This means that there should not be a parallel system operating, which allows individual treatments or patients to bypass prioritisation. The commissioning and operating policies that have been adopted by the DHSC allow for the funding of high priority service developments, or of individuals who have unusual and high priority clinical needs. This principle is intended to ensure fairness so that all claims on DHSC resources are considered against the same framework.

- ii) The second theme is that a commissioner should not give preferential treatment to an individual patient who is one of a group of patients with the same clinical needs. Either a treatment or service is funded in order to create the opportunity for all patients with equal need to be treated or, if this cannot be afforded, it should not be commissioned as part of NHS treatment for any patients. The DHSC considers that if funding for a treatment cannot be justified as an investment for all patients in a particular cohort, the treatment should not be offered to only some of the patients unless it is possible to differentiate between groups of patients on clinical grounds. A decision to treat some patients but not others has the potential to be unfair, arbitrary and possibly discriminatory.
- iii) The need to demonstrate clinical effectiveness and value for money is only the first stage in assessing priority. Effectiveness and value for money are minimum requirements to enable prioritisation for funding, but are not the sole criteria that must be met for funding to be agreed. This is because not all treatments which are effective and value for money may be affordable within the funding available.
- iv) Funding bodies are frequently asked to take on funding commitments made by another statutory body or other type of organisation (including pharmaceutical companies, research bodies or acute trusts) or indeed an individual who has funded the treatment themselves. The DHSC, like any other organisation, cannot assume responsibility for a funding decision in which it played no part unless there is a legal requirement to do so.
- v) Related to point iv) is the issue of financial support provided to research and development (R&D). Funding support for R&D is highly desirable but it needs to be placed within appropriate constraints. These constraints should protect high priority treatments and services of established value.

B. Factors taken into account when prioritising competing needs for healthcare

The DHSC has an obligation to provide a fair system for deciding which treatments to commission, recognising that the DHSC does not have the budget to fulfil all the needs of all patients within its area of responsibility.

This means that the key task of priority setting is to choose between competing claims on the DHSC's budget. This requires the DHSC to adopt policies that allow potential and existing demands on funds to be ranked, preferentially in the context of a strategic plan for the service. However the DHSC recognises that its internal resources will not allow every single service to be assessed and ranked within every annual commissioning round.

The DHSC will therefore have to allocate its own resource to decide which services to assess and rank each year as part of the annual commissioning round. The DHSC will decide which factors to take into account in identifying which services are a priority for funding review in any given year and what work is required to help define the relative priority of a service development or an individual funding request.

When prioritising both within and across healthcare programmes a commissioner has to make complex assessments and trade-offs. Section 2 sets out the common factors which are taken into account when making these decisions. This list is not exhaustive.

The DHSC will seek, within the resources available to it, to take rational decisions about which services to commission. As part of that process the DHSC is committed to examining existing services and reserves the right to withdraw funding from existing services which are not determined to justify their funding since this will release resources to fund other services which have a higher ranking.

2. Core Principles

Principle 1: The values and principles driving priority setting at all levels of decision-making must be consistent.

Principle 2: The DHSC has a statutory duty to promote a comprehensive healthcare service. Within that duty the DHSC must meet all reasonable requirements for healthcare, subject to the duty to live within its allocated resources.

Principle 3: The DHSC has a responsibility to make rational decisions determining the way it allocates resources to the services it funds. It must act fairly in balancing competing claims on resources between different patient groups and individuals.

Principle 4: Competing needs of patients and services within the areas of responsibility of the DHSC should have an equal chance of being considered, subject to the capacity of the DHSC to conduct the necessary healthcare needs assessments and services reviews. As far as is practicable, all potential calls on new and existing funds should be considered as part of a priority setting process. Services, clinicians and individual patients should not be allowed to bypass normal priority setting processes.

Principle 5: Access to services should be governed, as far as practicable, by the principle of equal access for equal clinical need. Individual patients or groups should not be unjustifiably advantaged or disadvantaged on the basis of age, gender, sexuality, race, religion, lifestyle, occupation, social position, financial status, family status (including responsibility for dependants), intellectual / cognitive function or physical functions.

There are proven links between social inequalities and inequalities in health, health needs and access to healthcare. In making commissioning decisions, priority may be given to health services targeting the needs of sub-groups of the population who currently have poorer than average health outcomes (including morbidity and mortality) or poorer access to services.

Principle 6: The DHSC should only invest in treatments and services which are of proven cost-effectiveness unless it does so in the context of well-designed and properly conducted clinical trials that will enable the NHS to assess the effectiveness and/or value for money of a treatment or other healthcare intervention.

Principle 7: New treatments should be assessed for funding on a similar basis to decisions to continue to fund existing treatments, namely according to the principles of clinical effectiveness, safety, cost-effectiveness and then prioritised in a way which supports consistent and affordable decision-making.

Principle 8: The DHSC must ensure that the decisions it takes demonstrate value for money and an appropriate use of the NHS funding based on the needs of the population it serves.

Principle 9: ALL NHS commissioned care should be provided as a result of a decision by the DHSC. No other body or individual, other than those authorised to take decisions under the policies of the DHSC, has a mandate to commit the DHSC to fund any healthcare intervention unless directed to do so by the Secretary of State for Health.

Principle 10: The DHSC should strive, as far as is practical, to provide equal treatment to individuals in the same clinical circumstance where the healthcare intervention is clearly defined. The DHSC should not, therefore, agree to fund treatment for one patient which cannot be afforded for, and openly offered to, all patients with similar clinical circumstances and needs.

Principle 11: Interventions of proven effectiveness and cost-effectiveness should be prioritised above funding research and evaluation unless there are sound reasons for not doing so.

Principle 12: Because the capacity of the NHS to fund research is limited, requests for funding to support research on matters relevant to the health service have to be subject to normal prioritisation processes.

Principle 13: If a treatment is provided within the NHS which has not been commissioned in advance by the DHSC, the responsibility for ensuring on-going access to that treatment lies with the organisation that initiated treatment.

Principle 14: Patients participating in clinical trials are entitled to be informed about the outcome of the trial and to share any benefits resulting from having been in the trial. They should be fully informed of the arrangements for continuation of treatment after the trial has ended. The responsibility for this lies with the party initiating and funding the trial and not the DHSC unless the DHSC has either funded the trial itself or agreed in advance to fund aftercare for patients entering the trial.

Principle 15: Unless the requested treatment is approved under existing policies of the DHSC, in general it will not, except in exceptional circumstances, commission a continuation of privately funded treatment even if that treatment has been shown to have clinical benefit for the individual patient.

3. Key Factors

Key factors that will be taken into account when assessing the relative priorities of competing needs for healthcare.

- i) Whether there is a legal requirement which mandates the DHSC to fund a particular proposed service development or an element of any proposed service development, including having due regard to relevant legislation and other legal instruments.
- ii) Whether or not the proposed service development and/or the benefits anticipated to be derived from the proposed service development have been identified as a priority within the strategic plan for that service.
- iii) The anticipated effectiveness of the proposed service development particularly in reference to patient-orientated outcomes.
- iv) The specific nature of the health outcome or benefit expected from the proposed service development.

-
- v) The anticipated impact on the population affected by the proposed service development.
 - vi) Potential impacts of the proposed service development on one or more other services funded as part of NHS treatment (positive or negative).
 - vii) The level of confidence the DHSC has in the evidence underpinning the case for the proposed service development or the individual funding request (i.e. the quality of the evidence).
 - viii) The level of confidence the DHSC has in the robustness of the business case for the proposed service development.
 - ix) Value for money anticipated to be delivered by the proposed service development (this includes cost-effectiveness where available).
 - x) The anticipated budgetary impact of the proposed service development including:
 - An assessment of the total budgetary impact of funding the proposed service development; and
 - Whether the proposed service development is cost saving in the short, medium or long term or cash releasing
 - xi) Any anticipated risks related to the proposed service development.
 - xii) Whether the proposed service development will improve access to healthcare and for whom.
 - xiii) The effect of the proposed service development on patient choice.
 - xiv) The level of uncommitted funds that the DHSC has at the time that it makes the decision and the affordability of the proposed service development.
 - xv) Whether or not extraordinary circumstances exist which would justify variance from any original funding plan (e.g. the management of a major outbreak).

4. Documents which have informed this policy

- Department of Health, The NHS Health Service Act 2006 (amended by Health and Social Care Act 2012), The NHS Health Service (Wales) Act 2006 and The NHS Health Service (Consequential Provisions) Act 2006
http://www.dh.gov.uk/en/Publicationsandstatistics/Legislation/Actsandbills/DH_064103
- Department of Health, The NHS Constitution for England, July 2009
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_093419
- The NHS Prescribing Centre, Supporting rational local decision-making about medicines (and treatments), February 2009
http://www.npc.co.uk/policy/resources/handbook_complete.pdf
- NHS Confederation Priority Setting Series, 2008
<http://www.nhsconfed.org/publications/prioritysetting/pages/prioritysetting.aspx>
- Commissioning Policy: Ethical Framework for Priority Setting and Resource Allocation, NHS England (formerly NHS Commissioning Board), April 2013
<http://www.england.nhs.uk/wp-content/uploads/2013/04/cp-01.pdf>

5. Glossary

TERM	DEFINITION
Annual commissioning plan	<p><i>The Annual Commissioning Plan</i> is a document prepared by the DHSC which defines the healthcare interventions that it will commission for defined categories of patients in each financial year.</p>
Annual commissioning round	<p><i>The Annual commissioning round</i> is the process by which major funding decisions are taken, including the allocation of new money coming into the NHS. This involved a complex process of prioritisation informed by a series of decisions. This process occurs during the months of April to September for the following financial year.</p>
Case by case decision-making	<p><i>Case by case decision-making</i> in the context of priority setting is when the decision maker opts to allocate resources for a specified treatment and for specified patients in the absence of policy or as a substitute to policy-making. A fundamental principle of the NHS is that is a treatment is made available to one patient by an NHS commissioner, it should be made available to all other patients for whom the commissioner is responsible and who have an equal need for treatment. However case by case decision-making means that the DHSC only considers an individual patient.</p>
Clinical trial	<p>A <i>clinical trial</i> is a research study in human volunteers to answer specific health questions. Clinical trials are conducted according to a plan called a protocol. The protocol describes what types of patients may enter the study, schedules of tests and procedures, drugs, dosages, and length of study, as well as the outcomes that will be measured. Each person participating in the study must agree to the rules set out by the protocol.</p> <p>The ethical framework for conducting trials is set out in the UK Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended). It includes, but does not refer exclusively to, randomised control trials.</p>

TERM	DEFINITION
Cost effectiveness	<i>Cost effectiveness</i> is an assessment as to whether a healthcare intervention provides value for money.
Effectiveness – general	<i>Effectiveness</i> means the degree to which pre-defined objectives are achieved and the extent to which targeted problems are resolved.
Effectiveness – clinical	<i>Clinical effectiveness</i> is a measure of the extent to which a treatment achieves pre-defined clinical outcomes in a target patient population.
Experimental and unproven treatments	<p><i>Experimental and unproven</i> treatments are medical treatments or proposed treatments where there is no established body of evidence to show that the treatments are clinically effective.</p> <p>The reasons may include the following:</p> <ul style="list-style-type: none"> • The treatment is still undergoing clinical trials for the indication in question • The evidence is not available for public scrutiny • The treatment does not have approval from the relevant government body • The treatment does not conform to an established clinical practice in the view of the majority of medical practitioners in the relevant field • The treatment is being used in a different way to previous studies or for which it has been granted approval by the relevant government body • The treatment is rarely used, novel, or unknown and there is lack of evidence of safety and efficacy • There is some evidence to support a case for clinical effectiveness but the overall quantity and quality of that evidence is such that the commissioner does not have confidence in the evidence base and/or there is too great a measure of uncertainty over whether the claims made for a treatment can be justified.

TERM	DEFINITION
Healthcare intervention	<i>A healthcare intervention</i> means any form of healthcare treatment which is applied to meet a healthcare need.
Healthcare need	<i>Healthcare need</i> is a health problem which can be addressed by a known clinically effective intervention. Not all health problems can be addressed.
In-year service development	<i>An in-year service development</i> is any aspect of healthcare, other than one which is the subject of a successful individual funding request, which the DHSC agrees to fund outside of the annual commissioning round. Unplanned investment decisions should only be made in exceptional circumstances because, unless they can be funded through disinvestment, they will have to be funded as a result of either delaying or aborting other planned developments.
NHS commissioned care	<i>NHS commissioned care</i> is healthcare which is routinely funded by DHSC. DHSC has policies which define the elements of healthcare which DHSC does and does not commission for defined groups of patients.
Opportunity cost	<i>Opportunity cost</i> is the loss of the ability for the NHS to fund other healthcare interventions when a decision is made to apply NHS resources to a particular healthcare intervention.
Priority setting	<i>Priority setting</i> is the task of determining the priority to be assigned to a service, a service development, a policy variation or an individual patient at a given point in time. Prioritisation is needed because the need and demands for healthcare are greater than the resources available.
Prioritisation	<i>Prioritisation</i> is decision-making which requires the decision maker to choose between competing options.

TERM	DEFINITION
Service Development	<p>A <i>service development</i> is an application to the DHSC to amend its commissioning policy to enable a particular healthcare intervention to be routinely funded by the DHSC for a defined group of patients.</p> <p>The term refers to all new developments including new services, new treatments (including medicines), changes to treatment thresholds, and quality improvements. It also encompasses other types of investment that existing services might need, such as pump-priming to establish new models of care, training to meet anticipated manpower shortages and implementing legal reforms. Equitable priority setting dictates that potential service developments should be assessed and prioritised against each other within the annual commissioning round. However, where investment is made outside of the annual commissioning round, such investment is referred to as an in-year service development.</p>
Similar patient(s)	<p>A <i>similar patient</i> is one who is likely to be in the same or similar clinical circumstances as the requesting patients and who could reasonably be expected to benefit from the requested treatment to the same or a similar degree.</p> <p>The existence of one or more similar patients indicates that a policy position is required of the DHSC.</p>
Strategic planning	<p><i>Strategic planning</i> is the process by which an organisation determines its vision, mission, and goals and then maps out measurable objectives to accomplish the identified goals. The outcome is a strategic plan which sets out what needs to be done and in what time scale. Strategic planning focuses on what should be achieved in the long term (3, 5, 7 or 10 year time span) while operational planning focuses on results to be achieved within one year or less. Strategic plans should be updated through an annual process, with major re-assessments occurring at the end of the planning cycle. Strategic planning directs how resources are allocated.</p>
Value for money	<p><i>Value for money</i> in general terms is the utility derived from every purchaser or every sum spent.</p>



**Isle of Man
Government**

Reilitys Eilan Vannin



This document can be provided in large print or in audio format on request

Department of Health and Social Care
Crookall House, Demesne Road, Douglas, Isle of Man, IM1 3QA
www.gov.im/dhscclinicalcommissioning

Ref: CRC02 Dec 2016