Making Difficult Decisions in NHS Boards in Scotland
Report of a short life working group

March 2010

www.nhsfife.scot.nhs.uk/difficuldecisions
Foreword

All NHS Boards are challenged with making difficult decisions, whether about prioritising which services they invest in, or whether to fund certain treatments for individual patients. With increasing scrutiny of the decisions that NHS Boards make, and concerns about how such decisions are reached, together with the challenges of trying to meet ever increasing demands for services and treatments, NHS Boards need to ensure that their decision making is robust and fair. I very much welcome this helpful and important report whose origins lie in discussions started off by senior clinical colleagues in NHS Fife. The report provides real and practical assistance for all of us whose responsibility it is to make difficult decisions on behalf of the people we serve.

George Brechin, Chief Executive, NHS Fife
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1 Executive summary

Background

This report originated from a workshop with the main Director groups in NHS Boards across Scotland (February 2008 – workshop report available at www.nhsfife.scot.nhs.uk/difficultdecisions). The Director Groups (Medical Directors, Directors of Public Health, Directors of Finance and Directors of Planning) and Scottish Government agreed in July 2008 that a small group of professionals from across NHSScotland, Scottish Government and academia should meet to build on the findings of the workshop to develop a framework that NHS Boards can use when making difficult decisions.

Context

Difficult decisions are made at all levels of a healthcare organisation on a regular basis – whether they relate to the planning/prioritisation of services for a population, or decisions about individual patients. The challenge is to ensure such decision-making is reasonable, transparent and justifiable.

This report offers advice that National Health Service (NHS) Boards may wish to consider when making difficult decisions. Though produced primarily for NHS Boards in Scotland, it will also have relevance to other healthcare organisations. Produced by a short life working group of NHS professionals from a range of disciplines, academics and a member of a non-departmental body that advises and supports consumer organisations (appendix 1), it describes the background and history of making decisions in healthcare organisations (chapters 2 and 3), explores the strengths and limitations of current approaches to making difficult decisions in NHS Boards across Scotland (chapter 4) and proposes a framework that encapsulates the overall process of decision-making, criteria that trigger the decision-making process, the values/principles used in making the decision and considers the qualities of decision-makers (chapter 5).

By following such an approach NHS Boards can demonstrate reasonableness, transparency, procedural fairness and accountability in their decision making processes.
Key recommendations:

NHS Boards should:

1. Review their own decision-making in the light of the framework shown in section 5.2 and work towards implementing processes based on the framework, both for planning/prioritisation and decisions for individual patients.

2. Develop criteria and values/principles for such decision-making that meet local requirements (see chapter 5 of this report).

3. Require decision-makers to reflect on the values/principles and qualities which inform their decision-making.

4. Have mechanisms that ensure that decisions made in planning/prioritisation and policy development link to decisions about individual patients, and vice versa.

5. Communicate clearly the process, values/principles and qualities involved in decision-making (to professionals, patients and the public).

6. Consider the terminology used around individual patients. Terms such as “exceptionality” and “complex cases” have become ambiguous over time through differences in interpretation. The term “individual treatment request” (ITR) is now entering common usage.
Abbreviations

**HEAT target** – Scottish Government target for NHS Boards relating to Health improvement, Efficiency, Access and Treatment

**ITR** – individual treatment request – a term that includes complex case panels, exceptional and off-label prescribing and other decisions about individuals

**NHS** – National Health Service

**NICE** – National Institute for Health and Clinical Excellence [www.nice.org.uk](http://www.nice.org.uk)

**PCT** – Primary Care Trust

**QALY** – Quality adjusted life year - a measure used in health economics that takes both the quality and the quantity of life lived into account when considering whether a healthcare intervention represents good value for money

**QIS** – NHS Quality Improvement Scotland [www.nhshealthquality.org](http://www.nhshealthquality.org)

**SIGN** – Scottish Intercollegiate Guidelines Network [www.sign.ac.uk](http://www.sign.ac.uk)

**SMC** – Scottish Medicines Consortium [http://www.scottishmedicines.org.uk](http://www.scottishmedicines.org.uk)
2 Introduction

2.1 Background

NHS Boards, clinical services and individual clinicians have to make “difficult decisions” on a regular basis. Such decisions may relate to planning of services at a population level – for example, whether to expand a service that meets the needs of one group of patients, or fund a medical technique that meets the needs of another group of patients. They may also relate to individual patients – for example, a decision about whether to prescribe a particular drug to a patient, or refer for a new type of surgical procedure.

This report considers decision-making at two levels – population and individual.

Planning at population level (macro/meso level): NHS Boards in Scotland, in common with healthcare organisations across the United Kingdom, have a duty to promote and provide for the health needs of the local population, while operating within financial, ethical and legal parameters.

The health needs of the population change over time, as do the public’s expectations of its health services and understanding of the measures that can improve health and prevent or treat disease. The finite resources available to the NHS necessitate tough choices over how the money is spent.

Decisions about individual patients (micro level): Decisions about the treatment provided by an NHS Board or clinical service are determined by a range of influences (e.g. the planning process described above, professional guidelines, and national and local protocols). There are times when decisions made at a population level may need to be reconsidered for an individual patient – where they become an “exceptional case”, or when established mechanisms have not yet considered whether the intervention in question should be made available on the NHS. Accordingly, there needs to be a system for considering the treatment options for individual patients and for deciding, justifying and explaining when certain options are not supported.
Such difficult decisions around planning and individual patients are influenced at national, regional and local levels. NHS Boards need to take account of national priorities (legislation, judicial rulings, policy and targets), the regional organisation of services, and the perspectives of patients, politicians, professionals and the public. For some specialist services, the decisions are made at a national level, for example for some transplant services. In other circumstances the National Institute for Health and Clinical Excellence (NICE) (in England, and can be validated by NHS Quality Improvement Scotland) and Scottish Medicines Consortium (SMC) issue national guidance on decisions around new drugs and technologies – these can have major implications for NHS Board budgets and can impact on local decision-making because similar mechanisms do not always exist to support decision-making around non-drug therapies or interventions (for example surgical procedures, the work of allied health professionals or health promotion programmes). Decisions made by consortia of NHS Boards (e.g. regional planning groups) or the services provided by neighbouring NHS Boards, can also impact on local decision-making.

Against this background, it was clear from discussions in many NHS Board regions across Scotland during late 2007 and early 2008 that there was a need to discuss how NHS Boards, clinical services and clinicians make difficult decisions and how help could be offered in such processes.

2.2 Aim of this report

Directors from NHS Boards across Scotland participated in the “Difficult Decisions” workshop (Feb 2008). That workshop (full report available at www.nhsfife.scot.nhs.uk/difficultdecisions) described the difficult decisions that NHS Boards have to make in the planning of new services, managing/optimising resources, and the care of individual patients. It was acknowledged that the workshop marked the start of a process that would help NHS Boards make difficult decisions that are “transparent, accountable and robust enough to withstand scrutiny”. This work is closely related to the Scottish Government Health Directorate’s current health strategy, as laid out in Better Health, Better Care, where the focus is on a mutual NHS, using evidence to support patients as partners and provide care that is safer, more reliable, more anticipatory and more integrated, as well as quicker.
It was agreed that the next stage of this work would be to bring together a small group of professionals from across NHSScotland, Scottish Government, academia (including representation from law and ethics) and Consumer Focus Scotland, to build on the findings of the workshop to develop a framework that NHS Boards can use when making difficult decisions (box 1). The membership of the group is listed in appendix 1. These individuals were identified for their personal contribution rather than any representative role.

**Box 1. Aim of this report**

To develop a framework that NHS Boards can use when making difficult decisions, both:

- in planning at a population level
- when making decisions about individual patients

### 2.3 Methods employed by short life working group

The short life working group has developed the ideas presented in this report in the following ways:

- Building on discussions and conclusions from the “Difficult Decisions” national workshop (22 February 2008)

- A consideration of the published literature on making difficult decisions in NHS Boards

- A survey of difficult decision-making in planning and for individual patients across NHS Boards and regional planning groups in Scotland

- Wider discussion of key concepts within the group

- An assessment of the legal and ethical frameworks within which decisions must be made.
3 Context

3.1 History of prioritisation and wider approaches to difficult decisions in healthcare

Priority setting has been discussed in healthcare organisations and academic journals for the past two decades, and can be considered in two waves.\(^2\) The first wave of priority setting (late 1980s and early 1990s), was epitomised by the Oregon Plan for Medicaid patients. The Oregon Plan, an attempt to increase population coverage by limiting the range of treatments on offer, used health economics to identify a ranked list of 587 services that would be provided by Medicaid. However, this simple technical approach was unable to provide a reliable basis for decision-making.\(^3\) For example, tooth capping was ranked above appendicectomy and surgery for ectopic pregnancy in the original Oregon list. Other criticisms of the Oregon Plan related to unfair treatment of people with disability (based on concerns that including quality of life risked undervaluing the life of these patients). While understanding of health economics has developed over the past 10-20 years, techniques such as quality adjusted life years (QALYs) are not sufficient, by themselves, for priority setting, though QALYs continue to be used for technical decisions (e.g. NICE and the SMC).

The second wave of priority setting (late 1990s and 2000s) identifies the importance of ethics, accountability and transparency, stressing the importance of “process” in decision-making. Elements of this approach can equally be applied to decisions about individual patients.

One framework from the “second wave” that is used widely across the world is “Accountability for Reasonableness” (Norman Daniels and James Sabin). This sets out four requirements for a fair process (box 2).
Box 2. Accountability for Reasonableness (after Norman Daniels and James Sabin) 4

**Publicity condition:** the public should be able to access information about decisions, and the reasons for these decisions.

**Relevance condition:** the reasons for decisions must be based on evidence, reasons and principles that all fair-minded parties (managers, clinicians, patients, and consumers in general) can agree are relevant to deciding how to meet the diverse needs of a population.

**Appeals condition:** there is a mechanism to challenge and dispute decisions, including the opportunity to revise decisions in the light of further evidence or arguments.

**Enforcement condition:** there is either voluntary or public regulation of the process to ensure that the first three conditions are met.

While Accountability for Reasonableness has been widely adopted, it does not provide a ready-made solution as to how decisions should be made. Nor does it tell us what to do when fair-minded parties reasonably (and justifiably) disagree – for example, when neighbouring NHS Boards make different decisions about the same treatment, or when members of a decision-making group cannot reach agreement. Furthermore, the “publicity condition” falls short of expectations in an era where consultation and public/patient involvement are expected to be undertaken as part of any decision-making in NHSScotland.

### 3.2 Approaches to making difficult decisions

There are overall two approaches that have emerged over recent years to making difficult decisions, both of which have strengths and weaknesses:

1) a **weighted numerical approach** used in planning, assigns a numerical score to each service/intervention based on an assessment of a wide range of considerations that might include, for example, cost and clinical effectiveness, size of the population affected, patient choice and whether it is a local/national priority/target (see appendix 2 for an example of such an approach, with panel members ranking submissions against the listed headings to produce an overall score). This approach has the advantage
that it produces rankings that can be ordered in a prioritisation process and can include weightings from managers, clinicians and the public. However, using numerical scores to capture the views of a panel of individuals is a crude approach that may not allow proper discussion of complex issues, and is not suitable for making decisions about individual patients.

2) **an ethico-legal framework** – some NHS Boards have drawn up a list of non-hierarchical ethical values/principles that can be used either in planning and/or for making decisions about individual patients. An example of an ethico-legal framework in widespread use (e.g. in complex case panels) is provided by NHS Highland (accountability, justice, quality, realism, engagement, flexibility, meaningful relationships – see appendix 3). However, the challenge with such an approach is in the implementation. Such frameworks offer many valuable concepts/principles, but they rarely suggest how they should be deployed.

### 3.3 The role of law and the courts

As a further essential element of any framework, it is clear that developing a system of decision-making for NHS Boards also requires a clear understanding of the law around such decisions.

We live in an age of human rights. Internationally there are rights that include the right to “the enjoyment of the highest attainable standard of physical and mental health”. Nationally, there are no such legal rights; rather the Scottish Ministers are duty bound to promote a “comprehensive” health service. Decisions on allocation of resources can be challenged at the national, service or individual level, and these challenges take the form of a *judicial review* of the original decision-making process. The grounds for such a challenge are limited to a few key arguments: illegality, irrationality and procedural impropriety. The traditional benchmark is whether a public authority (such as an NHS Board) has reached a decision which *no reasonable public authority* could have reached. To date the focus has been on the correctness of the decision-making process and not on the substance of the decision taken. Appendix 4 provides a more detailed exploration of the role of law in decision-making.

The courts will not intervene to direct a NHS Board on how to spend its money. At most, they might rule that a particular policy or approach is illegal.
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because it cannot be justified on grounds of reasonableness or logicality. This means that the Board must revisit and revise its position so that it is not unreasonable or illogical; it does not necessarily follow that patients previously denied care will now be entitled to it.

The key concepts in law as it applies to decision-making in the NHS are *reasonableness, transparency, procedural fairness* and, ultimately, *accountability*.

### 3.4 The ethical dimension – for individuals and organisations

While the approaches outlined above can guide decision-making, there are limitations, as illustrated by some of the most difficult decisions that are made by healthcare organisations – for example around reproduction/fertility and end of life. Such decisions are becoming more complex over time, with particular ethical challenges surrounding consent, confidentiality and disclosure, both in clinical practice and research. Furthermore, the implications of decisions made by healthcare organisations extend beyond the clinical realm, impacting also on the wellbeing of individuals and communities, and quality of life. With this complexity in mind it is unsurprising that good decision-making cannot satisfactorily be reduced to a simple check list or algorithm. Patients, professionals and the public have high expectations of the NHS, including compassion, consideration, empathy, integrity, reliability, rigour and sensitivity, with the balance of such factors varying according to the specific context or type of decision being made. Accordingly, in addition to values/principles and process there is also the need to consider the *qualities* of individuals and organisations in decision-making. Further examples and discussion are provided in appendix 5.

### 3.5 Conclusions

Neither ethics, nor the law and the courts can be relied upon to provide hard and fast answers. They do, however, provide parameters within which decision-makers must operate. If the courts are moving towards a ‘culture of justification’ (see appendix 4) it would be prudent that NHS Boards did so first. Law and ethics can operate together to provide decision-makers with tools to help in analysing difficult decisions and justifying more robustly the decisions that are reached.
4 Current approaches to making difficult decisions in NHS Boards

4.1 Introduction
The short life working group carried out a brief study of existing practices and policies in NHS Boards in Scotland with respect to difficult decision-making in the two areas of:

- Planning (prioritisation frameworks and approaches to disinvestment)
- Individual patients (e.g. complex/ exceptional case panels, non-formulary prescribing etc)

4.2 Approaches to making difficult decisions in use in NHS Boards
The short life working group identified a checklist of factors that they considered to be important or essential in decision-making and reviewed the decision-making approaches in territorial NHS Boards against these factors. Further detail is provided in appendix 6. From this review a number of observations were made as described below.

While there were examples of NHS Boards incorporating elements of Accountability for Reasonableness into their decision-making, and other examples of NHS Boards attempting to identify ethico-legal values/principles that could be used in making decisions, no single NHS Board had a approach that described each of the following: the criteria that trigger different types of decision-making processes, the processes themselves, the values/principles used in making decisions, and the qualities of decision-makers.

While there are a number of common approaches in use across Scotland, the returns from the various NHS Boards indicated that there are important differences in decision-making for both prioritisation/ planning and individual patients.

There are difficulties with the existing terminology for NHS Board decisions about individual patients in which the concept of “exceptionality” is often used. As noted in a recent court case in England (Ross – see appendix 4), this approach implies that the requirement is to demonstrate uniqueness rather than exceptionality. While it may be reasonable to suggest that, where a decision sets a precedent for a wider group of patients, such decisions
should link to the prioritisation/planning or policy development processes, the timescales for such a process are likely to be too long for the individual patient who may, for example, have severe symptoms or have terminal disease. Additionally, the term “complex case” may be used and interpreted differently by different groups – for example, the complexity may be seen to relate to the patient’s condition rather than the decision-making. As a result, the term “individual funding request” is now entering common usage in some parts of the UK, while in Scotland the term “individual treatment request” is favoured and will be used throughout this report.

Finally, it is important to note that decisions taken at individual patient level might, over time, have relevance to a wider group of patients. Accordingly, whenever more than a very small number of patients are considered to be “exceptional”, NHS Boards should consider appropriate mechanisms for sharing and reflecting on such decisions and the means by which they should feed into the planning/ prioritisation process. This would demonstrate that NHS Boards are being proactive rather than reactive in meeting the needs of their population.

4.3 Conclusions

Over recent years many NHS Boards in Scotland have worked towards more systematic approaches to decision-making, both at planning and individual patient level. However, there are major variations in approach across Scotland, and the approaches will require development and refinement. There needs to be more clarity about the criteria that trigger the decision-making process, the approaches used to make such decisions (the interplay of process, values/principles and the qualities of decision-makers), and how the planning/ prioritisation process and decisions about individual patients relate to each other.
5 The way forward: a framework for making difficult decisions

5.1 Introduction

This chapter builds on the ideas of the preceding sections to develop a specific framework for NHS Boards to make difficult decisions, whether for planning/prioritisation or for individual patients.

Box 3 provides a glossary of the key terms used in this chapter.

Box 3. Explanation of key terms (see section 5.2.2)

There must be clear criteria to trigger the decision-making process.

The values which we share are generally accepted judgements of what is valuable and important – for the NHS these include social solidarity, mutuality, effectiveness, efficiency, safety and quality.

Ethical principles are valuable tools to assist in deliberations to determine what is at stake. They can help us to assess the consequences of different possible outcomes and to assess the consequences of preferring any one option over another. Examples include respecting patient autonomy, seeking justice, doing good, and avoiding harm.

In understanding the qualities of individual decision-makers and the organisations they work for, we encounter the idea central to ethical thought in western and eastern traditions, and from ancient times through to the present-day, that good ethical decision-making involves developed powers of judgement, deliberation and choice. These can sometimes be referred to as "virtues" or, as in this report, "qualities".
5.2 The framework

The following diagram describes a framework that NHS Boards could use when making decisions about either planning/prioritisation or individual patients.

**Figure 1. Framework for making better decisions**

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<tr>
<th>Requirements</th>
<th>Approach</th>
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<tr>
<td><strong>Communication and involvement</strong></td>
<td>Good communication is essential at all stages of the process</td>
</tr>
<tr>
<td>Publicise, consult and involve professionals, patients and public in the development of approaches to be used in difficult decisions</td>
<td>Develop approach</td>
</tr>
<tr>
<td>Ensure clear communication of decisions</td>
<td>Publish approach in easily understood language</td>
</tr>
<tr>
<td><strong>Making difficult decisions</strong></td>
<td>Consult public, professionals (and patients)</td>
</tr>
<tr>
<td>Identify and clearly define: - the people involved in making the decisions and their roles, responsibilities and qualities</td>
<td>Refine approach</td>
</tr>
<tr>
<td>- criteria that trigger the decision-making process</td>
<td>Identify the dilemma</td>
</tr>
<tr>
<td>- values/principles for specific contexts</td>
<td>Identify the values/principles which frame the decision to be taken and where there is agreement and disagreement over these values/principles</td>
</tr>
<tr>
<td><strong>Appeals</strong></td>
<td>If agreement: identify justification and assess reasonableness of decision</td>
</tr>
<tr>
<td>Ensure the ability to appeal decisions with clearly defined referral criteria and process</td>
<td>If disagreement: consider reasonableness of disagreement and relative justifications; revisit core considerations if necessary</td>
</tr>
<tr>
<td><strong>Enforcement</strong></td>
<td>Decision should be communicated back to clinicians/managers and patients</td>
</tr>
<tr>
<td>Ensure accountability and responsibility at NHS Board level</td>
<td>If the decision is contested then there should be an appeals process, and this should be well publicised and meet the conditions of good decision-making summarised in the text.</td>
</tr>
<tr>
<td>The planning/prioritisation cycle, individual treatment request panels and appeals panel should report direct to the NHS Board, and should each include representation at director level.</td>
<td>By introducing the approach described here, the NHS Board will be able to build reasonableness, transparency, procedural fairness and accountability into its decision-making process.</td>
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The rest of this chapter considers each of the requirements laid out in this framework in turn:

5.2.1 Communication and involvement

Professionals and the public should be involved and consulted in developing approaches to making difficult decisions (for planning/ prioritisation or for individual patients). This might involve members of the public in weighting of values/principles or could include NHS Board non-executive members in developing and implementing approaches to decision-making. However, patients should not normally be involved in making decisions about other individual patients.

It should be acknowledged that certain groups may be under-represented in decision-making forums (e.g. children or people with learning disability), so it is important to think about how their interests are represented.

Once the policy for making Difficult Decisions is finalised, NHS Boards should make it available to:

- clinicians/ managers/ service for planning/ prioritisation
- patient and clinician for decisions about an individual patient
- general public

The results of the difficult decision-making process should also be communicated appropriately.

5.2.2 Making difficult decisions

The building blocks for making difficult decisions

How can difficult decisions be made? It is not possible to provide a single easy formula and this report does not pretend otherwise. It is possible, however, to provide guidance for the development of a framework by each NHS Board.

**Box 4. Better decision-making**

**Remember:** Better decision-making is when decisions can be justified, are taken with the right motives in mind, reflect commonly agreed values, and are taken against a background of considerations with which most reasonable persons would agree or, if they do not agree, they can at least see which considerations were used and how the particular decision was reached.
We propose a robust decision-making framework should include the following:

- **Clear timetable:** For planning purposes, decisions should be made to a clear timetable that is set well in advance and allows all parties to attend meetings, understand their role, review the submitted evidence and seek further information as required. For decisions about individual patients there will need to be more flexibility about the timing of decisions, but again there needs to be the ability for all parties to view and understand the evidence and for decisions to be timely.

- **The responsibilities of decision-makers:** Decide who is to be involved, in what role, and their responsibilities. Ensure that decision-makers are aware of the impact of their decisions on wider issues – for example the effect of prioritisation on health inequalities, or the consequences of an individual treatment request on future policy.

- **Clear criteria to trigger the decision-making process:**
  - For planning/prioritisation it will usually be necessary to demonstrate that this is a new service development, perhaps reflecting local priorities based on need, or a Scottish Government Health improvement, Efficiency, Access and Treatment (HEAT) target.
  - For an individual treatment request it will usually be necessary to identify whether the NHS Board has a policy on the issue that has arisen (see also section 4.2 on exceptionality). Specific criteria will need to be developed by the NHS Board to account for local structures and existing arrangements. For treatments where a policy already exists the criteria may include the requirement that the patient is significantly different to other patients or likely to gain significantly more benefit from the intervention. Other criteria may address new technologies that have not been considered by NICE or NHS Quality Improvement Scotland (QIS), or where these organisations have not reached a decision about the intervention.
  - These considerations are interconnected – if a series of individual treatment requests for a new treatment/procedure or
investigation are approved then that intervention should be considered through the planning/prioritisation and policy development processes.

- **A sound evidence base**: Identify the key relevant facts. Exclude those facts that are irrelevant. Decide what is fact and what is opinion. Decision-making at all levels requires evidence – for example around clinical effectiveness, size and needs of the affected population, cost and cost effectiveness (e.g. see appendix 2). These technical issues can be supported by information available either through a health needs assessment or published literature. However, for some treatments or services there will be limited or no evidence to support a decision one way or another, particularly for new and expensive treatments for rare conditions: it is even more important to have a proper difficult decisions process in these situations.

- **Values/principles to guide the deliberations**: Assess what is at stake, and what the consequences are of preferring one option over another. Identify which values/principles support which option and which do not. This point is discussed in more detail on the following page.

- **Justification and reasonableness**: Assess whether the final decision is justifiable. Values/principles and qualities of decision-makers are important here. Assess whether the decision is rational and reasonable and followed a fair and transparent procedure. This is the benchmark used by the courts.

- **Reasonable disagreement**: What happens if the decision-makers cannot agree? Consider: whether the dilemma has been correctly identified; whether values/principles at stake have been fully explored; whether the basis for the disagreement is a matter of values/principles or mere preferences; and ultimately whether it is necessary to revisit the core considerations.

**Box 5. Reasonable disagreement**

There may be several ethically justifiable outcomes to any given dilemma: which means that it may be entirely reasonable for different NHS Boards to come to different decisions about the same treatment or condition.
Values/principles and qualities

The approach described above requires NHS Boards to be clear about the values/principles required for different types of decision-making and the qualities of decision-makers (see also box 3).

NHS Boards should identify the values/principles and qualities that they wish to operate by and promote as an organisation – both in planning/ prioritisation and for decisions about individual patients – and these need to be consistent with codes of clinical conduct that relate to the clinical encounter (e.g. the General Medical Council’s Good Medical Practice). 

These values/principles and qualities will include those that are generic, and those that are specific to certain circumstances. Some, indeed, will relate directly to the “process” of decision-making – for example transparency and the need to communicate the approach to decision-making and rationale for decisions. No one consideration should over-ride and be pre-eminent. From this list of values/principles and qualities, decision-making groups within the organisation will need to identify which ones apply to the circumstances and decisions they are making, as not all will necessarily apply in all circumstances.

The following values/principles and qualities, grouped into procedural, scientific/clinical, and social/cultural, might be helpful as a starting point, and are based on values/principles in other ethico-legal frameworks (see appendices 4 and 5).

Procedural factors: These are integral to the process of decision-making and include transparency, accountability and flexibility. However, NHS Boards need to go beyond simply addressing transparency and accountability. They should also consider integrity and consistency - the ability of the public/ patients to trust the decisions made by healthcare organisations or clinicians is central to the clinical relationship. These are not demonstrated by reports and protocols, but by experience of healthcare and the actions of organisations and individuals.

The concept of respect is also important - healthcare organisations and their staff must respect the views of patients, relatives and carers and professionals – something that is helped by consultation, clear and prompt
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discussion of decisions that affect the patient and services, and excellent communication skills at all levels of the organisation.

*Balance and comprehensiveness* are also examples of procedural values. The care and treatment of individuals must be balanced against the need to improve health and wellbeing of the general population and specific subgroups, both in the short and longer term. The balance of decision-making should recognise the context – for example, for decisions around individual patients the balance may be in favour of compassion, while for planning/ prioritisation it may be towards maximising health gain for a population. Furthermore, while the most powerful evidence may be for interventions that reduce mortality, there is also a requirement to consider those interventions that ease suffering and minimise disability. For all decisions it is important to recognise equality and diversity.

**Scientific or clinical factors**: These include clinical and cost effectiveness, quality and safety (e.g. see appendix 2 – many of these considerations apply both to planning/ prioritisation and individual treatment requests).

**Social or cultural factors**: These can be taken account of, at least in part, through a process of consultation and engagement with the public. However, NHS Boards must go beyond this - considerations of social and cultural values are an important way of testing the impact of decisions against need, equity or discrimination.

In conclusion, the above examples are mainly for illustrative purposes. There is considerable overlap between some of these influences on decision-making – *respect*, for example, has relevance to both procedural and social/cultural values. Specific approaches are contained in Appendices 2, 3 and 5. The values/principles and qualities selected as being important by an individual NHS Board or for decisions around individual patients should be developed and adapted for the specific circumstances. These factors give us a means and a language to better justify the decisions that we reach, and there are likely to be similarities in those chosen by different NHS Boards.
5.2.3 Appeals

An appeals panel for individual treatment requests should consider whether the original process of decision-making was fair (assess reasonableness).

There should be transparency around the decision-making process, criteria for triggering an appeal, clearly defined membership of panel, public involvement and communication of the decision of the appeal. Ideally, the membership of the appeals panel should be different to the group that made the original decision. If new evidence becomes available that necessitates a review of a previous decision around an individual treatment request then that decision should be referred back to the panel that originally considered the individual treatment request, as long as it can be dealt with in a timely fashion.

There is not, however, a formal process of appeal for planning/prioritisation, either for service providers, patients or the public. Members of the public can, however, make their case through democratically elected representatives (e.g. Member of Scottish Parliament (MSP)) or by contacting the NHS Board directly (typically through the NHS Board’s complaints system – see the Health Rights Information Scotland website for more information on this process - www.hris.org.uk/index.aspx?o=1025). The involvement and public consultation process required in relation to major service developments provides a further opportunity for public and professionals to influence decision-making at a meso or macro level.

5.2.4 Enforcement

The NHS Board is ultimately responsible for the operation of its prioritisation process and individual treatment request panels.

5.3 Implementing the framework

The approach described provides a decision improvement cycle (figure 2). This process may be complex and iterative, such as some priority setting processes, or more simple such as making a decision about an individual patient. The decision-making process is not static. Rather, it is dynamic, to account for changes to systems and influences, and experience. This means regular review of the decision-making process itself, the criteria that trigger the decision-making process and the values/principles and qualities relied
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upon to guide the decision-making process. The training needs of decision-makers will also need to be considered.

**Figure 2. The decision improvement cycle**

Following the introduction of a decision-making process based on the framework described in section 5.2, NHS Boards will need to reflect on their decision-making, considering whether the approach is:

- **Reasonable**: the relevant criteria and values/principles and qualities have been identified for that situation and context; irrelevant values/principles and qualities have been excluded; there has been a clear and coherent process with clear objectives; if the decision-makers are legitimate and informed

- **Transparent**: the decision and its underlying process is open to public scrutiny; there is clear and concise communication of the reasons for the decision

- **Procedurally fair and accountable**: there is regular testing and reviewing of the criteria and values/principles and qualities as they are applied in the different contexts; there is a clear and coherent explanation of the decision outcome and the reasons for that outcome; the decision has been through a process that itself can be justified.
5.4 Conclusions

The approach proposed above identifies the key requirements that NHS Boards need to meet in addressing difficult decisions and, unlike other frameworks, demonstrates how process, values/principles and qualities can be addressed together, providing a practical and realistic approach to decision-making. The NHS Boards would, through this approach:

- work with public, patients and professionals at all stages
- develop a trusting relationship by demonstrating reasonableness, transparency, procedural fairness and accountability
- communicate with the public and professionals who may not currently understand the NHS Board’s approaches to making difficult decisions
- require decision-makers to reflect on the values/principles and qualities which inform their decision-making (which can be considered under three headings: procedural, scientific/clinical, and social/cultural)
- provide means to express reasons for decisions and justifications for outcomes
- embrace the evolving nature of decision-making: criteria and values/principles and qualities must be regularly revisited to ensure that they remain fit-for-purpose over time.

Therefore we recommend that NHS Boards:

- work towards implementing processes based on the framework presented in section 5.2 for planning/prioritisation and decisions for individual patients
- develop criteria, values/principles and qualities for such decision-making that meet local requirements
- review the process after a set period – what has been learnt, is it working, how to improve?
- NHS Boards should consider the training needs for those involved in the formal processes of making decisions.
6 Implications for NHS Boards

The short life working group’s findings summarised in this report have a number of implications for NHS Boards in Scotland.

In the short term, while many NHS Boards in Scotland have made progress in developing approaches to making difficult decisions, for prioritisation/planning and/or individual patients (chapter 4), further work is required in all NHS Board areas to ensure that these approaches are reasonable, consistent, comprehensive, and defendable. The framework presented in chapter 5 offers a detailed approach to making difficult decisions that captures process, values/principles and qualities – moving our understanding beyond other frameworks and approaches to making difficult decisions which have tended to focus on process or values/principles, but not both together. This framework should be adapted to the requirements of individual NHS Boards and their committees.

Once the NHS Board has decided to further develop its approaches to decision-making, the following points should be considered:

**Panels vs individuals**: Decisions may be perceived as being fairer if there has been involvement from a range of individuals rather than the result of the deliberations of one individual. Having representation from a variety of stakeholders allows different values to be reflected within the processes and helps ensure greater accountability in the system. It is essential that decision-makers are credible and competent so that the public, patients and professionals can trust their decisions. Any vested interests or conflicts of interest of panel members should be clearly stated and appropriate steps taken according to the specific circumstances.

**Patient and public involvement**: As stated in Better Health, Better Care,¹ a key component of ensuring quality in healthcare is to make care patient-focused by providing care that is responsive to individual patient preferences, needs and values and assuring that patient values guide all clinical decisions. However in deciding what treatments to provide, NHS decision-makers should balance the needs and wishes of individuals and the groups representing them, against those of the wider population. Incorporating this
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perspective into decision-making is important, but not always easy to achieve.

A key question is who to involve in order to reflect an appropriate range of perspectives within the process. Patients can provide a valuable insight into the impact of the disease but may find it demanding to be involved in decisions that could ultimately limit access to treatments for their conditions.

While there is no easy way to establish the social values of particular communities, whether geographical or communities of interest, or to obtain a picture of the “common good”, one way to approach this is likely to be a deliberative process involving a broadly representative group of the community. Involving members of the public, who bring their own values/principles and qualities, will give the decisions greater legitimacy.

Patient/public representation can be challenging and resource and time-intensive because the decisions they are being asked to be involved in are generally complex, leading to a significant information burden if engagement is to be informed and meaningful. Nonetheless, NHS Boards should have a clearly publicised approach to public involvement in making difficult decisions whenever possible. It is also clear that the difficult decisions made by healthcare organisations are not static, but are continuously evolving, which necessitates ongoing engagement with patients and the public.

**Documentation and communication:** Decision-making processes need to be written down and communicated. The discipline of capturing the criteria, values/principles and processes by which decisions are made can help all parties understand and refine the approach. Fair processes require publicity and accessible information about the processes, reasons and rationales that are important in reaching decisions. This not only aids appropriate engagement by stakeholders with the processes and ensures transparency, but it helps to ensure there is a common understanding of the objectives of the system being used. Clearly set out processes can also help to reassure stakeholders and the public that decisions are not being made arbitrarily behind closed doors. This also becomes important in the event of legal challenge to decisions.

A fundamental aspect of fair processes is that they should have the opportunity to be challenged and revised by stakeholders or individuals.
Understanding the basis on which decisions have been made is a vital step on the road to being able to appeal against a decision and/or improve the decisions made in the future. Appropriate documentation ensures that this can happen readily.

In addition, good practice in recording decisions should facilitate consistency in decision-making by providing ready access to precedent. The communication of decisions – to clinicians, patients and, when appropriate, the general public – is therefore essential. NHS Glasgow and Clyde provides an example of how to communicate decisions about individual patients (see appendix 6). NHS Boards should also publicise the outcomes of any prioritisation process, both to the public and to the clinicians and managers who make applications through the prioritisation process.

**Exceptionality vs complexity**: A particularly problematic issue concerns how to deal with the personal circumstances of individuals who may wish to have access to a treatment because they are judged to have “exceptional” circumstances. This could be for example, because they have a young family or are a carer, and consider that such factors are relevant to the decision being made (social factors). Or it could relate to specifics of their medical condition and likelihood to benefit from treatment. NHS Boards must decide how to address such cases, including the criteria around individual treatment requests (see section 4.2), the values/principles and qualities of decision-makers to be included in decision-making, and the implications for other similar cases that could be affected by the decision.

**Timescales**: Timescales for decision-making will vary depending on the context, and the mechanisms for making decisions should reflect these differences. For example, the decision-making cycle for planning/prioritisation may be made on a yearly basis. In contrast, decisions about individual patients will often be required much more urgently. However, the impacts of these timescales should be kept under careful review – a yearly cycle for planning/prioritisation may prove too inflexible for some decisions.

**Adequate resources to support processes**: The impact of the framework described in chapter 5 on NHS Boards should not be underestimated. There will be additional requirements on administration, professional, managerial and executive staff in the NHS Board and costs associated with publicity,
communication and public consultation. NHS Boards should also consider the training needs of decision-makers in their organisation in order to implement the framework.

**Application to other types of decision-making:** During the early stages of this work – principally the Difficult Decisions Workshop (February 2008 – full report available at [www.nhsfife.scot.nhs.uk/difficultdecisions](http://www.nhsfife.scot.nhs.uk/difficultdecisions)) – discussions were broader than this current report and included “disinvestment”. This topic has been addressed over the past decade in various forums, but has typically focused on relatively minor surgical procedures including grommet and varicose vein surgery (though it can be argued that NHS Boards do manage to reduce inefficiencies and unnecessary procedures or services through service redesign, with consequent improvements in quality of care: one example is provided by shifting the balance of care from hospitals to the community). More recently, NICE and the Scottish Intercollegiate Guidelines Network (SIGN) have signalled that they are starting to consider the topic of disinvestment in more detail. One possible outcome of the NICE and SIGN work will be that NHS Boards may be asked in the future to draw up approaches to discontinuing or limiting access to a range of procedures and treatments. The framework described in chapter 5 could be used to facilitate such a process in individual NHS Boards (or at a regional or national level).
7 Appendices

1. Membership of SLWG (page 32)

2. NHS Lothian prioritisation process (page 33)

3. NHS Highland ethico-legal framework (page 34)

4. Legal issues (page 36)

5. Ethical issues (page 40)

6. Analysis of approaches to making difficult decisions in Scottish NHS Boards (page 42)
Appendix 1. Membership of SLWG

Chair: Dr Gina Radford, Director of Public Health, NHS Fife (now working in NHS Cambridgeshire)

Ms Ailsa Brown, Principal Health economist, NHS Quality Improvement Scotland

Mr Brian Devlin, Interim Head of Strategic Support and Ethics, NHS Highland

Dr Sara Davies, Consultant in Public Health Medicine, Scottish Government

Professor John Haldane, Professor of Philosophy and Director, Centre for Ethics, Philosophy and Public Affairs, University of St Andrews

Professor Graeme Laurie, Professor of Medical Jurisprudence, University of Edinburgh

Ms Liz Macdonald, Senior Policy Advocate, Consumer Focus Scotland

Ms Jackie Sansbury, Director of Strategic Planning, NHS Lothian

Secretariat: Dr Graham Mackenzie, Consultant in Public Health, NHS Lothian
Appendix 2. NHS Lothian prioritisation process (2009/10) – principles against which proposals are assessed (see page 12 in report for further explanation)

<table>
<thead>
<tr>
<th><strong>Clinical Effectiveness</strong></th>
<th>An evidence based assessment of how well a treatment or intervention works, resulting in proven benefit to patients through symptomatic improvement or quality of life scores.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cost Effectiveness</strong></td>
<td>An assessment of the number of patients who are likely to benefit and the extent of that benefit for a given level of investment.</td>
</tr>
<tr>
<td><strong>Equity</strong></td>
<td>The extent to which an investment will achieve and ensure that all have access to services. This can apply to access at geographical locations or through time that they have to wait for treatment or appointment. People of equal ‘need’ are treated equally.</td>
</tr>
<tr>
<td><strong>Inequity</strong></td>
<td>The extent to which a service investment will target the most vulnerable sectors of the population to reduce inequalities in health status.</td>
</tr>
<tr>
<td><strong>Quality</strong></td>
<td>The extent to which investment will improve inputs, processes and environmental factors which impact on patients/staff perception of a service. This does not include clinical effectiveness, nor does it include compliance with mandatory standards.</td>
</tr>
<tr>
<td><strong>Strategic Fit</strong></td>
<td>The extent to which investment facilitates or is a necessary part of service modernization. This includes sustainability.</td>
</tr>
</tbody>
</table>
### Appendix 3. NHS Highland ethico-legal decision-making in healthcare – seven values/principles

(see page 13 in report for further explanation)

<table>
<thead>
<tr>
<th>Value/principle</th>
<th>Essence</th>
<th>Application of this value means:</th>
</tr>
</thead>
</table>
| 1. Engagement   | Engagement of all stakeholders in decisions into which they can have an input, and ensuring that they are involved, informed and listened to. | • Enabling and empowering people by supplying them with information so that their input can be informed.  
• Ensuring that mechanisms are in place for wide ranging participation, involvement, consultation and collaboration.  
• Facilitating quality communication, which in turn requires honest dialogue.  
• Being accessible and approachable.  
• Truly listening to and hearing, the preferences and opinions of those involved, giving a real opportunity to contribute to and participate in the setting of standards, aims and objectives.  
• Appreciating that even if the final outcome doesn’t satisfy all parties that this does not render the process of engagement either ineffective or valueless. |
| 2. Flexibility  | Ensures the ability to accommodate and be open to all needs, both within relationships formed by the NHS Board and in its organisation of services. | • Accessibility, both to contacts, people and services.  
• Remembering the individuality of every different person or patient and that there may be the need for the organisation of services at different levels in different areas to meet the needs of particular communities.  
• Having the capacity to adapt or modify to accommodate different needs at different times.  
• Being open to cooperation. |
| 3. Relationships | The establishment of meaningful relationships and the extent to which each party feels able to communicate freely and critically with others. | • Ensuring and facilitating a simple and effective communication process.  
• Being accessible, responsive and recognising the importance of letting voices be heard.  
• Being honest, open and cooperative.  
• Being respectful, considerate and sincere.  
• Being available to explain and to answer.  
• Ensuring that there is provision for the fair resolution of grievances and complaints. |
| 4. Accountability | Ensuring that throughout, the system is open and transparent, fostering a clear division of responsibility. Being clear ‘where the buck stops’. | • Being open and transparent in our decision-making and actions, with the decisions and the reasons behind them being clear and publicly accessible.  
• Explaining, and if necessary justifying, courses of action to interested parties.  
• Effective communication and freedom of information where appropriate.  
• Clarity as to responsibility for decisions.  
• Making sure people know they can question a decision, who to approach and that they will receive an answer. |
<table>
<thead>
<tr>
<th>Value/principle</th>
<th>Essence</th>
<th>Application of this value means:</th>
</tr>
</thead>
</table>
| 5. Justice     | Ensuring that those who come into contact with the delivery of healthcare can be sure that they will be dealt with on the merits of their case, without discrimination and with equity. | - Being even handed, just and fair in our actions.  
- Ensuring both procedural justice, i.e. the inherent fairness of the decision-making process and distributional justice, which means fairness characterised as equality of access to services and treatments, ensuring equal opportunities.  
- The delivery of services on a fair or equitable basis.  
- Realising that equity can sometimes involve treating people differently according to their circumstances but overall remembering that equal needs should get equal chances and opportunities.  
- Recognising that fairness is not always achieved by mere mechanistic or mathematical formulae. |
| 6. Quality     | The provision of the best possible healthcare and service in terms of experience, relationships, treatment and outcome. | - An assessment of the extent to which healthcare meets the needs, demands and expectations of those it is designed to serve.  
- Assessing the actual effectiveness of services in terms of health gain and benefit.  
- Using the best possible evidence and professional advice available and considering all options and alternatives.  
- Examining the totality of experience of one person’s care, not just the outcome, and assessing the levels of satisfaction with the system of all those involved.  
- Courtesy, consideration and sensitivity in all dealings.  
- Competence and reliability. |
| 7. Realism     | Realism demands that those charged with the provision of healthcare realistically take account of both limitations and opportunities and it plays an important role in the harmonisation of demands and expectations. | - Being honest and open.  
- The NHS Board fulfilling their explanatory and educational role to stakeholders, be they actual or potential recipients of healthcare, in an honest fashion so that expectations can be both reasonable and informed.  
- Examining alternatives and weighing up the pros and cons of each course of action.  
- Questioning effectiveness and appropriateness.  
- Recognising that sometimes there is a balance to be struck between aspirations and financial viability or feasibility. |
Appendix 4. Difficult decision-making in the NHS: the role of law and the courts

This appendix provides supporting evidence for section 3.3 in the full report (page 13).

We live in an age of human rights, bringing benefits across society. These human rights extend across a wide range of human experience from the right to life, to the right to respect for private and family life; from the right to liberty to the right to be free from torture or inhuman or degrading treatment.

In the international frame, there are rights that include the right to ‘the enjoyment of the highest attainable standard of physical and mental health.’

At the national level, however, there are no such legal rights; rather the Scottish Ministers are duty-bound to promote a ‘comprehensive…health service’, which raises more questions than it answers and does not provide specific help for NHS Boards as to the nature and scope of this duty and associated patients’ rights.

Law and lawyers are used to dealing with abstract concepts, such as justice, fairness, responsibility and accountability. It is something of a myth, however, that the law is concerned with clear rules that can be applied to produce the ‘right’ or ‘lawful’ answer; matters are often more complicated and it is the role of the courts to determine the lawful outcome when disputes arise between parties about the lawfulness or rightfulness of a particular course of action. So it is with disputes over the appropriate allocation of scarce health resources.

Decisions on allocation of resources can be challenged at the national, service or individual patient levels but in all cases the challenge takes the same legal form, being a judicial review of the original decision-making process.

Judicial review in the context of the health services is a procedure whereby the courts consider the appropriateness of a decision by a public authority which, it is alleged, has had an adverse effect on an individual’s rights or general welfare. A Scottish NHS Board or an English and Welsh Health Authority are unquestionably ‘public authorities’ whose decisions are subject to challenge. The grounds for such challenge are limited to a few key arguments: illegality, irrationality and procedural impropriety. The traditional
benchmark is whether the public authority has reached a decision which *no reasonable public authority* could have reached.

Notably, the courts in the United Kingdom north and south of the border have engaged in a culture of caution when it comes to exercising their role in judicial review. In particular, the focus has been on the correctness of the decision-making *process* and not on the *substance* of the decision actually taken. Put another way, the courts have not intervened to tell public authorities which decision they *should* have taken, but rather they have at best ruled that the decision that was taken was arrived at by an unacceptable means and that it cannot stand. Thus even in cases of ‘blanket bans’ the courts will not tell a Board or Authority what to do. In *North West Lancashire Health Authority v A,D and G*¹⁰ a blanket ban on gender reassignment surgery had been imposed by the Authority and this was found to be unlawful by the court. However, the court would not tell the Authority that it was required to offer the procedure; the unlawfulness of the policy came from the flawed reasoning in deciding to give no funding at all to a procedure without due consideration of the fact that it is supported by respectable clinicians and psychiatrists and said to be necessary in certain cases to relieve extreme mental distress.

The net effect of a successful judicial review is not, therefore, that a public health authority must come to a different conclusion; rather it must revisit its procedures for decision-making to ensure that they are not unreasonable, not illogical and so not illegal. The usefulness of this for decision-makers within the National Health Service will be lost on many readers.

The nadir of judicial assistance in resource allocation is arguably the case of *Child B*;¹¹ here the Court of Appeal declared lawful the decision of Cambridgeshire Health Authority not to fund treatment (c.£75,000) for a ten-year-old girl suffering from leukaemia despite evidence from external experts of 10-20% success. The Court said:

“Difficult and agonising judgments have to be made as to how a limited budget is best allocated to the maximum advantage of the maximum number of patients. That is not a judgment which the court can make. In my judgment [per Sir Thomas Bingham] it is not something that a health authority such as this authority can be fairly criticised for not having advanced in court.”¹²
The *reasonableness* of the Health Authority’s decision to follow its own advisors in this case held sway and the Court did not require the Authority to go further in justifying its decision to refuse to fund the treatment.

Perhaps more assistance can be found in the case of *Ms Rogers*. Ms Rogers circumstances involved a refusal by the Primary Care Trust (PCT) to fund the cost of her treatment with Herceptin for stage 1 breast cancer at a time when there was no Product Licence from the Department of Health for stage 1 care and before the drug had been assessed in this respect by the National Institute for Health and Clinical Excellence (NICE). (At that point in time the drug was only approved for more advanced (stage 2) breast cancer). Ms Rogers’ case was considered by the PCT’s Exceptional Case Committee but it ruled that her case was not ‘exceptional’ because she was, in effect, the same as other stage 1 patients of her class; because there was inadequate evidence to support the use of the drug in such cases; and it noted that cost was *irrelevant* to its decision. This policy was found to be *illogical* by the Court of Appeal at judicial review and remitted back to the PCT to be reconsidered. It was illogical because the PCT had itself stated that cost was irrelevant and that it would fund Herceptin for some of its patients; the only remaining *reasonable* basis upon which to decide between patients was their own clinical need and, since Ms Rogers’s own physician had wished to prescribe Herceptin, to deny a patient such as Ms Rogers the treatment on the basis of the policy as expressed would be discriminatory and so *illegal*.

NICE itself has come under judicial scrutiny. In *Eisai Ltd* the pharmaceutical company challenged guidance from NICE on the use of acetylcholinesterase inhibitors for Alzheimer’s disease which restricted use to patients moderately affected by the condition. The Court of Appeal held that NICE was subject to procedural fairness both with respect to the appraisal process and any consultation exercise. The failure of NICE to release a fully executable version of the economic model used to assess cost-effectiveness and which ultimately informed the guidance was unlawful; *fairness* required consultees to be given the opportunity to test the reliability of the model for themselves. A very high degree of transparency and disclosure was required, notwithstanding the Institute’s considered position and the additional time and cost involved.

Most recently, Mr Ross’s case has shed some light on ‘exceptional case’ policies. The claimant challenged the continuing refusal of his PCT to fund a
new cancer drug to treat his multiple myeloma, even after evidence that intolerable peripheral neuropathy made treatment with the original drug impossible; even when the only option arising from the refusal was palliative care; and after an internal appeal and review upheld the denial of treatment. The High Court held this refusal to be one that *no reasonable health authority* would take on the following grounds: (1) the trust's policy was unlawful because it contained a contradiction in terms and was *illogical*: a person was automatically disqualified if he was likened to another. This meant, in fact, a patient had to show uniqueness rather than exceptionality. ‘Exceptionality’ should be given its ordinary meaning, and on this meaning the claimant had shown that he was exceptional because his peripheral neuropathy rendered treatment with all existing means an impossibility. (2) Where matters of extending life were concerned, a trust should take a less restrictive approach to cost effectiveness when considering the case for funding; moreover, the panels had proceeded on a misunderstanding of evidence in relation to the survival rate of patients given the drug, as well as other factors, and ought to have upheld the case as one of clinical efficacy.

This last case should be read with a degree of caution because it was delivered by one judge sitting alone and is subject to appeal. Notwithstanding, it can be seen from this brief account of key cases that the courts in England & Wales (and we would speculate Scotland might follow suit) are becoming bolder with respect to their role in judicial review cases involving the allocation of scarce health resources. This may be evidence of a shift from a culture of caution to a ‘culture of justification’ whereby the courts will show themselves more willing in the future to require public authorities to justify their decisions more carefully and more robustly.
Appendix 5. Difficult decision-making: a consideration of values of individuals and organisations

This appendix provides supporting evidence for section 3.4 in the full report (page 14).

Decision-making is a form of practical reasoning which may concern either the process of achieving an outcome, or the outcome itself.

Experience reminds us that dilemmas often involve choosing between options, each of which promises to lead to a valued outcome. Option A may result in a few people having their lives extended, while option B may bring a small but significant improvement in quality of life to a much larger number of people. NHS Boards face such difficult decisions on a regular basis.

At the time of the creation of the NHS (1948) it was not thought that health services would need to be rationed, for it was assumed that as people’s health was improved, so spending would decline. It was, in other words, a quantifiable solution to a limited problem. What this overlooked is that ‘health’ is a partly normative, as well as an empirical idea, and that as health relative to one level improves, so the calibration of what counts as ‘health’ is revised upwards and with this expectations also rise. The eradication of polio and effective treatment of tuberculosis did not fulfil the aim of establishing health but merely raised the bar. The next successes were treatment of heart disease, strokes, cancer, infertility and many other conditions. So while resources are limited, demands are not.

With the wellbeing of individuals and populations at issue, decision-making in healthcare has a moral or ethical dimension. This introduces further complexity that extends beyond familiar life and death controversies such as abortion and cessation of treatment. Current ethical challenges include those surrounding consent, confidentiality and disclosure, autonomy and competence, non-therapeutic research, assisted reproduction and gene therapy, rationing and allocation, inter-professional relations and many others. This increasing complexity has coincided more or less with a decline of confidence in the existence of shared moral values in many parts of society, and in the moral authority of healthcare professionals.
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Where once life seemed relatively simple it is now complex and our resources for dealing with these complexities seem few and frail. One response has been to fashion professional ethical codes.

Another approach comes from first recognizing that decisions relating to values are complex, involving contested and conflicting goals, and locate decision-making within a more subtle framework than is usual. Within such a framework, one guiding principle should be to provide the greatest improvement in health to the greatest number of people (a utilitarian approach), but this must be balanced against respecting the autonomy of patients and clients (a rights-based approach). These two influences on decision-making are generally thought to represent exclusive and exhaustive options. However, there should also be a dimension to decision-making: that of the orientation of the healthcare provider or manager towards the fulfilment of certain values, or the realization of certain ideals. These approaches together constitute a ‘three dimensional decision space’ framed by utility, autonomy, and qualities or good character.

This approach has implications both for the training of healthcare professionals and for decision-making within healthcare. In addition to having a robust decision-making process, it is necessary to draw upon a range of qualities: compassion, confidence, consideration, courage, honesty, humility, humour, idealism, integrity, loyalty, modesty, perseverance, reliability, sensitivity, service, truthfulness and understanding.

Of themselves these will not determine a single solution, nor will the addition of regard for utility and attention to rights necessarily prove sufficient to resolve an issue beyond contention. That, however, becomes less of a problem when those involved, both healthcare professionals/ organisations and patients, recognize that the business of decision-making has been pursued not by consulting a rule book or applying a current algorithm, but by deliberating in a morally serious way about the needs and interests of those involved.

Difficult decision-making cannot be made easy, but it can be made manageable by recognizing the dimensions within which it occurs and by introducing practitioners to the relevant values/ principles and qualities through education and training.
Appendix 6. Analysis of approaches to making difficult decisions in Scottish NHS Boards

This appendix provides supporting evidence for section 4.2 in the full report (page 15).

<table>
<thead>
<tr>
<th>Prioritisation/ planning</th>
<th>Individual patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Levels of decision</td>
<td>Macro – typically conducted on a yearly basis and running over a period of several months</td>
</tr>
<tr>
<td>Decision-makers and responsibilities</td>
<td>Representation in NHS Board areas varies, but tends to involve: Executive director level Clinical representation.</td>
</tr>
<tr>
<td>Values/ principles</td>
<td>NHS Boards are at different stages in developing an approach to ranking different proposals. These range from lists of ethico-legal principles to scoring systems (see also section 3.2).</td>
</tr>
<tr>
<td>Appeals process</td>
<td>No appeals process for prioritisation/planning was described.</td>
</tr>
<tr>
<td>Prioritisation/ planning</td>
<td>Individual patients</td>
</tr>
<tr>
<td>--------------------------</td>
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</tr>
<tr>
<td><strong>Public involvement</strong></td>
<td></td>
</tr>
<tr>
<td>The general public can be involved in decisions about weighting – for example NHS Dumfries and Galloway used Discrete Choice Experiments to weight 10 values/principles.</td>
<td>There is limited public involvement in decisions around individual patients.</td>
</tr>
<tr>
<td><strong>Patient involvement</strong></td>
<td></td>
</tr>
<tr>
<td>No NHS Board reported patient involvement.</td>
<td>No NHS Board reported patient involvement in decision-making, but NHS Glasgow and Clyde Exceptional Case Appeal Panel invites the patient to attend (see above).</td>
</tr>
<tr>
<td><strong>Communication</strong></td>
<td></td>
</tr>
<tr>
<td>No NHS Board clearly described how decisions are communicated to clinicians or the general public.</td>
<td>The approach to communication of decisions relating to individual patients was not stated in the majority of policies and responses provided by NHS Boards. Where information was available, written communication was sent to the patient and clinician in a timely manner (e.g. within a week or month).</td>
</tr>
</tbody>
</table>
Making Difficult Decisions in NHS Boards in Scotland

8 References and notes


9. National Health Service Act 2006, s.1(1) [England] and National Health Service (Scotland) Act 1978, s.1(1) as amended by the National Health Service Reform (Scotland) Act 2004.

10. NW Lancashire Health Authority v A,D and G [2000] 1 WLR 977.


13. R v Swindon Primary Care Trust and the Secretary of State, ex parte Rogers [2006] EWCA Civ. 392.


15. R (on the application of Colin Ross) v West Sussex Primary care Trust [2008] EWHC 2252 (Admin).

16. For argument in favour of this role for the courts, see K Syrett, Law, Legitimacy and the Rationing of Health Care, Cambridge University Press, 2007.
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