Individual Funding Requests for Cancer Drugs and Other Treatments: A Legal and Ethical Analysis of Exceptionality

A thesis submitted to The University of Manchester for the degree of

PhD in Bioethics and Medical Jurisprudence

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Amy Ford

School of Law
‘When the NHS was founded in 1948, it was believed that the demand for healthcare would reduce once the backlog of problems caused by lack of access to healthcare were cleared. But, in practice, as the population increases and new technologies extend infinitely the possibilities for care and cure, and with budgets which are finite, demand for health care will always exceed supply.’

RCN Congress 99 Daily Report - 11th March 1999
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Abstract
The University of Manchester
Doctoral Programme in Bioethics and Medical Jurisprudence
Amy Ford – 28th March 2013

Individual Funding Requests for Cancer Drugs and Other Treatments: A Legal and Ethical Analysis of Exceptionality

This thesis seeks to examine how funding arrangements for cancer drugs and other treatments, which are not available to everyone within the NHS, are made available to some, on the basis of exceptionality. The escalating costs of cancer treatment and the life threatening nature of cancer make resource allocation decisions for cancer drugs particularly acute, and the recent changes to funding arrangements for cancer drugs within the NHS receive particular scrutiny.

In the three papers at the core of this thesis, the concept of exceptionality is explored from legal, ethical and empirical perspectives respectively. The first paper reviews the legal origin of exceptionality as the basis for the allocation of resources for expensive treatments, and explores how the concept has been interpreted by successive judicial reviews concerning access to cancer drugs. Particular attention is paid to the role of social factors in determining exceptionality. Choosing to fund treatment for one patient, and not another, involves a moral choice. In recognition of this, the Department of Health advocates that decision makers use an ethical framework to support decision making regarding exceptionality. The second paper examines the strengths and weakness of Daniels and Sabin’s Accountability for Reasonableness Framework, which is widely used to support resource allocation, focussing on the Relevance Condition, and its applicability to resource allocation within the NHS. The final paper reports the findings of an empirical study examining how PCTs interpret the concept of exceptionality in practice, providing the first comprehensive insight into the factors which are considered in determining whether a patient is exceptional, and exposing some of the external influences on the decision making process.

In conclusion, it is argued that whilst the need for discretionary health funding decisions arises in rare circumstances, where this is necessary such decisions should be made on a national, or at least supra-regional basis, to ensure consistency and fairness. If we cannot afford to fund all effective cancer drugs, and other treatments, we should not hide behind the concept of exceptionality, but should have a national debate about how we reach a consensus on which drugs to fund, and about how we pay for those treatments. Whilst acknowledging that cancer is a dreadful disease, it is also argued that, in the absence of any convincing evidence that the management of cancer deserves preferential treatment, the special status of cancer funding within the NHS, which has become increasingly apparent in recent years, should come to an end.
Declaration
No portion of the work referred to in the thesis has been submitted in support of an application for another degree or qualification of this or any other university or any other institute of learning.

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_________________________________________ 10th June 2013

Amy Ford

National Institute for Health Research
This report presents independent research commissioned by the National Institute for Health Research (NIHR). The views expressed in this publication are those of the author and not necessarily those of the NHS, the NIHR or the Department of Health. The author acknowledges the support of the National Institute for Health Research, through the Primary Care Research Network, with the empirical work reported in Paper 3.
Acknowledgements
Completion of this PhD would not have been possible without the support of a great number of people, and I feel fortunate to have been at the receiving end of so many opportunities over the course of the last four years.

I am grateful to the University of Manchester for funding the first year of my research, which enabled me to embark on this journey, and the NIHR for funding the remaining years which enabled me to complete it. I am indebted to the Brocher Foundation and its staff for their hospitality not just once, but twice, during the course of my research. On both occasions the warm and tranquil environment, paired with the intellectual companionship of people too numerous to mention, proved a combination conducive to both hard work and play.

Realisation of this thesis would not have been possible without the support and encouragement of my supervisors, Margot Brazier, John Harris and Gunn Grande, who have patiently guided me through the unfamiliar territory of undertaking a PhD. To all three, I owe a debt of gratitude. I am also grateful to others who have listened to, read and commented upon my research, including Rebecca Bennett, Barry Lyons and my peers on the Bioethics and Medical Jurisprudence programme, who have been my companions throughout my doctoral research.

I am indebted to the PCT staff who gave up their time to participate in my empirical research, and enthusiastically shared with me their knowledge and experiences, at a time of great uncertainly for the NHS.

To my clinical supervisors and senior colleagues at the Clatterbridge Cancer Centre I am especially beholden. Without the support of Susan O’Reilly it would never have been possible to take leave of absence to engage in this intellectual endeavour. I also owe a debt of gratitude to David Husband and Peter Clark for their encouragement and interest in my research, and for helping to facilitate the opportunity for ongoing clinical experience during my PhD.

Last, but by no means least, I am thankful to my friends and family for their unwavering support and encouragement through the highs and lows of research. Special thanks must go to Rupert Lavender who has, with love and good humour, put up with the significant time commitment at my desk which this thesis has required of me.

Dedication
This thesis is dedicated to an exceptional woman, Patricia Florence Beetham, whose courage and strength whilst undergoing treatment for oesophageal cancer during the final months of my doctoral research was a constant source of inspiration.
The Author
As a medical undergraduate, I was fortunate to have the opportunity to take a year out of medical training at the University of Liverpool, to study for a BSc in Healthcare Ethics and Law at the University of Manchester. I then pursued a full time clinical career, choosing to specialise in medical oncology as a Registrar, completing a part-time MSc in Medical Sciences. However, my interest in medical ethics and law continued to develop, and whilst my peers pursued doctoral programmes offering promises of new cures for cancer, I chose instead to examine how the NHS would finance such cures, once discovered. The first year of my research was funded by a School of Law scholarship, and subsequent years by an NIHR Doctoral Fellowship.

The training opportunities afforded to me during my doctoral research have been invaluable and diverse, from a week studying the economic evaluation of healthcare at the University of York, to courses in qualitative methodology. I have also been able to complete the NIHR trainees’ leadership programme and have benefited from two periods of residency at the Brocher Foundation, Geneva, in June 2010 and again in May 2012.

During the course of my doctoral research I have endeavoured to maintain my clinical skills, undertaking one oncology clinic a week and participating in the on-call rota, in anticipation of my return to clinical practice in 2013 to complete my specialist training in medical oncology. I have also developed my practical ethical problem solving skills through membership of a Clinical Ethics Committee. I intend to continue to pursue my research interests whilst working as a clinician and to this end, was appointed a National Institute of Health and Clinical Excellence (NICE) Scholar in 2012.

Recent Clinical Publications and Presentations
In addition to the publications directly contributing to this thesis, I have also published and presented research relating to the clinical speciality of oncology during the course of my research, including:


Presentations
Some parts of this thesis were presented at academic meetings:

Accessing Cancer Drugs – Are Social Factors Relevant? - Poster Presentation Abstract A152, National Cancer Research Institute, Liverpool, 5th Nov 2012


Ethics applied to exceptional funding decisions – (Invited speaker) Peninsula Public Health Network Seminar, Devon, 14th October 2011

Accessing Cancer Drugs; should age and social factors matter? - European Association of Health Law Conference, Leuven, Belgium, 6th-7th Oct 2011


Accountability for Reasonableness – A solution to the challenge of legitimacy in the funding of cancer drugs only for named individuals? (Abstract C1.5.4) - World Congress of Bioethics, Singapore, 28th -31st July 2010


Papers
The core of this thesis is made up of 3 articles.

One has been published:


The other two papers, Ford A. Individual Funding Requests in Healthcare: What Makes a Patient Exceptional?, and Ford A. Accountability for Reasonableness – Why the Relevance Condition is of no Relevance, have both been submitted for publication to peer-reviewed journals.

In addition, a joint editorial is also referenced in this thesis:

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Sunday Times v UK (1979) 2 EHR 245
Tysiac v Poland (2007) 22 BHRC 155
X and Y v Netherlands (1986) 8 EHHR 235

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Health and Social Care Act 2008
Health and Social Care Act 2012
Human Rights Act 1988
NHS Act 2006
Health Act 2009

Table of Statutory Instruments

Medicines for Human Use (Clinical Trials) Regulations 2004
Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994
NHS (Functions of Strategic Health Authorities and Primary Care Trusts Administrative
Arrangements (England)) Regulations 2002
List of Abbreviations

AMD Age related macular degeneration
CCG Clinical Commissioning Group
DoH Department of Health
ECTHR European Court of Human Rights
GMC General Medical Council
IFR Individual Funding Request
MCDA Multi-criteria decision analysis
NICE National Institute for Health and Clinical Excellence
NPC National Prescribing Centre (now integrated into NICE as the Medicines and Prescribing Centre)
PCT Primary Care Trust
PBMA Programme Budgeting and Marginal Analysis
QALY Quality Adjusted Life Year
SHA Strategic Health Authority

Glossary of Drug Names
Generic drug names have been used throughout this thesis. As some readers may be more familiar with their brand names, these are listed below alongside the generic names.

Bevacizumab - Avastin
Donezipil – Aricept
Erlotinib - Tarceva
Lenolidamide - Revlimid
Ranibizumab - Lucentis
Sunitinib – Sutent
Trastuzumab - Herceptin
PART I - INTRODUCTION
1.0 The Problem: Determining what it means to be exceptional

It is paradoxical that, despite a national health system in England, some treatments, in particular high cost cancer drugs, are only available at the discretion of Primary Care Trusts (PCTs) to those patients who successfully claim that they are exceptional to policies that preclude the provision of these drugs to the wider population. Such an approach begs the question of what it means to be exceptional. Who qualifies as exceptional? In what respect do they need to be exceptional? In comparison with whom are they exceptional? And how will exceptionality be determined? Using exceptionality as a criterion on which to allocate funding for cancer drugs is problematic for patients, and for clinicians, due to the lack of clarity as to who may be eligible for funding on this basis. In addition, the clinician faces a conflict between providing the best possible treatment for the individual patient in front of her, and considering the resource implications for the wider population. Funding patients on the basis of exceptionality raises issues of equity, and brings into question how we decide who will receive treatment when we cannot afford to provide it for all those in need. The judiciary, who tend to adopt an individualistic approach when such cases reach the courts, exacerbate this discord, resulting in a tension between clinical practice, ethics and the law.

This thesis reviews the legal origin of exceptionality as the basis for the allocation of healthcare resources for expensive treatments, and explores how the concept has been interpreted during successive judicial reviews concerning access to cancer drugs. Particular attention is paid to the role of social factors in determining exceptionality. Using evidence of how the concept of exceptionality has been construed by the judiciary, an attempt is made to establish a model of exceptionality to assist in determining whether a patient is likely to meet this criterion. I argue that reaching legally robust decisions regarding patients’ exceptionality is extremely challenging for decision makers, given the nebulosity of the concept in this context. Whilst acknowledging the need for discretionary health funding decisions in rare circumstances, I advance that where this is necessary such decisions should be made on a national, or at least supra-regional basis, in an effort to ensure consistency. It is argued that if we cannot afford to fund all effective cancer treatments, we should not hide

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1 As the changes enacted in the Health and Social Care Act 2012 take effect, this discretionary power will become the responsibility of the Clinical Commissioning Groups (CCGs) which will replace PCTs.
behind the concept of exceptionality, but should have a national debate about how we reach a consensus about which drugs to fund, and about how we pay for those treatments it is agreed should be provided.

Having reviewed the concept of exceptionality from a legal perspective, the notion is then examined through an ethical lens. Choosing to fund cancer treatment for one patient, but not another, involves a moral choice. In recognition of this, the Department of Health (DoH) advocates that decision makers use an ethical framework to support decision making regarding exceptionality.\(^2\) However, no guidance is provided as to which ethical framework is most suited to this role, or which moral values it should embrace. I outline a range of ethical frameworks with the potential to enhance decision making in this context, and select for a more detailed examination the one which, on balance, appears to best meet the requirements of decision making regarding exceptionality. The selected instrument, Daniels and Sabin’s Accountability for Reasonableness framework, consists of four conditions.\(^3\) Despite the framework’s international popularity with policy makers, one of these conditions, known as the relevance condition, has never been adopted in practice. It is this condition which is the focus of the thesis. I establish the constraints on the relevance condition imposed by the framework’s authors, prior to reviewing the theoretical limitations of the relevance condition identified in the literature to date. Acknowledging the limitations of the relevance condition identified thus far, I then examine whether allocating resources to patients on the basis of their exceptionality meets the requirements of the relevance condition. I demonstrate that the relevance condition is too indeterminate to establish this and that, in fact, the relevance condition does not provide a method for distinguishing between legitimate and illegitimate reasons on which to allocate resources for healthcare. I advance that the four conditions of the Accountability for Reasonableness framework are insufficient as an ethical framework for priority setting on the basis of exceptionality, because the relevance condition is unable to do the work claimed, and the framework does not


promote the deliberation which is essential to determining whether a particular reason is relevant to decision making.

This thesis is completed by an empirical study which provides the first comprehensive insight into how PCTs interpret the concept of exceptionality in practice. Although PCT policy documents concerning priority setting are widely available on the Internet, the detail of how the concept of exceptionality is understood and applied has remained something of a mystery. The review of ethical frameworks demonstrates that any tool for improving resource allocation needs to be more than a theoretical template, with applicability to the external world. This requires an understanding of the intricacies of priority setting in real life. The earlier part of this thesis unveils aspects of the concept of exceptionality which have been revealed by the courts. However, observation of PCT meetings and interviewing individual decision makers provides a level of insight into the decision making process, and the opportunity to probe deeply into the factors which are considered in the assessment of a patient’s exceptionality, which could never be achieved by theoretical study alone. The empirical research establishes the issues which decision makers consider relevant to exceptionality, and exposes some of the external factors which influence the decision making process, including the impact of judicial proceedings in this sphere.

Oncology is a speciality which brings into sharp relief questions of how we distribute healthcare resources. One consequence of our ageing population is an increasing incidence of cancer, and early diagnosis paired with better survival has further compounded this, resulting in an increased prevalence of the disease. These factors alone have led to soaring expenditure on cancer treatment, but alongside the rising costs of increasingly sophisticated diagnostics and molecularly targeted drugs, the escalating financial challenge of cancer management is inescapable. The high costs associated with cancer treatment and the life threatening nature of the disease make resource allocation decisions for cancer drugs particularly acute. At the outset of this research, requests for cancer drugs made up the majority of funding requests based on exceptionality. For these reasons, it was initially my intention to focus my analysis of exceptionality on cancer drugs alone. However, if a week is a long time in politics, a year is a very long time indeed. Before the ink on my preliminary paper was dry, two political

changes paradoxically widened access to cancer drugs in a time of increasing national austerity. Firstly, the government, on the advice of the Richards’ Review, approved the use of top-up payments to purchase drugs not funded by the NHS, without obliging the recipient to forego free NHS care. Secondly, David Cameron, then leader of the opposition party, announced a pre-election promise that, were his party to gain power, it would fund all cancer drugs recommended by clinicians, irrespective of cost or cost-effectiveness. A consequence of these changes is that the number of requests for cancer drugs, grounded in exceptionality, which are being considered by PCTs, has fallen significantly in many regions. In light of this, when undertaking my empirical research examining how PCTs assess individual funding requests, I widened my enquiry beyond decisions regarding cancer drugs, to include other high cost treatments. However, the broad principles and approaches to decision making in this context are the same. The fundamental challenge of determining who receives treatment on the basis of their exceptionality, and who goes without, remains unchanged.

This thesis aims to contribute to the debate about how we decide which treatments to fund when we cannot afford them all. The purpose of my contribution is to challenge the use of the concept of exceptionality as a basis for funding decisions, particularly at a local level, and to question the special status which has insidiously emerged for the funding of cancer drugs, at the expense of other equally devastating conditions.

Over the years, the problem of which drug treatments to fund when we cannot fund them all has not changed; but the words used to characterise the problem have. Described as rationing in the eighties and resource allocation in the nineties, current terminology favours the phrase priority setting. Whilst I use these terms interchangeably throughout the thesis, others have argued that they are conceptually distinct. There is speculation that in the next decade we will be talking about sustainability, rather than priority setting. For this to amount to more than rhetoric, the increasingly critical challenge of how we choose between expensive treatments when faced with a limited

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7 Klein, for example, has argued that priority setting describes decisions about allocation between competing claims, whereas rationing describes the effect of these decisions on individuals. Klein R. Rationing in the fiscal ice age. Health Economics, Policy and Law 2010;5(04):389-96.
budget will need to be addressed upfront, rather than hidden behind artificial concepts like ‘exceptionality’.

The introductory section of this thesis progresses in the following way: the *Ethical Legal and Policy Background* examines how it is decided which drugs will be provided by the NHS in the broader context, from the national level down to a local level, including how the concept of exceptionality arose in this setting. The impact of the introduction of the NHS Constitution on local decision making is reviewed, followed by an overview of why PCT decision making relating to claims of exceptionality must be morally fair and just, in addition to being within the bounds of the law. It would be remiss of any thesis examining access to cancer drugs to overlook the two developments mentioned previously relating to the funding of cancer treatments which have emerged recently. A contextual chapter, Chapter 3, providing an overview of the recent changes relating to the purchasing of additional treatment within the NHS, and the Cancer Drugs Fund, is therefore incorporated at this point. Chapter 4, the *Legal Approach*, provides the background to the work presented in Paper 1, and addresses some of the additional issues raised during the research for the paper, which could not be included in the paper itself. The chapter analyses the role which the courts have played in historic controversies regarding access to treatment, why no absolute right to cancer drugs exists within the NHS, and how resorting to the courts can be used strategically by both patients and pharmaceutical companies. Chapter 5, the *Philosophical Approach*, provides the background to the work presented in Paper 2. The chapter evaluates the need for ethical frameworks in resource allocation and reviews what constitutes an ethical framework in this context. An overview of ethical frameworks which hold the potential to support decision making regarding exceptionality is presented, and the reason for choosing the Accountability for Reasonableness framework as the subject for Paper 2 is justified. Chapter 6, the *Empirical Approach*, introduces the empirical element of the research. It is short in comparison to Chapters 4 and 5 dealing with the legal and philosophical approach, as the background to the empirical research is comprehensively explained within Paper 3 itself. The submitted articles follow the introductory section, and in the final section the findings of this doctoral thesis are concluded. This thesis takes into account changes in English law up until 31st March 2013.
2.0 Ethical, Legal and Policy Background: The Decision Making Process for the Funding of Cancer Drugs and other Treatments, within the English NHS

2.1 Introduction

In order to put into context PCT decision making regarding the funding of drugs in exceptional circumstances, this section starts by providing an overview of how it is determined which drugs will be available on the NHS. The National Institute for Health and Clinical Excellence (NICE) plays a significant role in this, but decisions emanating from the Institute can also have consequences on the funding of drugs which do not fall within its remit. PCTs, soon to become Clinical Commissioning Groups (CCGs), remain responsible for regional health budgets, with decision making relating to claims of exceptionality comprising just a small part of the healthcare commissioning they undertake. The impact of the NHS Constitution is reviewed, from the perspective of both patients and PCTs. This section concludes with a brief discussion of the aims of the NHS, and why these have created an expectation from patients that funding decisions should be morally just, not simply legally correct.

2.2 How it is decided which drugs will be available on the NHS in England

2.2.1 From NICE downwards

On a national level the main responsibility for deciding which new drugs will be available on the NHS lies with NICE, through its system of new technology appraisals. The establishment of NICE was seen as an attempt to depoliticise priority setting decisions in healthcare. It signalled the transition from implicit rationing, at the level of individual patients, to explicit rationing by guideline, with the advantage of maintaining some autonomy for clinicians whilst reducing the responsibility attributed to government for limiting access to care. NICE has always been more concerned with clinical and cost effectiveness than affordability, basing its cost-effectiveness assessments on the quality adjusted life year (QALY). The cost of many new cancer drugs exceed NICE’s

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2. Reference to the QALY unit of measurement cannot be made without mentioning its controversial nature. QALYs have been criticised for systematically discriminating against the chronically ill and the old, whilst others have argued that they might not be ageist enough. As a consequence, the use of QALYs has been debated extensively in the academic literature. Whilst it...
nominal cost-effectiveness threshold of £30,000/QALY, below which drugs are approved and above which they are rejected.\(^3\) In recognition of this, NICE issued new guidance to its appraisal committees in 2009, permitting the threshold to be raised for patients with less than two years to live, where the treatment is indicated for small populations of patients lacking alternative comparable treatment, and likely to extend life by more than three months.\(^4\) This was the first signal that cancer treatments would be prioritised differently from treatments for other diseases within the NHS. Although the guidance is described as being for ‘end of life’ treatments, in reality, the 10 drugs which have been approved under these new criteria have all been for cancer drugs.\(^5\) The first was Sunitinib, for metastatic renal cancer, with an approximate cost of £50,000/QALY.\(^6\) Prior to this, NICE’s value threshold for the QALY had been the same, irrespective of who benefitted from the QALY. This move has broken the universal applicability of the QALY measure, and sets a precedent for other groups to claim that their QALYs should also be valued at a higher threshold. Indeed, it is hard to see how the higher QALY value can be justified for end of life treatments, but not for, to give just two examples, dementia, or arthritis treatments, where the impact of treatment on quality of life could be significantly greater. Patient groups representing diseases other than cancer have every right to feel incensed. It would be no surprise if these groups created increasing political pressure to gain concessions for their drugs, with the risk that NICE’s amended cost-effectiveness threshold becomes unsustainable. As the NHS operates within a limited

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\(^3\) Rawlins M, Culyer A. op. cit. note 1.


budget, other patient groups will suffer a double jeopardy as a result of the decreased cost-effectiveness threshold for cancer drugs. Not only must non-cancer treatments meet a higher cost-effectiveness threshold but, in addition, some non-cancer patients will inevitably be denied treatment as resources are diverted to meet the rising costs of newly approved end of life treatments. Although the NICE end of life criteria may increase the availability of cancer drugs, and hence reduce the number of applications to PCTs for cancer drugs on the basis of exceptionality, the budgetary squeeze on other treatments may result in an increase in applications based on exceptionality for non-cancer treatments.

If the government deems a NICE recommended technology unaffordable to the NHS, the DoH could authorise the NHS to disregard the recommendation, or it could invoke a clause in its directions to NICE, requiring NICE to take account of:

‘advice from ministers on available resources’. 8

To date, neither of these actions has been taken. PCTs and NHS Trusts have a legal obligation to fund technologies recommended in NICE appraisal guidance, 9 but not those awaiting NICE appraisal.

The legal requirement to fund NICE approved technologies, whilst ensuring equity of access to those drugs funded, is skewing PCTs’ priorities and preventing funding of more cost-effective healthcare priorities in favour of nationally mandated service developments. 10 This has been illustrated by several studies. In one scoring exercise, representatives from PCTs ranked implementation of NICE appraisal guidance as a lower priority than funding proposals to relieve local pressures and facilitate the implementation of specific National Service Framework criteria. 11 Lack of resources

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8 Rawlins M, Culyer A. op. cit. note 1.


11 National Service Frameworks are long-term strategies for improving standards in specific areas of healthcare.
prevented funding of a significant number of high scoring proposals in this study.\textsuperscript{12} In a separate pilot application of a prioritisation tool, at a different PCT, it was similarly found that the implementation of NICE approved technologies ranked lower than other healthcare interventions.\textsuperscript{13} Unlike PCTs, NICE does not have to account for the opportunity costs of its recommendations. As a result, the mandatory provision of NICE approved treatments is displacing the funding of more cost effective interventions which have not been subject to a NICE appraisal. To illustrate this point, a study in 2008 examining the link between PCT spending on healthcare and health outcomes, revealed that PCT spending on circulatory diseases has equated to approximately £15,000/QALY.\textsuperscript{14} This figure falls below NICE’s nominal QALY threshold for cost-effectiveness approval of £30,000/QALY, and is significantly less than the £50,000/QALY cost of the first drug approved under NICE’s end of life criteria. The NICE QALY threshold is evidently not in keeping with PCTs’ spending on non-NICE approved treatments. This has resulted in calls from PCTs for NICE to bring its cost-effective threshold more in line with what the NHS can afford.\textsuperscript{15} If the current NICE QALY thresholds are to be maintained, justification of the differential treatment of diseases commonly treated by NICE approved drugs, such as cancer, is required.

Despite dissatisfaction with the cost of NICE’s decisions, the proposal in the recent Health and Social Care Bill\textsuperscript{16} that NICE should be stripped of its powers,\textsuperscript{17} with its recommendations no longer being mandatory, met with strong disapproval from General Practitioners. As a result, the decision was reversed during the consultation process on the Bill.\textsuperscript{18} It is clear that whilst PCTs may perceive the level at which NICE has set its cost-effectiveness limit to be too generous, healthcare professionals are

\textsuperscript{16}Since incorporated into statute in an amended form, as the Health and Social Care Act 2012, on 27 March 2012.
\textsuperscript{17}Health and Social Care HC Bill 2010-11 [132].
\textsuperscript{18}Gulland A. NICE confirms its role in new NHS after government U turn. \textit{BMJ} 2011;\textbf{343}d4525.
unanimous that some external limits on the availability of expensive treatments are needed.

2.2.2 Individual funding requests and exceptionality: access to drugs which are not approved by NICE

PCTs are responsible for the local healthcare budget. Funding decisions follow a yearly cycle, known as the annual commissioning round, which sits within a longer term strategic planning process. In addition to the treatments approved by NICE technology appraisals, for which PCT funding is mandatory, PCTs consider local healthcare strategies to decide how the budget will be allocated. New service developments since the previous commissioning round may necessitate disinvestment and redistribution of resources. As the budget is finite, new treatments are compared against existing services, and clinical effectiveness, cost and impact on health outcomes are considered. A new treatment may either be funded, in which case a commissioning policy will be drawn up outlining its use, or, if it is considered a low priority, it may be excluded from funding.

Clinicians who feel that a particular patient would benefit from a treatment not approved by NICE, and not funded under a local agreement with the PCT, may put forward a funding request to the PCT for the treatment to be funded on a named patient basis, on grounds of the patient’s exceptional circumstances. The National Prescribing Centre has coined the term ‘individual funding request’ to describe funding requests in exceptional circumstances, defining such applications as:

‘a request to fund, for an individual patient, a treatment or medicine which falls outside existing contracts or policy.’

These funding requests, based on exceptionality to an established policy, are distinguished from individual funding requests for treatments which are so rare that the PCT is unlikely to receive another, and for which it is therefore not worthwhile producing a commissioning policy. Such requests can clearly not be on the grounds of exceptionality, as in these cases there is no policy, or similar cohort of patients, to which

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to be an exception. It is the former type of individual funding request, grounded in exceptionality, which is the focus of my research.\textsuperscript{20}

The concept of exceptionality has arisen from the well established principle of administrative law that a public body is not entitled to fetter the exercise of its own discretion.\textsuperscript{21} In the context of healthcare, the notion of exceptionality was established in \textit{R v North West Lancashire Health Authority, ex p A, D & G}, a case where three transsexuals were refused funding for gender reassignment treatment.\textsuperscript{22} North West Lancashire Health Authority had a policy of not funding such treatment in the absence of ‘overriding clinical need’, or other exceptional circumstances. Auld LJ held that it was:

‘proper for an authority to adopt a general policy for the exercise of such an administrative discretion, to allow for exceptions from it in ‘‘exceptional circumstances’’ and to leave those circumstances undefined...’\textsuperscript{23}

Auld LJ emphasised that there should be consideration of each individual case on its merits, and that a ‘blanket policy’ which did not allow exceptions was not acceptable. The term ‘exceptional circumstances’ has never been explicitly defined, either by the courts or the DoH, but it emerged in \textit{R v North West Lancashire Health Authority} that a claim of exceptionality needs to be substantiated by more than a clinician’s recommendation that a particular treatment would be of value.\textsuperscript{24} A more detailed history of the evolution of the legal concept of exceptionality is provided in Paper 1, which subsequently proceeds to address the intriguing question of how the law has interpreted the concept of exceptionality in this context.

The process of assessing applications for funding on the basis of exceptional circumstances, or individual funding requests (IFRs) as they are now more commonly known, has historically varied hugely between PCTs. Previously some PCTs had formal written policies, and an established mechanism for appeals, whilst others processed

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\textsuperscript{20} The National Prescribing Council guidance identifies a further potential type of individual funding request, usually for newly licensed interventions, which would apply to a population of patients. It is advised that such requests should trigger the development of a new policy, and not routinely be considered by an IFR panel. National Prescribing Centre. \textit{Supporting rational local decision-making about medicines (and treatments) - A Handbook of Good Practice}. op. cit. note 19, p 3.

\textsuperscript{21} \textit{R v Port of London Authority, ex p Kynoch Ltd} [1919] 1 KB 176; \textit{R v Secretary of State for Home Department, ex p Venables} [1998] AC 407.

\textsuperscript{22} \textit{R v North West Lancashire Health Authority, ex p A, D & G} [2001] 1 WLR 977.

\textsuperscript{23} \textit{Ibid.}, para 990.

\textsuperscript{24} \textit{Ibid.}, para 998.
applications in a more ad hoc fashion. At the outset of my research, in 2009, the success rate of cancer patients in applying to PCTs for funding of drugs not approved by NICE varied widely across the country, being as high as 96% in Mid Essex, compared with 0% in South West Essex. Correspondingly, the average level of resources spent on cancer patients differed hugely between PCTs, from £5,182 per patient in Oxfordshire, to £17,028 in Nottingham. What was colloquially described as a ‘postcode lottery’ in access to cancer drugs had emerged, which politically was seen as a problem in need of addressing. Since then, three pivotal changes have impacted significantly on IFRs. It was claimed that the first change, the implementation of the NHS Constitution, would end the postcode lottery in access to treatments. Whilst it has not achieved that, one of the outcomes of the NHS Constitution has been a reshaping of the individual funding request decision making process at many PCTs. The NHS Constitution and the effect it had on IFRs is reviewed in Section 2.3 below. The second change was a clarification of the law concerning the purchasing of additional private treatment for conditions being treated within the NHS. The potential impact of this change on the number of IFRs for cancer drugs was much diminished by the introduction of the Cancer Drugs Fund, which followed soon after in 2010. The Cancer Drugs Fund has altered the pattern of individual funding request applications considerably. Both the clarification of the law on the purchasing of additional private care and the introduction of the Cancer Drugs Fund raise particular ethical, legal and political issues. In order to ensure that these two recent developments receive the attention which their complexity warrants, they are examined separately in Chapter 3.

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27 Department of Health. Public Expenditure on Health and Personal Social Services 2006: Memorandum containing replies to a Written Questionnaire from the Health Select Committee 16 November 2007 http://www.publications.parliament.uk/pa/cm200708/cmselect/cmhealth/excel2/table%20a%20b%20c%20d%20e%20f%20g%20h%20i%20j%20k%20l%20m%20n%20o%20p%20q%20r%20s%20t%20u%20v%20w%20x%20y%20z.xls (accessed 20 August 2008).  
2.3 The impact of the NHS Constitution on individual funding requests

2.3.1 Old principles in new clothes, or extended patient rights?
Following the successful passage of the Health Act 2009, all providers and commissioners of NHS care have had a duty to have regard to the NHS Constitution for England. With respect to IFRs, the NHS Constitution states that:

‘You have the right to expect local decisions on funding of other drugs and treatments to be made rationally following proper consideration of the evidence. If the local NHS decides not to fund a drug or treatment you and your doctor feel would be right for you, they will explain that decision to you.’

This ‘right’ is legally underpinned by Directions issued to PCTs by the Secretary of State for Health under Section 8 of the NHS Act 2006, concerning decisions about drugs and other treatments. These Directions stipulate that PCTs should have policies detailing how they will determine requests for drugs which are not routinely funded, and that these policies should be readily accessible to the public on PCT websites. Effectively, the Directions, issued in 2009, have formalised the principles regarding the exercise of administrative discretion with respect to general healthcare policies which had emerged seven years earlier in the case of *R v North West Lancashire Health Authority, ex p A, D & G* mentioned above, and discussed in more detail in Paper 1. Arguably, however, the NHS Constitution extends patients’ rights beyond those established in *R v North West Lancashire Health Authority, ex p A, D & G.* For example, in the event that a request for funding of a healthcare intervention is declined, the Directions oblige PCTs to provide a written explanation of the reasons for their decision to individual patients. As will be reviewed in Chapter 4, this places a higher requirement for transparency on PCTs than has historically been expected of health authorities by the courts.

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31 *R v North West Lancashire Health Authority, ex p A, D & G* (n 22).

32 *R v North West Lancashire Health Authority, ex p A, D & G* (n 22).

2.3.2 The NHS Constitution – ‘Fine words, but no teeth’?

There is little evidence that patients are using the Constitution directly as a benchmark against which to challenge their access to cancer, or other drugs. Despite being in effect for over three years, the NHS Constitution has only been used as the basis for two legal claims to date. The first, *R v Secretary of State for Health, ex parte Unison*[^34] was brought on behalf of NHS employees, rather than patients, and centred around a challenge by Unison that the Secretary of State had failed to consult others on the principle of the proposed changes to the NHS contained within the White Paper ‘Equity and Excellence: Liberating the National Health Service’.[^35] The White Paper set out changes to the NHS which the Secretary of State planned to implement via the Health and Social Care Act 2012.[^36] Unison claimed that the NHS employees it represented had an unfulfilled legitimate expectation that they would be consulted on proposed changes to the NHS, based on statements made in documents issued by the Secretary of State for Health, including the NHS Constitution. That part of the NHS Constitution which Unison claimed was relevant reads:

> ‘any government which seeks to alter the principles or values of the NHS, or the rights, pledges, duties and responsibilities set out in this Constitution, will have to engage in a full and transparent debate with the public, patients and staff.’[^37]

The court found that, in accordance with the Health Act 2009 (which prevailed at the time),[^38] there were certain bodies within the NHS which had a statutory duty to have regard to the NHS Constitution, but the Secretary of State had no such obligation. The only statutory duties binding on the Secretary of State were found to be contained within Section 3 of the Health Act 2009, and did not enshrine in statute the apparently explicit obligation to engage in transparent debate with staff and others as stated in the quote from the NHS Constitution above. In this case, the DoH’s own description of the NHS Constitution as having ‘fine words but no teeth’, could not be more apposite![^39] The

[^34]: *R v Secretary of State for Health, ex parte Unison* [2010] EWHC 2655 (Admin).
[^36]: The Health and Social Care Act 2012 is discussed in more detail in Chapter 4, Section 4.2.2.
[^38]: The Health Act 2009, Part 1, Section 2.
outcome in *R v Secretary of State for Health, ex parte Unison*\(^40\) suggested that the NHS Constitution might not be worth the paper it was written on.

However, the second case which used the NHS Constitution as the basis of its claim demonstrated that, in some circumstances, the NHS Constitution does amount to more than ‘fine words’. *R v NHS Oldham, ex parte Booker*, involved a claim to ongoing access to NHS services. The case is discussed in depth in Chapter 3, and to avoid unnecessary repetition is not detailed here, but fundamentally, the court found that Oldham PCT was bound by a principle contained within the NHS Constitution and could not legally withdraw treatment from the claimant as it had planned.\(^41\)

Given the contrasting judgments in these two cases, it remains somewhat unpredictable how a failure to comply with the NHS Constitution will be treated by the courts. At the time of its publication, the DoH was quite clear that the Constitution was:

> *not intended to create a “lawyer’s charter”* \(^42\)

and the Constitution itself states that it does not alter the content of patients’ legal rights.\(^43\) Despite this, PCTs are bound by statute to have regard to the NHS Constitution and this was pivotal to the outcome in *Booker*. To complicate the picture further, the NHS Health and Social Care Act 2012 created a new duty on the Secretary of State for Health to have regard to the NHS Constitution in exercising his functions in relation to the health service.\(^44\) It seems unlikely that this duty is intended to alter the legal status of the NHS Constitution itself, but it begs the question of whether the outcome of *R v Secretary of State for Health, ex parte Unison*\(^45\) would be different today from what it was in 2010.

Aside from *Booker*, there is little evidence that patients are using the Constitution directly as a benchmark against which to challenge their access to cancer, or other drugs and services. Condliff, whose claim is examined in more detail in Chapter 4, sought judicial review of North Staffordshire PCT’s decision to reject his IFR for gastric bypass

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\(^{40}\) *R v Secretary of State for Health, ex parte Unison* (n 34).

\(^{41}\) *R v NHS Oldham, ex parte Booker* [2010] EWHC 2593 (Admin) para 27.


\(^{44}\) Health and Social Care Act 2012 s 1(3).

\(^{45}\) *R v Secretary of State for Health, ex parte Unison* (n 34).
surgery.\textsuperscript{46} One of Condliff’s claims was that the PCT had failed to provide reasons for its decision. It is telling that rather than seeking a remedy in the right provided by the NHS Constitution for patients to receive a written explanation of a PCT’s decision\textsuperscript{47}, he chose instead to seek redress using Section 6 of the Human Rights Act.

\textbf{2.3.3 The NHS Constitution – a bigger player behind the scenes than on stage}

Whilst the DoH’s report on the effect of the NHS Constitution documents the extent to which many of the Constitution’s commitments are being delivered, it is disappointing to learn that outcomes with regard to IFRs are not reportable, because of the limited data available.\textsuperscript{48} It is questionable whether the NHS Constitution itself, with all its hyperbole of rights and pledges, has done anything at all to directly empower patients with respect to IFRs. Even awareness of the existence of the Constitution amongst the public is low. In a national survey, only 27\% of the public were aware of the Constitution.\textsuperscript{49} Notwithstanding this, and unbeknown to the majority of patients, the Directions underlying the NHS Constitution have been central in altering the individual funding request process at many PCTs. In order to support PCTs in meeting the legal requirements set out by the Directions, the DoH commissioned the National Prescribing Centre ((NPC) now integrated into NICE as the Medicines and Prescribing Centre) to develop two handbooks to aid PCT decision making.\textsuperscript{50} Nine guiding principles for IFRs were established, which include defining and consistently applying standard criteria for decision making, and taking into account ethical frameworks and statutory requirements.\textsuperscript{51} The need to establish an appeals process, with defined grounds for appeal, was also listed as a guiding principle.\textsuperscript{52}

\textsuperscript{46} R (Alexander Condliff) v North Staffordshire Primary Care Trust and the Secretary of State [2011] EWCA Civ 910.
\textsuperscript{47} Department of Health. Directions to Primary Care Trusts and NHS Trusts concerning decisions about drugs and other treatments. op. cit. note 33.
\textsuperscript{49} Ibid.
\textsuperscript{51} Department of Health. Defining guiding principles for processes supporting local decision making about medicines. op. cit. note 50, p 6.
The effect of the NPC guidance has been to streamline the processes for managing IFRs at many PCTs. The ad hoc processes, which were widespread, have been replaced by more systematic approaches and formalised IFR decision making panels, with separate panels to consider appeals. The need for this was overdue, as illustrated by the weaknesses found in PCT decision making processes in the judicial reviews of IFR decisions analysed in Paper 1. The decreasing frequency of judicial reviews of IFR decisions since 2009\(^53\) may in part be attributable to the improvement in IFR decision making processes, resulting from the NPC guidance which stemmed from the NHS Constitution. The courts have found in the PCTs’ favour in all of the IFR cases which have reached the courts since 2009.\(^54\) This contrasts with those prior to that date where the PCTs’ decisions, which all centred on cancer drugs, were without exception quashed by the courts.\(^55\) Whether this is a reflection of PCT decision making becoming more legally robust, or simply a greater judicial sympathy for cancer patients, than for the obese and transgender patients who have resorted to judicial review to access treatment since 2009, remains open to speculation.

The impact of the NHS Constitution on the IFR process has undoubtedly been greater on PCT decision making practices behind the scenes, than as a lever for use by patients in trying to access treatments not readily available on the NHS. The NHS Constitution is currently undergoing revision.\(^56\) None of the proposals appear to significantly alter patients’ rights with respect to accessing treatments, but there is a focus on increasing awareness of the Constitution. Whether an increased awareness of the NHS Constitution will result in more patients using it as a basis for legal claims remains to be seen.

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\(^53\) The other major contributory factor is the increased availability of cancer drugs on the NHS, primarily as a consequence of the Cancer Drugs Fund, reviewed in Chapter 3, Section 3.2. All five judicial reviews of IFR decision making, prior to 2009, centred on cancer drugs.

\(^54\) R (Alexander Condliff) v North Staffordshire Primary Care Trust and the Secretary of State (n 46); AC v Berkshire West Primary Care Trust [2011] EWHC Civ 247.

\(^55\) If not in the first instance, then at appeal. The cases include R (Ann Marie Rogers) v Swindon Primary Care Trust and the Secretary of State [2006] EWCA Civ 392; R (Linda Gordon) v Bromley NHS Primary Care Trust [2006] EWHC 2462 (Admin); R (Victoria June Otley) v Barking and Dagenham NHS Primary Care Trust [2007]EWHC 1927 (Admin); R (Jean Marie Murphy) v Salford Primary Care Trust [2008] EWHC 1908 (Admin); R (Colin Ross) v West Sussex Primary Care Trust [2008] EWHC 2252 (Admin). These cases are discussed in more detail throughout this thesis, but particularly in Chapters 4 and 8.

2.4 The ethical challenge of determining which patients to fund on the basis of exceptionality

As this introductory background section has outlined, the legal framework within which IFR decision making is conducted has become increasingly well delineated, even if the nature of what constitutes exceptionality in this context remains poorly defined. Whilst a clear legal framework aids PCTs in keeping within the bounds of the law in reaching decisions about who to fund on the basis of exceptionality, patients are interested in more than legal correctness. Patients, and the wider public, want to be assured that when NHS treatment is not available to everyone, the decisions which determine who will benefit from taxpayers’ money are not simply legally faultless, but morally right and fair. The young mother with breast cancer wants to know that, if limited healthcare resources are not to be spent on drugs which will provide her with her only chance of life extension, then that decision was not arbitrary. The man whose debilitating arthritis has resulted in depression due to lack of treatment requires convincing that the resources which are not available to ease his life of pain have been justly spent on someone else.

2.4.1 What is the fundamental aim of the NHS?

In order to achieve a just and fair distribution of healthcare resources it is first necessary to understand what the NHS is trying to achieve. One of the paramount difficulties is that despite its long existence, the fundamental goal of the NHS has never been defined.\(^{57}\) There has been extensive debate as to whether the purpose is principally to maximise aggregate health\(^{58}\) or to achieve equity. If the latter, it remains uncertain on what grounds we should aim to achieve equity. Resources could be distributed according to need, or according to capacity to benefit from treatment.\(^{59}\) This would not always result in the same outcome, as patients with equal health needs can benefit by different amounts from the same treatment.\(^{60}\) Resources could be distributed with the aim of reducing health inequalities, which paradoxically could result in some people’s health status being diminished. Harris has argued that rather than aiming to maximise

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\(^{58}\) Culyer A. The rationing debate: maximising the health of the whole community. The case for. *BMJ* 1997;314:667.


health outcomes, or achieving equity however defined, the principal aim of the NHS should be to offer every individual equal protection from threats to life or liberty, with each citizen being entitled to an equal chance of having their health needs met. In light of his view that everyone has an equal claim on resources, irrespective of the cost of their health needs and prospect of success, Harris has suggested that in the absence of good reasons for choosing between patients, fair distribution could be achieved by lottery. An alternative view has been advanced that every person should have equal access to a defined basic level of healthcare, irrespective of level of need.

2.4.2 ‘Free at the point of delivery and available to all based on clinical need, not ability to pay.’

In the absence of a consensus on the fundamental goal of the NHS, it does not seem unreasonable to resort to the founding principles of the NHS and to reflect on these as the overarching aims of the NHS. The founding principles stated that the NHS should meet the needs of everyone, on the basis of clinical need, rather than ability to pay. In July 2000, The NHS Plan reiterated these aims, adding new core principles, including that the NHS should work to reduce health inequalities. This leaves the NHS with a complex composition of goals to achieve. The message that the NHS should be provided ‘free at the point of delivery and available to all based on clinical need, not ability to pay’ has been restated countless times over the years, most recently in the NHS Constitution and NHS Mandate. Through the numerous reorganisations of the NHS since 1948, and despite the recent austerity measures, the message has been left ringing in our ears. It

61 Harris J. The rationing debate: maximising the health of the whole community. The case against: what the principal objective of the NHS should really be. BMJ 1997;314:669.
is no wonder then that, where this promise remains unfulfilled, patients question not just the legal basis of PCT decision making, but the moral basis too.

2.4.3 Achieving just and fair outcomes using an ethical framework

One of the aims of this thesis is to examine how PCTs can reach decisions regarding which patients to fund on the basis of exceptionality that are not only within the bounds of the law, but which are also accepted by the patients and public as just and fair. In order to achieve this, decisions need to be justifiable in terms that the public will accept as fulfilling the mission of the NHS. If this is attainable, and patients can be satisfied that PCTs’ decisions are just and fair, even if not in their favour, it is feasible that legal action by patients will become less frequent. Unfortunately, the composite nature of the aims of the NHS means that there is no straightforward way to prioritise resources to achieve the stated aims. I will return to address this issue in Chapter 5. The DoH’s recommendation that PCTs use an ethical framework to aid the processing of IFRs was mentioned in Chapter 1. In attempting to address the issue of how PCTs can reach just and fair decisions in this context, Chapter 5 starts by reviewing which existing ethical frameworks might be best suited to this task, before selecting the one which shows the most promise to scrutinise in more detail in Paper 2, which can be found in Chapter 9.

2.5 Conclusion

This section has outlined the different routes via which treatments can be approved for provision on the NHS and introduced the first example of cancer drugs being treated differently from other drugs; through the provision of a lower NICE cost-effectiveness threshold for end of life treatments. The introduction of the NHS Constitution appears, as yet, to have done little to alter patients’ rights to NHS treatment, but has resulted in increasing standardisation of how IFRs are processed. The difficulty in establishing the fundamental goals of the NHS was reviewed, with the objectives most closely resembling the overarching goals of the NHS revealed by the founding principles of the NHS:

‘Free at the point of delivery and available to all based on clinical need, not ability to pay’.69

Many of the themes introduced in this section will be investigated in greater depth in the chapters which follow. Chapter 4, the Legal Approach explores in more detail the legal perspectives relating to access to treatment, including how judicial attitudes to

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69 Department of Health. A consultation on strengthening the NHS constitution. op. cit. note 56.
issues of resource allocation have evolved, why no absolute right to treatment exists
either under domestic law or Human Rights legislation, and how recourse to the courts
can be used not solely to obtain justice, but strategically, for other means. Considerable
attention is given to the notion of exceptionality, the central focus of this thesis. The
characteristics of the concept of exceptionality, as revealed by judicial reviews of IFRs to
date, are addressed in detail in Paper 1, which can be found in Chapter 8. Chapter 5, the
Philosophical Approach, takes up the issue of ethical frameworks and examines why an
ethical framework is required for IFR decision making, as advocated in the recent NPC
guidance, commissioned by the DoH. This is followed by a review of existing ethical
frameworks with the potential to meet this function, and the one best suited to this
purpose is selected for more detailed scrutiny. The focus then returns once more to the
notion of exceptionality in Paper 2, Chapter 9, where the chosen framework is used to
test whether the concept of exceptionality is a morally relevant factor in the allocation
of scarce healthcare resources. Following this legal and ethical analysis of the concept of
exceptionality, Paper 3, in Chapter 10, reports an empirical study into how the term
exceptionality is applied and interpreted by IFR panels at the coal face of resource
allocation.

70 National Prescribing Centre. Supporting rational local decision-making about medicines (and
treatments) - A Handbook of Good Practice. op. cit. note 19, pp 20,24,35,44. http://npc.nhs.uk/
/local_decision_making/resources/handbook_complete.pdf (accessed 23 March 2009);
Department of Health. Defining guiding principles for processes supporting local decision making
about medicines. op. cit. note 50.
3.0 Recent Developments

This thesis has as its central concern the concept of exceptionality as a basis for resource allocation, within the individual funding request process. During the course of this research, three policy developments impacted considerably upon IFRs for cancer treatments. The first of these, the NHS Constitution, primarily affected the procedures PCTs used for processing IFRs, and its consequences were not specific to IFRs for cancer. The effect of the NHS Constitution has been reviewed in Chapter 2. The other two policy developments, which have already been briefly mentioned, were the Richards’ review of top-up payments for drugs not available on the NHS, and the Cancer Drugs Fund. The former had the potential to alter the pattern of IFR applications for cancer drugs, but in actuality never did, because of the introduction of the Cancer Drugs Fund. The Cancer Drugs Fund has affected the pattern of IFR applications for cancer, though in a more complex manner than might have been anticipated.

In addition, the introduction of the Cancer Drugs Fund and the handling of top-up payments for cancer drugs serve to highlight the privileged status of cancer funding within the NHS. The first hint of cancer receiving preferential consideration for funding came with the lowering of the cost effectiveness threshold used by NICE for cancer drugs, though this has become almost insignificant in contrast with the scale of the Cancer Drugs Fund. The oncologist Sidney Farber remarked that cancer was

‘an illness that gripped patients not just physically, but psychically, socially and emotionally.’

Today, it would seem fair to state further that cancer has also gripped the purse strings of the NHS. Not only is cancer a disease for which treatments are sought on the basis of exceptionality, but it would appear that cancer is a disease which has become an exception in itself – at least in as far as NHS funding is concerned. This idea that cancer is distinct from other diseases and deserving of special status has been dubbed ‘cancer exceptionalism’. It is not a phenomenon limited to the UK.

The purpose of this contextual chapter is to provide a critical overview of recent policy developments related to the funding of cancer drugs within the NHS and to highlight the

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3 Ibid.
consequences of privileging cancer funding within the NHS. The level of public support for treating cancer as a special case is reviewed. I argue that singling out cancer for special attention has introduced double standards within the NHS, and has been to the detriment not only of non-cancer patients, but some cancer patients too. The differential treatment of expensive cancer drugs makes the need to address the question of how we decide which drugs are to be funded on the NHS, when we cannot fund them all, more pressing. Singling out high cost diseases for special funding is not sustainable.
3.1 Purchasing ‘additional care’: blurring the boundaries between NHS and private provision

3.1.1 Introduction

The issue of people being simultaneously private and NHS patients for the same condition, within a single visit, was brought to the public’s attention by several high profile cases in the media, where patients with incurable cancer were paying privately for drug treatments, whilst at the same time continuing to receive NHS cancer care. The Richards’ review, which resulted in new guidance regarding the purchasing of additional private healthcare, is relevant to this thesis because it was driven by the unmet demand for cancer drugs from the NHS, and hence had the potential to impact on requests for the funding of cancer drugs on the basis of exceptionality.

There were fears that the practice of patients paying for concurrent private treatment, in addition to their NHS treatment, was creating a two-tier NHS split between those patients who could afford additional drugs and those who could not. The practice was perceived to threaten the founding principles and ideology of the NHS, and some PCTs withdrew NHS treatment from patients who purchased private care. This chapter highlights how, irrespective of top-up payments, the founding principles of the NHS are no longer an entirely accurate reflection of the values inherent in the delivery of the health service. It is demonstrated that PCTs which withdrew NHS care from patients may have been acting outside existing law, and that, as the NHS is unable to provide patients with all effective treatments, it is incoherent to prohibit the purchase of additional concurrent treatment. The question which actually needed to be addressed was how concurrent private treatment should be facilitated: either entirely separately from NHS care, which would require measures to address the safety concerns which arise from care which is not necessarily overseen by a single doctor, or together with NHS care, which would require acknowledgement that a two-tier NHS has evolved. The guidance

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failed to adequately address if, and how, private care should be separated, effectively fudging this critical issue. Scrutiny of the wording of the new guidance reveals that, despite the apparently explicit requirement that private care be delivered separately from NHS care, the guidance does, in effect, allow both types of treatment to be delivered together. Further, I argue that the guidance has inadvertently condoned the introduction of several new double standards within the NHS, where additional payments for care are involved. I conclude that the muddle surrounding top-up payments should lead us to consider whether it is time to end the pretence that the service provided by NHS is universal, free and comprehensive.

3.1.2 The nature of payments within the NHS

Patients who purchased private cancer treatments, not available on the NHS, were perceived to be ‘topping up’ their NHS care, creating inequality within the NHS between those patients who could afford to buy additional drugs and those, potentially being treated in adjacent beds, who could not. It was argued that this could have a destabilising effect on the NHS and potentially undermine public support for the health service. Fears were raised that if the practice of ‘topping up’ were allowed to continue, the NHS might contract to provide a basic core service of treatments, no longer fulfilling its founding principles of providing of a universal, free and comprehensive service. The truth, of course, is that the NHS has long ceased to provide a universal, free and comprehensive service (if indeed it ever did) and those who have failed to notice this have either had no cause to use the NHS in recent years, or are wearing strongly rose-tinted spectacles. That some treatments are only available to patients on the basis of their exceptional circumstances is indicative that the NHS has departed from providing comprehensive healthcare. It is equally self-evident that the NHS is not entirely free. For many years, two types of charges have existed in the NHS: those which are obligatory

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7 Bloor K. Should patients be able to pay top-up fees to receive the treatment they want? No. BMJ 2008;336(7653):1105-05.
8 The provision of a comprehensive service was not a founding principle of the NHS. However, the Health Service Act 1946 Section 1 (1) put the Minister of Health under a duty to promote a comprehensive service. This duty has been retained in every National Health Service Act since. The Health and Social Care Act 2012 may have diluted this duty, although the wording is retained. The legal implications of the Health and Social Care Act are discussed further in Chapter 4, Section 4.2.2. The assertion that the NHS will provide a comprehensive service is also the first principle of the NHS Constitution. Department of Health. Handbook to the NHS Constitution. March 2010 p 3. http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_113614 (accessed 14 July 2011); Jackson E. Top-up payments for expensive cancer drugs: rationing, fairness and the NHS. Modern Law Review 2010;73(3):399-427.
for patients not in receipt of certain state benefits, such as charges for NHS prescriptions, and those which patients may choose to pay for services above and beyond standard NHS treatment, effectively combining NHS and private care. For example, NHS patients can pay for an ‘amenity bed’ on a NHS ward, often in a side room, with en-suite facilities. They can obtain private prescriptions from an NHS GP, or pay for private fertility services prior to NHS antenatal care. The difference between these payments and the practice of purchasing cancer treatment alongside NHS treatment was twofold. Firstly, with the exception of fertility treatments, payments for private care within the NHS treatment have, up until this point, been of a relatively low magnitude. Indeed, many additional costs, such as prescription charges, are means tested to ensure the cost is not prohibitive to those on low incomes. Secondly, where charges are not means tested, they have tended to be for the provision of superior facilities, rather than for additional treatment.

Preventing patients from ‘topping up’ NHS treatment with additional private care would not, on its own, have restored the NHS to being a free and comprehensive service. However, ensuring that private treatment was delivered outside the NHS, entirely separate from NHS care and services, would have avoided the potential scenario of identical patients receiving differential treatment within the NHS, based on their ability to pay, effectively creating a two-tier NHS.

Despite widespread acceptance of the historic practice of charging for some services within the NHS, outlined above, it was generally perceived prior to March 2009 that a patient was not allowed to be a private and NHS patient simultaneously for the same condition. Although not legally binding, this was seemingly explicit in the 2004 DoH Code of Conduct for Private Practice, which stated that:

’a patient cannot be both a private and a NHS patient for the treatment of one condition during a single visit to a NHS organisation’.9

This perception was further supported by Section 1(3) of the National Health Service Act 2006, which stated that health services provided:

‘must be free of charge except in so far as the making and recovery of charges is expressly provided for by or under any enactment, whichever passed.’10

In the absence of any legislation allowing charges to be raised for the provision of drugs administered in hospital, this statutory provision was understood by many to prevent payment by patients for drugs administered within NHS facilities.11

3.1.3 The cancer patient’s perspective
In some instances, patients paying for concurrent private cancer treatment had their NHS treatment withdrawn, although this was not consistent across England.12 Those patients argued that paying privately for cancer drugs was already extortionately expensive and that they simply could not afford to pay for all of their cancer care privately, in addition to the cancer drugs. They felt it unfair that they were deprived of care they would otherwise have received, but for choosing to pay for additional treatment not available to them on the NHS. The additional treatments purchased were licensed, and therefore at least to some extent clinically effective, but in many cases had not been deemed cost effective by NICE. However, just because a drug is not cost effective on a population level does not mean that it is necessarily an imprudent choice for people with the means to purchase such a medication for themselves, especially if it represents the only possible treatment with the potential to extend life. Irrespective of this, preventing patients from spending their money on whatever treatment they wish, effective or not, is to deprive them of their autonomy.13 Many cancer patients purchase additional treatment for their disease in the form of complementary therapies and herbal remedies. Other than concerns that patients may be misled by inaccurate marketing claims, objections have not been raised to patients supplementing their care in this fashion. The difference is, of course, that complementary therapies can be provided separately from a patient’s NHS care. This is harder to achieve with orthodox anti-cancer treatments, which require medical supervision and often, contemporaneous administration with chemotherapy provided by the NHS. However, prohibiting patients from purchasing effective cancer treatment which the NHS is unable to afford, especially when there are no such prohibitions on the purchasing of complementary therapies, for

10 NHS Act 2006, Section 1(3).
12 Dyer C. Patient challenges trust’s right to deprive her of NHS treatment for buying drugs privately. op. cit. note 4; Templeton S. Cancer victim told to pay for his own drugs by NHS. op. cit. note 4; Templeton S. NHS scandal: dying cancer victim forced to pay. op. cit. note 4.
13 Weale and Clark have examined the normative arguments for and against NHS top-up payments from the perspectives of both equity and patient autonomy, and reason that both can be used in favour of, and against, co-payments. See Weale A, Clark S. Co-payments in the NHS: an analysis of the normative arguments. Health Economics, Policy and Law 2010;5(2):225-46.
which there is much less evidence, is incoherent. Insisting that patients separate their cancer care into that which they receive on the NHS, and that which they receive privately would generally necessitate the involvement of two consultants, neither wholly responsible for the patient’s care, and raises issues of patient safety. If the Richards’ review had insisted on such a separation, it would have been possible to overcome safety concerns by ensuring good communication between the teams and designating one of the consultants as lead clinician to oversee the treatment.

3.1.4 Were PCTs acting outside the law by withdrawing NHS care?

It is questionable whether PCTs which withdrew NHS care from patients receiving concurrent private treatment for the same condition were acting within the law. At that time the Secretary of State for Health had a duty to promote a comprehensive health service.\(^{14}\) Withdrawing basic NHS provision from those who sought to supplement their care with clinically effective treatment that the NHS would not provide could barely be considered compatible with the aim of promoting a comprehensive health service. Although not in the sense it was originally intended, withdrawing NHS care from those who concurrently received private treatment for the same condition could also be considered to contravene the tenet that universal NHS care should be provided irrespective of ability to pay.\(^{15}\) This hypothesis is illustrated by *R v NHS Oldham, ex parte Booker*, which will be described in more detail below.\(^{16}\) Further, the NHS Constitution, which was under consultation at the time that NHS top-ups hit the headlines, but has since been placed on a statutory footing by the Health Act 2009, pledges to patients that:

‘You have the right to access NHS services. You will not be refused access on unreasonable grounds.’\(^{17}\)

Would the plain language meaning of the Constitution have been stretched too far by the suggestion that denying NHS care to patients buying additional treatment represented the denial of access to NHS treatment on unreasonable grounds?\(^{18}\)

\(^{14}\) Under the NHS Act 2006, S 1(1). This duty arguably still exists, even after the passing of the Health and Social Care Act 2012. See Chapter 4, Section 4.2.2. for an analysis of the impact of the Act on the Secretary of State’s duties.

\(^{15}\) Jackson E. Top-up payments for expensive cancer drugs: rationing, fairness and the NHS. *op. cit.* note 8.

\(^{16}\) *R v NHS Oldham, ex parte Booker* [2010] EWHC 2593 (Admin).


\(^{18}\) Jackson E. Top-up payments for expensive cancer drugs: rationing, fairness and the NHS. *op.
Although in a different context, reference to the duty to promote a comprehensive health service, the principle that NHS care should be provided irrespective of ability to pay, and the provisions of the NHS Constitution, were all made the following year in *R v NHS Oldham, ex parte Booker.*¹⁹ Oldham PCT decided that it would no longer provide ongoing health and social care for a ventilator dependent tetraplegic patient, who had sustained injuries in a road traffic accident. Oldham PCT claimed that the patient could potentially fund such care for herself by forcing the periodic payments to cover the cost of her care package, which were part of the settlement of her injury claim, to commence sooner rather than later. Pelling J, deemed that the PCT was:

‘bound to have regard to the principle that access to NHS services is based on clinical need not on an individual’s ability to pay and that a person who is otherwise eligible for treatment is entitled to receive it free of charge.’²⁰

Whilst one might have assumed that the reference to access to NHS services irrespective of ability to pay in the NHS Constitution was to safeguard the needs of those who might not be able to afford care, *R v NHS Oldham, ex parte Booker* illustrates that the court is also prepared to interpret this principle to protect free entitlement to care for those with the means to fund their own care. It is not beyond the realms of possibility that had any patient challenged their PCT’s decision to deprive them of NHS care because they were simultaneously purchasing additional private treatment for the same condition, the court would have found in their favour, on similar grounds to those cited in *R v NHS Oldham, ex parte Booker.*

### 3.1.5 The Richards’ Review

In June 2008, before the legality of ‘topping up’ NHS care with private treatment could be challenged in the courts, the DoH requested Professor Mike Richards, National Cancer Director, to review if, when and in what circumstances patients should be able to buy additional drugs not funded by the NHS, in what became known as the Richards’ review. Although the guidelines on top-up payments which materialised following the Richards’ review were not specific to cancer drugs, it is telling that the task was assigned to the National Cancer Director. The issue was clearly perceived to be cancer specific. Like the amended NICE cost-effectiveness threshold for end of life drugs discussed in

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¹⁹ *R v NHS Oldham, ex parte Booker* (n 16).
Chapter 2, this is a further illustration of treatments for cancer being managed differently from those for other diseases.

Given that the number of patients who had their NHS care withdrawn after paying for concurrent private treatment was small,\(^{21}\) a national review could have been perceived as a disproportionate response. Klein describes the episode as:

‘representing a regrettable surrender to lobby power and media pressure’.\(^{22}\)

The influence of the media on public attitudes towards, and PCTs’ and politicians’ responses to, patients’ requests for cancer and other treatments is not to be underestimated. It is worthy of further examination and is discussed in more detail in Chapter 4.\(^{23}\)

Irrespective of external pressures on the government with respect to the access of cancer drugs, the cluster of patients purchasing additional private care within the NHS care were undoubtedly representative of a rising tide of well informed patients who, given the opportunity, would also be prepared to pay for private treatment in addition to NHS care.\(^{24}\) The conditions of increased access to knowledge about drugs via the Internet, more explicit limits on treatments determined not to be cost effective by NICE, and the increasing cost of targeted anti-cancer treatment had created a fertile ground for the development of widespread discontent, which would have been inevitable if the issue of co-payment within the NHS had not been addressed. Given the extent to which this issue had the potential to alter the fundamental character of the NHS, it is nonetheless surprising that the Richards’ review, and the public consultation which followed, were not incorporated into the NHS Constitution development process\(^{25}\) as this would have provided the opportunity for much wider public consultation and would have allowed the recommendations which followed to be integrated into the framework of the Constitution.


\(^{23}\) Section 4.5.1


Professor Richards consulted widely on the issue of NHS top-ups, reporting back to the Secretary of State for Health in November 2008.\(^\text{26}\) The DoH response was rapid, with draft guidance on NHS patients who wished to pay for additional private care being issued the same month. Despite being issued for consultation, the recommendations nonetheless came into immediate effect.\(^\text{27}\) Final guidance, amended in light of the consultation, was published in March 2009.\(^\text{28}\) Addressing the issue of improving access to cancer drugs was clearly regarded as something which needed to be tackled with urgency. In addition to allowing NICE to lower the cost-effectiveness threshold for end of life drugs,\(^\text{29}\) the guidance on top-up payments was presented as part of a package of measures to improve access to medicines via the NHS, including increasing the speed with which NICE appraisals are undertaken so as to shorten the delay between licensing and availability on the NHS, improving local PCT decision making for IFRs, through the NPC guidance commissioned by the DoH\(^\text{30}\) and more flexible drug pricing arrangements through an amended Pharmaceutical Price Regulation Scheme.\(^\text{31}\)

### 3.1.6 Fudging the issue by temporarily designating NHS space as private

The main recommendation of the Richards’ review was that patients should be allowed to continue to receive NHS care simultaneously with private care, provided that the private care is delivered separately to NHS care, where separate is defined as being at a different time and place to NHS care. However, a different place does not simply mean the premises of a private healthcare provider as one might immediately assume. It includes part of an NHS facility which has been permanently, or even temporarily, designated for private care, such as a private room or amenity bed. In effect, a patient


\(^\text{29}\) See Chapter 2, Section 2.2.1.

\(^\text{30}\) Discussed in Chapter 2, Section 2.3.2.

could attend an NHS chemotherapy suite in the morning to receive chemotherapy funded by the NHS. She could return to that same chemotherapy suite in the afternoon, now temporarily designated for private care, and receive a privately funded cancer drug, paying in addition for the cost of staff involved in the provision of the drug and any blood tests or scans indicated only because of the unfunded drug. In cases where, for reasons of efficacy, the two drugs need to be administered in quick succession, the patient could attend for her privately funded treatment less than an hour after her NHS treatment, at a separate private appointment in a room designated for private care close to, or even within, the NHS chemotherapy suite. In both instances, the patient is allowed to have additional private care because the guidance considers the NHS element of care and the private element of care to have been delivered separately. How close can the two elements of care become and still remain separate? By allowing the temporary designation of NHS space as private, it would be possible for two identical patients in adjacent beds to receive differential treatment based on their ability to pay. The Richards’ review had the opportunity to avoid the creation of a two-tier NHS, by insisting on the separation of NHS and private care, but failed to take it. Although a superficial reading of the guidelines provides the impression that the guidelines aimed to achieve separation of the two types of care, scrutiny of the detail reveals that the guidelines permit a different reality.

3.1.7 The Richards’ review introduces double standards

Double standards in determining ‘separateness’ for medical and surgical care.

The guidance on NHS patients wishing to pay for additional treatment created a strange anomaly between medical and surgical care. Contained within the guidance is an illustrative scenario describing a patient undergoing cataract surgery, who would like a privately funded multifocal lens to be inserted during his NHS surgery, rather than the standard single focus lens provided by the NHS. The guidance advises that, as the private element of care cannot be delivered separately from the NHS element of care, the patient cannot pay for the additional care he desires. It does not take a huge leap of imagination to conceive that, if the NHS operating theatre were to be temporarily designated for private care for the short period of time during the operation that lens insertion is undertaken, this case is not so different from a patient returning to the NHS chemotherapy suite to receive her privately funded chemotherapy. After all, the operation for the multifocal lens will be the same as for the single focus lens – why not
separate the operation from the lens insertion? The new guidance is inconsistent in setting different standards of separateness for surgical interventions and for drugs.

**Double standards for the management of complications arising from private treatment**

The guidance advises that the private provider should normally deal with non-emergency complications resulting from the private element of care. Whilst in keeping with the principle of separateness outlined in the guidance, and a mechanism to limit the extent to which the NHS cross-subsidises the cost of private treatment, this is not consistent with current practice. Patients undergoing private cosmetic surgery can attend for NHS care if complications occur. This was well illustrated when it was discovered that the implants manufactured by Poly Implant Prosthese, used in the private breast augmentation of thousands of women in the UK, were not fit for human use. Removing them was estimated to cost the NHS hundreds of thousands of pounds.³²

In practice, if NHS treatments are being given concurrently with privately funded treatments, particularly with cancer treatments which cause a myriad of side effects, it may be hard to determine in any case which complications are attributable to which treatment. Of equal gravity is the potential problem of determining legal liability between the NHS and private provider in the event of negligence. With two teams sharing the management of disease, it may not be straightforward to determine which is at fault.

**Double standards in the departure from the principle of separation on grounds of safety**

The principle of separating NHS treatment and additional private care may not always be in the patient’s best interests. Aside from the need for adequate communication between NHS and private systems, receiving care from two providers may prove disruptive to patient care. The DoH guidance on patients seeking additional care allows for departure from the principle of separation on the grounds of patient safety. However, despite the somewhat nebulous idea of separateness outlined in the guidance in relation to the administration of cancer drugs, no such flexibility was afforded to the women who suffered the misfortune of receiving Poly Implant Prosthese implants, again reflecting the different parameters being applied for medical and surgical interventions. Women who had unsafe implants removed on the NHS were not provided with

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³² Torjesen I. Hundreds of thousands of pounds of NHS funds have been spent on care of private patients with PIP implants. BMJ 2012;344:e1259.
replacement implants, and were not allowed to pay to cover the additional cost of having this undertaken on the NHS, despite the argument on safety grounds that this would avoid the need for a second operation and anaesthetic.\textsuperscript{33}

3.1.8 The impact of top-up payments on exceptional funding requests

The guidance on NHS patients who wish to pay for additional care has an impact on the practice of individual doctors, irrespective of whether or not they are in the business of private healthcare. In addition to the existing obligations on doctors, the DoH guidance on patients who wish to pay for additional care creates a new duty on the medical profession, stating that:

_Doctors, working with NHS managers, should exhaust all reasonable avenues for securing NHS funding before suggesting a patient’s only option is to pay for care privately._\textsuperscript{34}

Reference in the guidance is made to the option of applying to PCTs for funding on the basis of the patient’s exceptional circumstances, although no guidance is provided in the document as to what factors might be relevant in this regard. The lack of guidance on what constitutes ‘exceptional’ in this context is highlighted and explored further in Paper 1.\textsuperscript{35} In fact, by making the purchase of additional care alongside NHS treatment more affordable, by not withdrawing free NHS care to those paying for additional treatment, patients at the end of life may actually choose to self fund treatment, in preference to risking delays in treatment and additional bureaucracy by applying for funding on the basis of exceptional circumstances. As a result, the volume of IFRs for cancer drugs could fall. Alternatively, patients may strategically purchase a short course of cancer treatment prior to submitting an IFR, with the aim of maximising their chances of being considered exceptional. Whilst the issue of what constitutes exceptionality is extensively addressed in Paper 1, it is worth mentioning briefly here that one element of being exceptional that has been advanced is the ability to gain significantly greater benefit from the requested treatment than others with the same condition.\textsuperscript{36} By virtue of the fact that the treatment is being requested on the basis of exceptionality, it is not widely available on the NHS. Therefore, one of the few ways in which a patient will be

\begin{itemize}
\item \textsuperscript{33} O’Dowd A. Health department refuses plea for private PIP implants to be replaced on NHS. BMJ 2012;345:e4658.
\item \textsuperscript{34} Department of Health. _Guidance on NHS patients who wish to pay for additional private care._ March 2009. op. cit. note 28.
\item \textsuperscript{35} Chapter 8.
\item \textsuperscript{36} This specific definition of exceptionality is discussed in more detail in Paper 1, Chapter 9, Section 9.4.1.
\end{itemize}
able to demonstrate the ability to benefit more from treatment is by paying privately for a trial course of the required drug. NHS top-up payments put this option within reach of more, but not all, patients. Whether a PCT would be compelled to consider the effect of a privately funded treatment in its assessment of a patient’s exceptionality has yet to be addressed directly by the courts. If PCTs are obliged to do so, this will place those patients who can afford a trial of treatment at an unfair advantage over those who cannot, in trying to prove their exceptionality.

3.1.9 Old regional variations may be replaced by new ones
It might be hoped that the new guidance on patients who wish to pay for additional care would abolish the regional variation in access to care previously in existence, whereby patients in some areas who paid for additional treatment lost their entitlement to NHS care, whilst patients in other areas did not. However, new regional variations are likely to emerge. Private care provision varies across the country, tending to be concentrated in larger cities. The DoH has stated that it is not its role to ensure that there is an even spread of private practice across the country.37 NHS and Foundation Trusts can choose to provide private care, recovering costs from patients who use these services. The guidance emphasises that the NHS should not subsidise the private element of care, but nor should the NHS be seen to be profiting ‘unreasonably’ from patients in these circumstances. Given that private healthcare providers have no such restrictions on their profits, it seems likely that those who are able to access private care provided by the NHS will be able to do so at lower cost. For some smaller NHS centres providing private care may not be viable, either due to a lack of facilities, or a lack of NHS doctors willing to undertake private work, resulting in inequality of access to more affordable private services.

3.1.10 When is a patient not an NHS patient?
Prior to the Health and Social Care Act 2012, Foundation Trusts were limited by the statutory private patient income cap in what they could earn from providing private healthcare. This cap was set at the proportion of income which the Trust earned from private patients in the financial year ending in 2003 and had been included in legislation to appease Labour backbenchers who feared that the creation of Foundation Trusts might result in privatisation by the back door. The average cap was 1.5%, but this was lifted by changes in the Health and Social Care Act 2012 to a universal limit of 49% of a

Trust’s income. How will Foundation Trusts look to maximise their private income? Already a growing range of services are available from NHS hospitals for patients who are prepared to pay, such as fertility services and bone density scans. These are generally used by patients who fall outside the cohorts for whom these services are usually commissioned, and who are therefore not entitled to receive them free of charge. However, at least one Trust is allowing patients to pay for blood tests and scans for the purpose of ovarian cancer screening, despite the fact that this intervention has not been recommended by the UK National Screening Committee for any population.

Many of these Trusts do not perceive themselves to be providing private treatment, highlighting that their charges are much lower than commercial private providers and in some cases are provided on a not-for-profit basis. Consequently, these Trusts do not consider patients who pay for their own treatment to be private patients. A medical director of one Trust is quoted as saying:

‘These patients are seen in NHS time. They are NHS patients entitled to NHS care. They are seen in NHS premises. They are not private patients. The nurses and staff who deal with them are NHS staff.’

These patients are clearly ‘NHS patients who wish to pay for additional care’ as described in the title of the DoH guidance stemming from Professor Richards’ review, yet in spite of this, the extent to which the guidance applies to them is less clear. The central principle of private care being delivered separately from NHS care seems to have been overlooked, but is this because these patients are not regarded as simultaneously receiving private and NHS care? If this is the case, how can it be justified that those who are not entitled to any NHS treatment for their condition can self fund the intervention they desire at favourable NHS ‘private’ rates, whereas those who are entitled to sub-maximal treatment from the NHS for their condition must find, at least in theory, a service which can deliver the additional treatment they need at a separate time, in a separate place? One of the concerns which triggered the Richards’ review of top-up payments within the NHS was that it would lead to a two-tier system within the NHS, of

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39 Ibid.
40 O’Dowd A. Health department refuses plea for private PIP implants to be replaced on NHS. op. cit. note 33.
41 Ibid.
42 Ibid.
those who could afford to pay for additional NHS care, and those who could not. Ironically, this is exactly what we have ended up with, with one NHS hospital website listing fertility services for NHS patients, self-funding NHS patients and, in a separate category again, private patients.⁴⁴

3.1.12 Conclusion

If, as I outlined in Section 3.1.4, PCTs were acting outside the law by withdrawing NHS treatment from patients receiving concurrent private care, it is possible that a legal challenge of PCTs’ actions might have resulted in greater clarity on the issue of top-up payments than the Richards’ review has achieved. The guidance materialising from the review seems in principle to support the idea of keeping NHS and private treatment separate, but in practice allows them to be given together. The guidance has also inadvertently introduced double standards relating to private payment in three separate areas: between medical and surgical treatments in determining what constitutes a separate place; in the management of adverse consequences arising from private cancer treatment compared with private cosmetic treatment; and in the departure from the principle of separation of private from NHS treatment on the basis of safety concerns which now appears to differ between cancer and non-cancer treatments. Further, the Richards’ review has resulted in an anomaly whereby purchasing stand alone care within the NHS is regarded very differently from purchasing additional care on the NHS which is being given concurrently with another treatment. Arguably, payment for treatment on the NHS in either situation raises the same issues of equity between those patients who can afford to buy treatment and those who cannot, and should be managed in the same way.

The acceptance of top-up payments within the NHS is an open acknowledgement that the NHS does not provide a universal, free and comprehensive service. It is time to question the continued pretence that the founding principles of the NHS still prevail. One of the consequences of maintaining this fallacy has been a continued rise in patient expectations of the NHS. This has resulted in a sense of entitlement to treatment, with patients seeking IFRs on the basis of exceptionality when no other route to access NHS treatment remains open.

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The review of top-up payments within the NHS was triggered by cancer patients purchasing expensive drugs which were not funded by the NHS. Paradoxically, since the unforeseen introduction of the Cancer Drugs Fund, which has undeniably increased access to cancer drugs on the NHS to a much greater extent than the whole package of measures implemented as a result of the Richards’ review put together, less has been spent by NHS patients on ‘topping up’ their care with cancer drugs. Those who ploughed money into the insurance policies which emerged onto the market after the Richards’ review, offering to cover the cost of cancer drugs not funded by the NHS, have found themselves with a worthless investment.45 Any impact of the Richards’ review on IFR applications has, it turns out, been negligible to date. This may alter when the Cancer Drugs Fund closes, if this happens as originally planned.

If the consultation on NHS patients purchasing additional care was hasty, the consultation which preceded the establishment of the Cancer Drugs Fund was virtually non-existent, though its impact on patient equity is potentially much greater. The Cancer Drugs Fund creates inequity between those patients who have a cancer which will benefit from high cost treatment, and those patients who do not, rather than between those who can afford additional NHS care and those who cannot. This, and other issues relating to the Cancer Drugs Fund, are analysed in the following section.

3.2 The Cancer Drugs Fund – an oncologist’s honey pot?

3.2.1 Introduction

Some of the recent changes in access to cancer drugs within the NHS, such as the formalisation of IFR decision making process and the guidance on top-up payments, were perhaps predictable. However, at the start of my research, few would have anticipated the introduction of the Cancer Drugs Fund – the result of a promise made by the then opposition leader, David Cameron, in the run-up to the 2010 UK general election, that no patient would be denied access to cancer drugs on grounds of cost.46 Cameron offered to establish a Cancer Drugs Fund to ensure patients had access to all treatments which their clinicians felt to be beneficial, until the introduction of value-based drug pricing, planned for 2014.47 The move was an act of political opportunism in

47 See Chapter 11, Section 11.4 for more detail on the proposals for value-based drug pricing.
a pre-election climate, at a time when Ipsos Mori reported cancer to be top of people’s health concerns. Why else prioritise cancer treatments over those for dementia, or multiple sclerosis, whose sufferers face similar difficulties accessing treatment? Advocates of increased spending on cancer drugs with poor cost-effectiveness might respond that the public’s fear of cancer and universal desire for a cure, especially at a time when the development of molecular based drugs holds so much promise, justifies spending NHS resources on cancer drugs irrespective of the opportunity costs. Widespread use allows the full potential of new drugs to become apparent and motivates the pharmaceutical industry to push forward the frontiers of research. It has been argued that, with victory imminent, now is not the time to conclude that winning the war was not a significant priority after all, by failing to provide the resources to pay for cancer drugs.

If the lowered NICE cost-effectiveness threshold for cancer drugs, and the subsequent rush to address the demand for top-up payments raised suspicions that cancer was being treated as a special disease, the arrival of the Cancer Drugs Fund confirmed the privileged position of cancer treatment within the NHS. Once the most frequently requested treatments on the basis of exceptionality, cancer drugs have become an exception in themselves, no longer subject to the cost-effectiveness standards expected of other treatments available on the NHS. I will argue that the Cancer Drugs Fund fails patients, both those with cancer, and those without. There is limited, if any, public support to suggest that cancer is considered worthy of special funding status. The costs of the Cancer Drugs Fund are significantly greater than advertised, as the money allocated to the Fund does not cover the associated expenses of cancer drugs, such as intra-venous administration and management of adverse effects. Further, the Cancer Drugs Fund is exacerbating geographical inequalities in access to cancer drugs and there is speculation that it is having a negative effect on the market price of cancer drugs in England. The Cancer Drugs Fund has undoubtedly impacted on the application and approval rates for cancer drugs in exceptional circumstances, though the manner in which this has occurred is more complex than might have been anticipated. As funding is diverted from the treatment of other disease groups into the Cancer Drugs Fund, a likely consequence is the rise of IFRs for non-cancer treatments.

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48 Ibid.
49 The opportunity cost describes the alternative health care that must be foregone by others, to provide resources to fund cancer drugs.
3.2.2 Do the public support the prioritisation of spending on cancer drugs?

Ring-fencing money for expensive cancer drugs which offer limited health benefits ‘drives a coach and horses through NICE’, but more than that, it undermines the entire concept of allocating limited resources in a well reasoned and evidence based manner.\(^5\)

The media has been vociferous in its support for patients denied access to cancer drugs, but is this endorsement representative of the view of the public more generally? And if so, does this simply reflect human sympathy for the suffering of others, without a full appreciation of the opportunity costs which would arise if resources were diverted to address the problem? The DoH expresses some uncertainty over the issue. The Impact Assessment of the proposal for a Cancer Drugs Fund states that:

\[\text{‘The primary rationale for the fund is the possible preference of society for providing treatments to patients suffering severe conditions.’}\]\(^5\)\(^3\) (emphasis added)

Whilst the wisdom of basing healthcare priorities on public opinion alone is questionable,\(^5\)\(^4\) if the rationale that society values health benefits provided to cancer patients more than those provided to other patients is being used to justify the Cancer Drugs Fund, then this fundamentally empirical question should be asked of the public.

Since the establishment of the Cancer Drugs Fund, Hughes and Linley have done just this. Their UK based study, of over 4,000 patients, revealed no support for the special funding status of cancer.\(^5\)\(^5\)

3.2.3 The real costs of the Cancer Drugs Fund

The Impact Assessment of the proposal for a Cancer Drugs Fund calculates that, over the course of the Fund’s lifetime, the health losses to patients elsewhere in the NHS will be £1,345 million. It arrives at this conclusion using an estimated cost of £50,000/QALY for drugs paid for by the Fund, and assumes that this will displace other treatments.

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\(^5\)\(^4\) The Oregon experiment is perhaps the best example of this, see Klein R. On the Oregon trail: rationing health care. BMJ 1991;302(6767):1-2.

available representing double this value, at the median of NICE’s cost-effectiveness range, £25,000/QALY.\textsuperscript{56} However, this assessment overlooks the fact that the Cancer Drugs Fund is only intended to pay for the purchase of medicines and associated molecular diagnostic testing necessary to ensure their optimum use. The costs of drug delivery, monitoring scans, and management of side effects, which might in some cases necessitate hospital admission, must be met by PCTs,\textsuperscript{57} so the total opportunity cost of the Fund to the NHS is likely to be greater than the conjectured £1,345 million. These additional costs have been estimated to amount to £73 million between April 2011 and March 2012 alone.\textsuperscript{58}

3.2.4 The Cancer Drugs Fund losers

Those individuals who are forgoing treatment to release the money required for the Cancer Drugs Fund make up an unknown, and likely diverse group. This makes it almost impossible for them to unify and present a vocal campaign against the decision to make treatments for their conditions a lower concern than cancer. Amongst them are, no doubt, patients with equally poor or worse prognoses, such as patients with advanced heart failure.\textsuperscript{59} Paradoxically, the Cancer Drugs Fund, by prioritising only the funding of high cost drugs, and radiopharmaceuticals\textsuperscript{60} will inevitably mean that some cancer patients within the disease group the Fund was designed to help will also be amongst those paying the opportunity costs of the Fund, by forgoing access to cheaper, more cost-effective treatments and palliative care. Some have argued that in many instances the extra money allocated to the Cancer Drugs Fund would, in fact, be better invested in palliative care.\textsuperscript{61} The Royal College of Radiologists has questioned the additional discrimination between cancer patients that the Fund creates by financing only cancer drugs, rather than more expensive forms of radiotherapy, such as stereotactic

\textsuperscript{56} A standard discount factor for health benefits of 1.5% is also applied over three years. Discounting makes current costs and benefits worth more than those in the future, allowing for the opportunity cost of spending money immediately, and the desire to enjoy health benefits sooner rather than later.


\textsuperscript{60} A product containing one or more radioactive isotopes for a medicinal purpose.

\textsuperscript{61} Graham J, Cassidy J, Hughes D, et al. op. cit. note 59.
If the rationale for the Cancer Drugs Fund is, as the Impact Assessment suggests, that society values health benefits provided to cancer patients more than those provided to other patients, there seems no reason why this should be limited to the provision of high cost pharmaceuticals only, and not other cancer services.

Sir Mike Rawlins, previous chairman of NICE, has questioned the ring-fencing of money to fund cancer drugs, commenting;

‘There are rotten diseases apart from cancer.’

Rawlins has suggested that the Fund should not be limited to patients with cancer. As it currently operates, the Cancer Drugs Fund penalises both non-cancer patients and those cancer patients not in need of new, high cost treatments.

3.2.5 The Cancer Drugs Fund winners

Whilst the Cancer Drugs Fund losers remain unidentified, who are the winners? Some would argue that they are those who are now able to receive high cost cancer drugs, previously restricted by NICE cost-effectiveness appraisals. In fact, this is questionable. A recent analysis suggested that drugs being funded by the Cancer Drugs Fund are being used for shorter periods and/or at lower doses than reported in clinical trials. A proportion of approved treatments are never even commenced. The most likely reasons for this are early disease progression or significant side effects. As is not uncommon in clinical practice, the benefits of treatment evident in clinical trials are not always directly applicable to the broader population of patients. To examine this in more detail, the newly commissioned Chemotherapy Intelligence Unit is undertaking a retrospective and prospective audit of drugs funded by the Cancer Drugs Fund. The other beneficiaries of the Cancer Drugs Fund, clearly listed in the Impact Assessment of the proposal for a Cancer Drugs Fund, are shareholders in the pharmaceutical industry,

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62 Stereotactic radiotherapy is administered via multiple beams of radiation, in more than two dimensions, reducing the dose to normal tissues, and hence side effects. See Barrow, M. Cancer Fund doubts. The Times 5 December 2012. http://www.thetimes.co.uk/tto/health/news/article3620478.ece (accessed 5 December 2012).


64 Barrow, M. op. cit. note 62.

65 More than a negligible number of approved requests remain unfulfilled, but the number has not been formally reported. Personal Communication, Professor Peter Clark, Chair of North West Cancer Drugs Fund, Oct 2012.


whom it has been calculated stand to gain an additional £77 million in additional profits as a result of the Cancer Drugs Fund. The interests of Pharma would appear to have been put above efficient investment in NHS services.

3.2.6 How is the Cancer Drugs Fund financed and administrated?

In response to the immense expectation created by his pre-election promise, whilst awaiting the establishment of the £200 million a year Cancer Drugs Fund in operation today, David Cameron launched an interim Cancer Drugs Fund of £50 million within just five months of taking office. Unlike the substantive Cancer Drugs Fund, established in April 2011, which has been resourced by top slicing PCT budgets, the interim Cancer Drugs Fund was centrally funded with ‘new’ money, released by abandoning the previous government’s plans to provide free personal care to the elderly. Both the Cancer Drugs Fund, and the interim Fund which preceded it, have been administered on a regional level, via Strategic Health Authorities. Each Strategic Health Area has been allocated a share of the Fund using a national weighted capitation formula. In keeping with the ethos expressed in the then evolving Health and Social Care Act, to put more power in the hands of clinicians and allow them to provide patients with the drugs they felt would benefit them, clinically led panels were swiftly recruited within each SHA.

There was an expectation that decision making processes would be clear and defined, but again, in accordance with the tenor of the Health and Social Care Act, these were allowed to be determined at a local level. As a result, there has been some variation in operational practices of Cancer Drugs Funds across the country. Many Strategic Health Authorities have developed inclusion lists of drugs which their Cancer Drugs Fund will automatically fund, subject to a patient meeting specified criteria, to aid rapid access. However, the number of treatments contained on these inclusion lists varies by SHA,

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71 Department of Health. Dear Colleague letter from NHS Medical Director clarifying financial arrangements for the Cancer Drugs Fund in 2011-2012. op. cit. note 69.
73 The national weighted capitation formula takes account of factors such as the age of the population in determining the allocation of funding.
74 Health and Social Care Act 2012.
from 8 in NHS South West to 76 in NHS East of England. It is claimed that some of these disparities can be explained by differences in baseline commissioning. More controversially, two SHAs have additionally developed exclusion lists of drugs they do not consider it to be appropriate to fund. This has been criticised by a cancer patient’s advocacy group as going against the spirit of the Fund.

At the present time, drugs financed by the Cancer Drugs Fund are either awaiting appraisal by NICE, have been deemed cost-ineffective by NICE, or fall into a category where demand for treatment is unlikely to ever reach a sufficient level to warrant a NICE appraisal (either because they are only licensed for cancers with small patient populations or are drugs being used outside their licensed indication, to treat rare cancers with similar biology to those for which they have been licensed). This latter group are described as ‘off label’ treatments and are collectively estimated to make up approximately 10% of Cancer Drugs Fund approvals. Nationally, over 12,000 patients have had applications for treatment granted by the Cancer Drugs Fund. The three most requested drugs between April 2011 and March 2012 were bevacizumab, cetuximab, and abiraterone, accounting for 48.5% of applications. Approval rates are high, with 97% of requests approved overall, and show consistency between Cancer Drugs Funds, ranging from 94 to 99%. However, behind this veneer of uniformity there are some discrepancies which warrant further investigation. The first is the difference in spending between Cancer Drugs Funds. Given that this funding was distributed on a weighted capitation basis, expenditure would be expected to be similar across Funds. In fact, the proportion of Cancer Drugs Funds spent is reported to vary from 50% of the allocation in NHS North West, to 99% in NHS South East Coast. It is unclear if these differences can be explained wholly by differences in SHA accounting practices, whereby some SHAs allocate funding at the time of application approval, and others only once the drug is received.

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76 Baseline commissioning refers to the range of cancer drugs routinely funded by a PCT, outside the Cancer Drugs Fund. See National Cancer Action Team. *Cancer Drugs Fund Bulletin.* op. cit. note 67.
78 Ibid.
79 Ibid.
81 Ibid.
83 Ibid.
administered.\textsuperscript{84} Contrasting expenditure may also be linked to the second discrepancy apparent; the variation in application and approval rates between SHAs, once adjusted for population.\textsuperscript{85} This variation may be warranted if there are differences in cancer incidences between populations, leading to differences in demand for high cost cancer drugs. It may also be explained by differences in base line commissioning for cancer drugs mentioned previously. Interestingly, evidence of variation in access to the Cancer Drugs Fund within regions is also starting to materialise.\textsuperscript{86} Whilst investigation into these issues is beyond the scope of this doctorate, the author has commenced some postdoctoral research in association with NICE to examine these emerging variations in more detail.

\textbf{3.2.7 The effect of the Cancer Drugs Fund on NICE and cancer drug pricing}

There is speculation as to whether the Cancer Drugs Fund has impacted on the outcomes of NICE appraisals of high cost cancer drugs. Figures currently on the NICE website reveal that between January 2000 and December 2012, overall 35\% of appraised cancer drugs were rejected, though in the most recent period, between January 2012 and December 2012, the rejection rate has been higher, at 57\%.\textsuperscript{87} The total number of drugs appraised in the latter period is low and by chance may have included a high number with low cost-effectiveness. However, given the introduction of the higher QALY threshold for end of life treatments in 2009,\textsuperscript{88} one might have expected to see a trend of more, rather than fewer cancer drugs receiving NICE approval. Has the Cancer Drugs Fund inadvertently pushed drug prices up, therefore reducing their cost-effectiveness? Pharmaceutical companies are renowned for charging as much as the market will bear. Failing to gain NICE approval due to exorbitant prices must now be an attractive prospect to drug companies, as it opens up the prospect of a drug being financed by the Cancer Drugs Fund, with its very high approval rates and absent QALY threshold. Whilst DoH guidance advises SHAs that they may choose not to fund drugs where a NICE appraisal has not been possible due to lack of cooperation by a

\textsuperscript{84} Ibid.
\textsuperscript{85} Ibid.
\textsuperscript{86} Personal Communication, Professor Peter Clark, Chair of North West Cancer Drugs Fund, Oct 2012.
\textsuperscript{88} See Chapter 2, Section 2.2.1
manufacturer, there is nothing to stop manufacturers setting their prices at a level they know will fail to meet NICE’s cost-effectiveness threshold.

One argument presented by the DoH for regional administration over national administration of the Cancer Drugs Fund was that manufacturers might be more open to price negotiation at a local level, and hence this might achieve lower prices for the NHS. The reasoning behind this was that local negotiations would be subject to less international scrutiny, and hence manufacturers would be less fearful that local discounts would impact on pricing, and profit margins elsewhere. Equally, however, it could be argued that local Cancer Drugs Funds lack negotiating power because of their size, and given the smaller drug volumes used, especially for rarer cancers, local Cancer Drugs Funds would be in a weaker position to negotiate than a nationally administered fund. Due to commercial confidentiality agreements, information about local price negotiations is not in the public domain. However, it is evident that pharmaceutical companies have become less willing to offer the DoH patient access schemes for cancer drugs appraised by NICE. Patient access schemes were offered for approximately one-third of cancer drugs in 2011-12, compared with over a half in 2009-10. This may explain, at least in part, why fewer cancer drugs than previously are meeting NICE’s QALY threshold. Even if the Cancer Drugs Fund is not pushing prices up, it has certainly released the downward pressure on drug pricing in the UK. If, over time, this leads to a

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90 The UK sets national drug prices through the Pharmaceutical Price Regulatory Scheme (PPRS). As a result, the UK has a national list of drug prices which are widely used by other countries as a basis on which to set their own prices. It is therefore in the interests of drug companies seeking to maximise profits for UK list prices to be as high as possible. Department of Health. The Cancer Drugs Fund: guidance to support operation of the Cancer Drugs Fund in 2012-13. op. cit. note 57.
91 Patient access schemes are proposed by drug manufacturers as an indirect way of offering a price discount. They may make provision for a discount (usually in the form of a refund) dependent on the number and type of patients using the drug, or if the drug fails to be effective in some patients. Companies prefer these schemes over offering a direct discount, because the effective price agreed through a patient access scheme is not reflected in a drug’s UK list price and hence does not influence international drug pricing. Historically, patient access schemes were created in attempt to meet NICE cost-effectiveness thresholds, and increase the chance of a positive appraisal. As NICE has no negotiating power, patient access schemes must be agreed with the DoH prior to being reviewed by NICE. Such schemes are often unpopular with the PCTs and hospitals which have to implement them, as they are cumbersome to administrate, and because of this, the full refund due is not claimed and the anticipated savings are not made.
92 Rarer Cancers Foundation. There when you need it most? The Cancer Drugs Fund: 2011-12 annual report. op. cit. note 58.
rise in cancer drug prices, and cancer treatment continues to be prioritised over other
diseases, this will further reduce the resources available to non-cancer patients.

3.2.8 The impact of the Cancer Drugs Fund on IFRs

The effect of the Cancer Drugs Fund on IFRs for cancer drugs submitted to PCTs has
been significant, but is difficult to formally quantify because the impact on application
rates has not been uniform across the country. This appears to be a consequence of
differing interpretations by SHAs of the DoH’s guidance on how the individual funding
process should interrelate with the Cancer Drugs Fund, the guidance itself having been
varied three times since the Cancer Drugs Fund was established. Initially, the DoH
guidance advised that the option of an IFR should be ‘explored’ prior to every
application to the Cancer Drugs Fund.94 The DoH then changed its guidance to advise
that an IFR should only be considered prior to applying to the Cancer Drugs Fund if this
were justified by aspects of the patient’s case.95 The DoH has since further refined its
guidance, emphasising that an IFR is only indicated if the patient is requesting a
treatment that is not on the local Cancer Drugs Fund’s inclusion list.96 The effect of
multiple revisions of the guidance on how IFRs at PCT level should sit alongside the
Cancer Drugs Fund at SHA level has been to change the picture from one where a prior
IFR was almost mandatory before an application was made to the Cancer Drugs Fund, to
a situation where an IFR is only rarely required prior to an application to the Cancer
Drugs Fund. It is hardly surprising that IFRs relating to cancer drugs are in a state of flux
nationally. The current picture of IFRs in England is probably best illustrated by an audit
conducted by the Rarer Cancers Foundation.97 Figure 1, reproduced with kind
permission of the Rarer Cancers Foundation, shows a snapshot of how the numbers of
IFRs for cancer drugs have varied over the last three years, amongst the 81 PCTs which
responded to the Rarer Cancers Foundation. It is not possible to distinguish from the
data provided how many IFRs were made as exceptional requests to existing policies,
and how many were true individual commissioning requests for one.98 What is clear is

94 Department of Health. Dear Colleague letter from the NHS Medical Director, on Interim Cancer
Drugs Funding. op. cit. note 70.
95 Department of Health. The Cancer Drugs Fund: guidance to support operation of the Cancer
96 Department of Health. The Cancer Drugs Fund: guidance to support operation of the Cancer
Drugs Fund in 2012-13. op. cit. note 57.
97 Previously known as the Rarer Cancers Forum.
98 The difference between these two types of applications is explained in Chapter 2, Section 2.2.2.
Figure 1: Number of exceptional case applications for cancer treatments received by PCTs, 2009-10 to 2011-12
Figure 2: Outcomes of exceptional case applications for cancer treatments received by PCTs during 2011-12
that the number of IFRs currently varies hugely between PCTs, from 1 to 244 per year in 2011-12. However, the majority of PCTs report fewer than 25 IFRs for cancer drugs in the last year, and for many the volume of requests is much lower. A broader picture of IFR activity is provided by examining not just the total number of applications at each PCT, but the number of applications accepted and rejected at each PCT. The Rarer Cancers Foundation reports the number of IFRs approved and rejected per 100,000 population within the 81 PCTs which responded to its request for information. With kind permission of the Rarer Cancers Foundation this data is reproduced in Figure 2. This figure reveals that not only does the acceptance rate of IFRs vary hugely between PCTs, but that several PCTs have very high IFR rejection rates, compared with their application rates. It is likely that these relatively high rejection rates are related to how IFR application processes are interlinked to Cancer Drugs Fund application processes within these regions. The high rejection rates could be explained if those PCTs were still operating policies in 2011-12 which required the majority of applications to the Cancer Drugs Fund to first go through the IFR process, as discussed above.

3.2.9 Conclusion

Four years on from the start of my research, the number and success rate of cancer patients applying for funding of drugs on an individual basis continues to vary across PCTs. Whereas in 2009 this variation was attributable, in part, to the range of policies and processes which were in place, some degree of consistency has been achieved in this respect by the changes brought about by the NHS Constitution. The current variation in IFRs for cancer drugs is likely to be influenced by differing interpretations of the DoH’s guidance on how local individual funding request processes should interrelate with the process of applying to the Cancer Drugs Fund, and the number of drugs included on regional Cancer Drugs Funds’ ‘approved drugs’ lists. In real terms, this means fewer IFRs are being granted for cancer treatments, with drugs financed instead by the Cancer Drugs Fund. However, numbers of IFRs are being artificially boosted in some areas by the pre requisite that applications for the funding for cancer drugs are first submitted to PCTs as IFRs. In areas where this is not mandatory, volumes of IFRs for cancer drugs are miniscule, as illustrated by Figure 1 above. The reduction in IFRs

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99 Figures provided by the Rarer Cancers Foundation. (1 application a year at Telford and Wrekin, Suffolk and Hartlepool PCTs. 244 applications a year at Surrey PCT.)
100 Rarer Cancers Foundation. There when you need it most? The Cancer Drugs Fund: 2011-12 annual report. op. cit. note 58.
101 See Chapter 2, Section 2.3.
specifically for cancer drugs impacted on the empirical work planned at PCTs. All the PCTs participating in this aspect of the research reported a significant drop in IFRs for cancer drugs following the introduction of the Cancer Drugs Fund. As outlined earlier, instead of focussing solely on IFRs for cancer drugs in my empirical work, I examined the principles of decision making across all IFRs, irrespective of the drug or technology requested.

It now appears that, in the very near future, IFRs for cancer drugs, at least to PCTs and the CCGs which will replace them, will become extinct altogether, as part of the amalgamation of the ten regional cancer drugs funds into one National Cancer Drugs Fund, with a single budget. Following the implementation of the Health and Social Care Act 2012, the commissioning of chemotherapy will be managed as a specialised commissioning service and undertaken by the NHS Commissioning Board. In an attempt to reduce the geographical variation in access to cancer drugs which has emerged with regional Cancer Drugs Funds, it has recently been announced that there will initially be a national list of 28 cancer drugs approved by the new National Cancer Drugs Fund. The recently established national Clinical Reference Group for chemotherapy will undertake horizon scanning to allow the rapid evaluation of new cancer treatments and consider whether or not they should be supported by the Fund. The Cancer Drugs Fund will continue to operate within a limited budget, which means that, unlike NICE, it will continue to consider affordability as well as clinical and cost effectiveness. If new drugs approved by the Cancer Drugs Fund will cause the Fund to exceed its budget, drugs of lower priority must be removed from the list. With the establishment of a National Cancer Drugs Fund, it is expected that all IFRs for cancer drugs will be made directly to the Cancer Drugs Fund, rather than to the CCGs which will replace PCTs. Any individual requesting a drug which is not on the pre-approved list

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102 See Chapter 1.
103 See Chapter 6, Section 6.1.
105 To be known as NHS England as of 1st April 2013.
107 Ibid.
will have to show that either they have a particularly rare condition or that they are clinically exceptional compared with other patients in their cohort.\textsuperscript{108}

The prioritisation of high cost cancer drugs over treatments for other diseases is short-sighted. Resources are being siphoned away from more cost-effective treatments for cancer and other diseases to pay for high cost cancer drugs. If the speculation that the Cancer Drugs Fund has released the downward pressure on cancer drug prices proves to be true over time, the problem will be further exacerbated.

At a time when access to cancer drugs has become almost unfettered, it should not be forgotten that the Cancer Drugs Fund was only ever intended as a temporary measure, pending the transition to value-based pricing.\textsuperscript{109} It is unclear where IFRs for cancer drugs will be directed after this time. Meanwhile, the expectations of patients and clinicians are being raised – an effect which may not be so transient. Despite the hype, no absolute right to cancer drugs exists, or is ever likely to. The reasons for this will be examined from a legal perspective in the following chapter.

\textsuperscript{108} Ibid. The Standard Operating Procedures for the Cancer Drugs Fund define rarity as a condition likely to present in fewer than 20 patients a year. Clinical exceptionality is described as when ‘the patient is significantly different to the general population of patients with, and at the same stage of, the condition in question and the patient is likely to gain significantly more from the intervention than might normally be expected for patients with that condition.’ This bears a striking resemblance to the definition of exceptionality advanced by the NHS Confederation. See Chapter 8, Section 8.5. In addition, the Standard Operating Procedures for the Cancer Drugs Fund explicitly exclude social value judgments from decision making.

\textsuperscript{109} See Chapter 11, Section 11.4 for more detail on the proposals for value-based drug pricing.
4.0 Legal Approach: Resorting to the Courts when an Individual Funding Request Fails

4.1 Introduction

The first of the papers which make up the core of this thesis, ‘The Concept of Exceptionality – A Legal Farce?’, reviews the notion of exceptionality from clinical and moral perspectives, before proceeding to examine how the courts have interpreted the concept of exceptionality in judicial reviews of PCT decision making to date. This approach was chosen because, despite the recent proliferation of guidance regarding the process of IFR decision making, there has remained a distinct lack of detail on how the actual concept of exceptionality should be interpreted and applied.1 Approaching this issue through doctrinal analysis is not to suggest that the courts are necessarily the best establishment to shape and define the concept of exceptionality, but simply reflects the absence of other authoritative sources to turn to in attempting to elucidate this concept.

Judicial attitudes and reasoning reveal a range of ideas about the notion of exceptionality, including the extent to which both clinical and social factors are relevant to the assessment of whether an individual should be deemed exceptional, one of the central questions addressed by Paper 1. Using the detail elicited from the case reports, an attempt is made in Paper 1 to establish a set of criteria against which to determine whether a given individual would be considered exceptional. The model was tested using the five patients who have been the centre of judicial reviews concerning access to cancer drugs on the basis of exceptionality to date. The doctrinal analysis itself gave rise to further questions of a legal nature, in particular, whether it is possible for there to be more than one lawful answer to a policy question, and whether it must be possible to envisage exceptions to every policy that precludes the provision of treatment to the wider population. Both of these issues are addressed in Paper 1.

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The preceding introductory chapters have provided the context in which IFRs based on exceptionality occur, and how the IFR process relates to NICE appraisals and PCT commissioning. The effect of the NHS Constitution has been reviewed, and the impact of two significant changes, the Richards’ review of top-up payments and the introduction of the Cancer Drugs Fund, were examined. Both of these changes have served to elevate the status of funding for cancer drugs above that for other treatments, and the Cancer Drugs Fund in particular has impacted on the pattern of IFRs for cancer drugs. The purpose of this chapter is to provide the background to the work presented in Paper 1, and to address some of the additional issues raised during the research for the paper, which could not be included in the paper itself. Section 4.2 reviews why there is not an absolute right to treatment under the NHS Act 2006, and then proceeds to analyse the potential implications of the NHS Health and Social Care Act 2012 on the legal right to treatment. Although all claims founded on Human Rights have so far been dismissed during the judicial review process, this possible avenue for legal redress when access to treatment is denied is worthy of exploration and is examined next.

Despite the absence of a legal right to NHS treatment, analysing cases where patients have pursued access to treatment through judicial review reveals the prominent role played by the courts in priority setting decisions. Section 4.4 examines how the judicial attitude towards decision makers has altered since the establishment of the NHS, and how it continues to evolve. The gradual move from purely procedural review, to an evaluation which increasingly includes substantive elements of decision making is highlighted. Whether the judiciary are best placed for this role is also considered.

Judicial review does not occur in isolation, and this is particularly evident from the media frenzy which ensues when IFRs relating to cancer drugs are challenged. However, some of the consequences of legal action or threatened legal action are not purely incidental. Section 4.5 examines how legal action can be used strategically, not just by patients, but also by Pharma. It is argued that in the face of this, PCTs, and the CCGs which will succeed them, must proactively engage with both the law and the media, and harness the power they offer to establish a wider understanding of the need for priority setting and the processes involved.

Finally, Section 4.6 provides more extensive background on the judicial review cases referred to in Paper 1, which it was not possible to include in the article itself. Some of the differences in how the cases were handled by the courts are highlighted, and a
couple of widespread misconceptions about judicial review and cancer drugs are challenged.

4.2 Why there is no absolute right to treatment for cancer, or other conditions

Few, if any, cancer patients are undeserving of treatment. Even when drugs have low response rates and a significant risk of side effects, most would agree that a competent patient should be allowed to exercise his autonomy to undergo treatment if he chooses, especially when the alternative is a rapid demise. People feel that their expectation that the NHS will provide them with the treatment they need is not unreasonable, especially when faced with a life threatening condition. Compulsory taxes and national insurance contributions do not come with a caveat that if the treatment one needs is expensive, or has a poor chance of success, the NHS will not provide it. People perceive that they have a right to the healthcare they need. This perception has been reinforced by constant reiteration of the founding principles of the NHS, that healthcare will be:

‘Free at the point of delivery and available to all based on clinical need, not ability to pay’,

an issue that will be explored further in Chapter 5. However, the reality is that the NHS is a social insurance system with limited funds. If one person draws on resources, less is available to others. Few people consider that they may have an obligation to others to help conserve these resources, by taking preventative measures against ill health and accessing healthcare responsibly.

People who wish to access treatments which are not universally available can apply to their local PCT, through the IFR process, for funding on the basis that they are exceptional compared with others with their condition. DoH guidance advises that PCTs should provide a process to enable patients to appeal the outcomes of individual funding request decisions internally. In the absence of a satisfactory response at a local level, judicial review is a mechanism which allows decision making by public bodies to be

3 Section 5.2
4 Brazier M. Do no harm - do patients have responsibilities too? *Cambridge Law Journal* 2006;65:397-422.
5 National Prescribing Centre. *Supporting rational local decision-making about medicines (and treatments) - A Handbook of Good Practice*. op. cit. note 1.
challenged. It involves judicial scrutiny of the decision making process, rather than the outcome of the decision. Historically, the English courts have limited their involvement in decisions relating to resource allocation to whether or not they are rational, or reasonable, according to the Wednesbury principle. \(^6\) The courts can also review if the decision making body is guilty of procedural impropriety or has acted beyond its powers. The courts are largely concerned with procedural rather than substantive rights. The role of the judiciary is not to provide what they believe is the right decision, and they have refrained from ordering that one treatment be given over another, although they can order that a decision is remade, in accordance with the proper procedures.

The reality is that there is no absolute right to healthcare in English law. Limits of space prevented exploration of this issue in Paper 1, but this section analyses why this is the case. It is relevant to establish why no absolute right to specific health services exists, because it explains why patients seek to access treatment through judicial review when IFRs fail; there are few, if any, alternative routes available to them to access treatment via the NHS.

**4.2.1 The NHS Act 2006**

The NHS Act 2006 imposed on the Secretary of State a duty to

\[
(1)\ldots \text{continue the promotion in England and Wales of a comprehensive health service designed to secure improvement (a) in the physical and mental health of the people of those countries, and (b) in the prevention, diagnosis and treatment of illness. (2) The Secretary of State must for that purpose provide or secure the provision of services in accordance with this Act.}\;
\]

The scope of this duty is elaborated upon in Section 3 (1), which specifies that with regard to the Secretary of State’s duty to provide specified services, these should be provided:

\[
\text{‘to such an extent as he considers necessary to meet all reasonable requirements.’}\;
\]

In practice, the duties in Sections 1 and 3 of the NHS Act 2006 have been implemented by PCTs on behalf of the Secretary of State, according to Section 7 of the 2006 Act and

\(^6\) The Wednesbury principle originated from Associated Provincial Picture Houses Ltd v Wednesbury Corp [1948] 1 KB 223. It set the standard at which the courts could intervene with decisions of public administrative bodies as being when a decision has been made that is so unreasonable, no reasonable authority could have arrived at it.

\(^7\) NHS Act 2006, Section 1.

\(^8\) Ibid., Section 3(1).
the NHS Regulations 2002. In the context of resource allocation for the funding of drugs in exceptional circumstances, the duty to promote a comprehensive health service has to be balanced with Section 229 of the NHS Act 2006, which states:

‘Each Primary Care Trust must, in respect of each financial year, perform its functions so as to secure that its expenditure ... does not exceed [its income...].’

As this Act also empowers the Secretary of State to remove board members from office if they fail in this duty, the pressure not to overspend is significant.

Attempts to claim that Sections 1 and 3 of the 2006 Act imposed an absolute duty on the Secretary of State to provide specified health services have failed. In R v North and East Devon Health Authority, it was deemed that:

‘while he [Secretary of State] has the duty to continue to promote a free health service ... a comprehensive health service may never, for human, financial and other resource reasons, be achievable. Recent history has demonstrated that the pace of developments as to what is possible by way of medical treatment, coupled with the ever increasing expectations of the public, mean that the resources of the NHS are and are likely to continue, at least in the foreseeable future, to be insufficient to meet demand.’

More recently, in R v NHS Oldham, ex parte Booker, a case already discussed in Chapter 3, Section 3 of the 2006 Act was interpreted slightly differently. Having cited R v North and East Devon Health Authority, Pelling J explained Section 3 as creating:

‘an enforceable duty to provide facilities for those who are ill or have suffered illness subject to the qualification that the secretary of state or the PCT as his delegate need not provide such services where he or it does not consider they are reasonably required or would be necessary to meet a reasonable requirement’.

The tone of this comment is palpably different from that passed in R v North and East Devon Health Authority. Rather than emphasising the practical limitations of attempting to provide a comprehensive health service, more prominence is given to the discretionary power of the Secretary of State, or his delegate, in considering what he deems reasonable in the circumstances. CCGs are soon to replace PCTs as the Secretary of State’s delegate as a consequence of the Health and Social Care Act 2012. It remains

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9 NHS (Functions of Strategic Health Authorities and Primary Care Trusts Administrative Arrangements (England)) Regulations 2002.
10 NHS Act 2006, Section 229.
11 Ibid., Sections 66-68.
12 Birmingham Area Health Authority (Teaching), ex parte Hincks (1980) 1 BMLR 93.
14 Section 3.1.4.
to be seen whether, in response to fiscal pressures, the CCGs will use their perception of what is ‘reasonably required’ to dilute the concept of a comprehensive health service and how the courts will respond to this if CCGs do.

4.2.2 The Health and Social Care Act 2012

The consequences of the Health and Social Care Act 2012 are multiple and complex. However, it is relevant to review here the impact of the Act on the Secretary of State’s responsibilities. It was initially proposed to amend the duty of the Secretary of State from one of providing or securing the provision of services in Section 1 (2) of the NHS Act 2006 to one of acting:

‘with a view to securing the provision of services for the purposes of the health service.’\(^{16}\) (emphasis added)

This change was widely unpopular and perceived as removing direct responsibility for the NHS from the Secretary of State.\(^ {17}\) In a bid to appease the angry masses\(^ {18}\) this was reworded, omitting the nebulous phrase ‘with a view to’, to make the duty one of securing services to be provided in accordance with the Act,\(^ {19}\) and inserting a clause explicitly stating that:

‘The Secretary of State retains ministerial responsibility to Parliament for the provision of the health service in England.’\(^ {20}\)

Some have accepted this at face value,\(^ {21}\) but the extent to which the Secretary of State will remain directly accountable for health services remains questionable. The original duty on the Secretary of State, contained in Section 3 (1) of the NHS Act 2006, to:

‘provide throughout England, to such an extent as he considers necessary to meet all reasonable requirements’\(^ {22}\)

\(^{16}\) Health and Social Care Bill 132 2010-11 (as introduced) Part 1, para 2.


\(^{19}\) Health and Social Care Act 2012, Section 1 (1).

\(^{20}\) Ibid.

\(^{21}\) Ham C. What will the Health and Social Care Bill mean for the NHS in England? BMJ March 2012; 344:e2159.

\(^{22}\) NHS Act 2006, Section 3(1).
has been transferred on to CCGs in the Health and Social Care Act 2012, and a CCG must individually arrange for the provision of services:

‘to such extent as it considers necessary to meet the reasonable requirements of the persons for whom it has responsibility’.

Although in the new 2012 Act the Secretary of State retains the duty to promote a comprehensive health service, the ensuing shift of responsibility from the Secretary of State to Clinical Commissioning Groups in Section 3 (1), essentially fragments a national responsibility into a local one, and removes the means by which the Secretary of State would most effectively be able to promote a comprehensive health service. It could be argued that under the NHS Act 2006 the Secretary of State, in practice, delegated his functions to PCTs, but this was a discretionary power, rather than a duty as will be the case with CCGs. The overall control of the NHS by the Secretary of State under the 2006 Act was reinforced by his capacity to give legally enforceable directions to PCTs by means of Section 8. This direct influence over the actions of PCTs has been replaced by a duty on the Secretary of State to promote the autonomy of those exercising functions in relation to the health service. A similar duty not to interfere is placed on the new NHS Commissioning Board, which will share the Secretary of State’s duty to promote a comprehensive health service, other than with respect to the provision of public health services. Members of the NHS Commissioning Board will be appointed by the Secretary of State. The Board will be tasked, like CCGs, with arranging the provision of services, a function which, as discussed above, has been removed from the direct control of Secretary of State. Whether by oversight, or intention, the duty set out on the NHS Commissioning Board no longer delineates the scope of services to be provided as that:

‘necessary to meet all reasonable requirements’ as was previously the duty on the Secretary of State in Section 3 (1) of the NHS Act 2006. Such specific wording is retained only with reference to the duty of CCGs. Whilst the duty to promote a comprehensive national health service remains with the Secretary of

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23 Health and Social Care Act 2012 Section 1 (13).
24 Cragg S. In the matter of the Health and Social Care Bill 2011 and in the matter of the duty of the Secretary of State for Health to provide a National Health Service. July 2011. http://38degrees.3cdn.net/75856a0564e9244f2a_rum6i66sh.pdf (accessed 2 October 2012).
26 Health and Social Care Act 2012 Section 1 (5).
27 Ibid., Section 1 (23).
28 Ibid., Section 1 (9).
29 NHS Act 2006, Section 3 (1).
30 Health and Social Care Act 2012 Section 1 (13).
State, this has been effectively severed from the duty to provide the services considered necessary to meet reasonable requirements, which will soon be fragmented and fall to individual CCGs at a local level.\textsuperscript{31} It is hard to be convinced that the Secretary of State’s current power and national oversight will not be diluted and his accountability reduced. If those seeking judicial remedy of resource allocation decisions under the NHS Act 2006 failed to prove that the Act imposed an absolute duty on the Secretary of State to provide a specific health service, the Health and Social Care Act 2012 has done nothing to make this easier. The appropriate target of legal action under these circumstances would now appear to be individual CCGs, but it remains to be seen how the courts will interpret the tangled web of duties now carved up between the Secretary of State, CCGs and the NHS Commissioning Board which sits between them.

4.3 A Human Right to treatments for cancer and other conditions?

It is evident from the preceding section that no absolute right to treatment exists under domestic law. However, it is not unreasonable to question whether access to treatment, especially when the disease in question is life threatening, is a Human Right, and as such protected by the European Convention on Human Rights. As no cases involving IFRs have reached the European Court of Human Rights (ECtHR), this judicial system has yet to add directly to the clarification of the concept of exceptionality. Despite this, review of other cases involving resource allocation suggests that the ECtHR is unlikely to disregard the constraints imposed on states by limited resources. Although the European Convention on Human Rights is addressed further in Paper 1, this section allows the background of these issues to be more comprehensively explained.

4.3.1 Human Rights within the English courts

Even before the Human Rights Act 1998 came into force in October 2000, there was a suggestion that its role in resource allocation cases would be limited when the judges in \textit{R v North West Lancashire Health Authority, ex p A, D & G}\textsuperscript{32} rejected claims that either Article 8; the right to privacy, or Article 3; the prohibition on torture and inhuman and degrading treatment, were applicable to the case in which three transsexuals were challenging the Health Authority’s refusal to fund gender reassignment treatment. Recourse to this jurisprudence was described as ‘unfocused’\textsuperscript{33} and:

\footnotesize{\textsuperscript{31} Cragg S. \textit{op. cit.} note 24. \\
\textsuperscript{32} \textit{R v North West Lancashire Health Authority, ex p A, D & G [2001] 1 WLR 977.} \\
\textsuperscript{33} Ibid., at 978.}
'positively unhelpful to the court',\textsuperscript{34} with the explicit statement that Article 3:

\begin{quote}
‘did not apply to policy decisions on the allocation of finite resources between competing demands for which it was plainly not designed.’\textsuperscript{35}
\end{quote}

In light of this, is it perhaps not surprising that whilst reference to the Human Rights Act occurred in all the judicial reviews of IFRs for cancer drugs,\textsuperscript{36} the courts were reluctant to address any claims founded on Human Rights and ultimately all such claims were dismissed. Condliff, a 62-year-old retired policeman suffering from diabetes and morbid obesity, whose case was mentioned briefly in Section 2.3.2, is the first patient to have had an individual funding request declined, who has subsequently sought recourse to the ECtHR. Condliff was not obese enough to meet his PCT’s criteria for a gastric bypass. He therefore applied for funding of this procedure on the basis that he was exceptional, and sought judicial review of his PCT’s decision when his application was declined.\textsuperscript{37} The grounds for this included that North Staffordshire PCT’s policy of excluding social factors from the assessment of exceptionality breached Article 8 of the European Convention on Human Rights.\textsuperscript{38} The UK courts have previously held that Article 8 imposes no positive obligation to provide treatment. In \textit{A v West Middlesex University Hospital Trust}, Mitting J commented that:

\begin{quote}
‘Article 8 of the Convention does not impose on a Convention state the obligation to provide medical treatment at any specific level to persons within its territory... By providing treatment to deal with life-threatening emergencies and situations in which serious injury may result if the patient is left untreated, the state is fulfilling its minimum obligation under Article 8’.\textsuperscript{39}
\end{quote}

It is therefore not surprising that the court did not find in Condliff’s favour. Condliff appealed against the decision, with the breach of Article 8 remaining central to his appeal.\textsuperscript{40} When Condliff lost his appeal, he submitted a claim to the ECtHR that his right to respect and family life under Article 8 had been violated. As Condliff has since

\begin{flushleft}
\textsuperscript{34} Ibid.
\textsuperscript{35} Ibid.
\textsuperscript{36} \textit{R (Ann Marie Rogers) v Swindon Primary Care Trust and the Secretary of State} [2006] EWCA Civ 392; \textit{R (Linda Gordon) v Bromley NHS Primary Care Trust} [2006] EWHC 2462 (Admin); \textit{R (Victoria June Otley) v Barking and Dagenham NHS Primary Care Trust} [2007] EWHC 1927 (Admin); \textit{R (Jean Marie Murphy) v Salford Primary Care Trust} [2008] EWHC 1908 (Admin); \textit{R (Colin Ross) v West Sussex Primary Care Trust} [2008] EWHC 2252 (Admin).
\textsuperscript{37} \textit{R (Alexander Condliff) v North Staffordshire Primary Care Trust} [2010] EWHC (Admin).
\textsuperscript{38} Ibid.
\textsuperscript{39} \textit{A v West Middlesex University Hospital Trust} [2008] EWHC 855 para 31.
\textsuperscript{40} \textit{R (Alexander Condliff) v North Staffordshire Primary Care Trust and the Secretary of State} [2011] EWCA Civ 910.
\end{flushleft}
undergone the gastric bypass he sought, following the submission of a further individual funding request to North Staffordshire PCT containing new information, it is unlikely that his case will be expedited for consideration by the ECtHR. Irrespective of this, his chances of achieving a positive outcome are slim. Like the UK courts, the ECtHR has consistently held that Article 8 has a limited role in decisions regarding the allocation of health resources. The cases cited in Condliff v North Staffs PCT illustrate this and are reviewed below.41

4.3.2 Human Rights law in European cases

In Sentges v Netherlands,42 which concerned a person with muscular dystrophy who sought a robotic arm, Article 8 was interpreted to protect the individual, creating negative obligations on public bodies and, only exceptionally, positive obligations. In the latter instance, it was advised that a fair balance must be struck between individual and community interests, with a wide margin of appreciation in cases involving the allocation of resources. It was expressed that national authorities are in a better position to undertake this balancing act than the ECtHR.

In Pentiacova v Moldova,43 where it was claimed that the state failed to provide adequate resources for dialysis it was acknowledged that the boundaries between a state’s positive and negative obligations do not lend themselves to precise definition. The need for a fair balance between competing individual and group interests, and the margin of appreciation enjoyed by the state were re-iterated. The ECtHR has sent a strong message that, in the context of allocating healthcare resources, complying with Article 8 requires the balancing of conflicting interests, best undertaken by the state, and involves a margin of appreciation.

Other relevant cases include Tysiac v Poland44 and X and Y v Netherlands.45 Tysiac v Poland concerned limited access to abortion, where the rights of eligible women were more apparent than real.46 A positive obligation on states was found, to ensure that rights provided for, and within the remit of Article 8, could be properly adjudicated upon. X and Y v Netherlands did not concern access to medical care, but is relevant, because it identified a positive obligation on states to provide a framework for the

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41 Ibid.
42 Sentges v Netherlands, no 27677/02, 8 July 2003.
43 Pentiacova v Moldova, no 14462/03, 4 January 2005.
44 Tysiac v Poland (2007) 22 BHRC 155.
45 X and Y v Netherlands (1986) 8 EHHR 235.
46 Tysiac v Poland op. cit. note 44.
enforcement of Article 8 rights.\textsuperscript{47} These two cases were considered in \textit{Condliff v North Staffs PCT.}\textsuperscript{48} The judge felt that it was nonsensical to consider a framework to either adjudicate or enforce Article 8 rights in this context, given that Article 8 rights are not generally engaged in resource allocation decisions in healthcare, and IFRs represent part of this process.\textsuperscript{49}

\textbf{4.3.3 Successful outcomes using Human Rights law}

 Despite the lack of success in employing Article 8 to support rights based claims to healthcare, there are a few cases where the Human Rights Act has been successfully engaged in cases which have involved the failure to provide medical treatment. \textit{Price v United Kingdom}\textsuperscript{50} concerned a prisoner deficient of all four limbs, who successful claimed a breach of Article 3, having been detained in accommodation inadequate for her needs. Strictly speaking, this case could be interpreted as a failure to provide basic nursing and social care rather than medical care. It remains to be seen how transferable this judgment would be to a case involving failure to supply a cancer drug with a limited chance of success. The principles might be more readily applied to a situation where a dying patient was being deprived not only of oncological treatment, but all palliative care.

 A health related claim based on Article 2, the right to life, was also successful in the House of Lords.\textsuperscript{51} Savage was a suicidal patient detained under a Section, who was poorly supervised and absconded, subsequently committing suicide. A positive obligation on the state to protect the lives of its citizens was identified, but there was significant emphasis in this case on the fact that the patient was being detained for her own protection. This positive obligation does not appear to extend to the provision of funding for expensive life-saving drugs. In \textit{Scialacqua v Italy} the ECtHR deemed that Article 2 could not require states to fund life-preserving treatment not on a country’s official list of recognised medicines.\textsuperscript{52} The fact that a medicine is officially recognised does not inevitably alter this; in \textit{Nitecki v Poland}, a man with a life-threatening condition was prescribed a drug which he could not afford to purchase. In this case, his claim failed under both Article 2 and 8, although the ECtHR held that:

\textsuperscript{47} X and Y v Netherlands op. cit. note 45.
\textsuperscript{48} R (Alexander Condliff) v North Staffordshire Primary Care Trust and the Secretary of State op. cit. note 37.
\textsuperscript{49} Ibid., para 62.
\textsuperscript{50} Price v United Kingdom [2001] 34 EHRR.
\textsuperscript{51} Savage v South Essex Partnership NHS Foundation Trust [2008] UKHL 74.
\textsuperscript{52} Scialacqua v Italy (1998) 26 EHRR CD 164.
‘an issue may arise under Article 2 where it is shown that the authorities of a Contracting State put an individual’s life at risk through the denial of healthcare which they have undertaken to make available to the population generally’.53

Such a situation would be analogous to a PCT refusing to fund a drug approved by NICE, which was otherwise widely available.54 However, the very nature of IFRs means that the treatments sought have not been made available to the general population. It is unlikely then, that Article 2 would provide a right to treatment in these circumstances.

Claims for treatment based on Article 14, the prohibition of discrimination, look likely to have a greater chance of success than claims based on the Articles reviewed so far. An outright ban on treating patients above a certain age, unless based on clinical grounds, would seem likely to fall foul of this Article, even if limited resources were claimed to justify the restriction.55 However, as domestic law such as the Equality Act 2010 legislates quite rigorously against such discrimination, recourse to the ECtHR is unlikely to be necessary. What remains to be tested is the extent to which anti-discrimination legislation would support requests for costlier alternative treatments, as a result of religious objections to standard treatment.

4.3.4 Human Rights in the context of limited resources

Examining how the European Convention on Human Rights is interpreted in other contexts where limited resources are an issue, also provides some insight into how it might be applied to the healthcare setting. In Osman v UK,56 where the challenge of limited resources was recognised, it was deemed that the obligation on the authorities should not be interpreted so as to place an unreasonable duty on the state. Further,

53 Nitecki v Poland 21 March 2002, Application No 65653/01.
54 For example, had the SHIP PCT Cluster failed to commission NICE approved Ranibizumab for Wet AMD, rather than just offering off-licence Bevacizumab as an alternative option, as discussed below in Section 4.5.5, it is feasible that it would have been breaching Article 2.
55 The Human Rights Act was not in force at the time of R v Sheffield Health Authority, ex parte Seale (1995) 25 BMLR 1, but it is possible that the outcome might have been different if it had been. Sheffield Health Authority did not fund IVF for women over the age of 35, on the grounds that it was less likely to be effective after this age. The claimant argued that the age limit was irrational, as some clinicians would consider the threshold of 35 to be too low. Her application was rejected, although IVF treatment is used successfully in older women. What is also surprising in this case is that the court seemed to accept what was, effectively, a blanket ban on IVF by Sheffield Health Authority, and did not require the individual’s case to be considered on its merits. The case predates R v North West Lancashire Health Authority, ex p A, D & G (op. cit. note 32), in which the concept of exceptionality was established. If the case was heard today, it is likely that the actions of Sheffield Health Authority would receive greater scrutiny and there would be an expectation that provision would be made for exceptional cases.
with reference to the desirability of universal housing, the ECtHR said the issue of whether or not this was funded by the state was a:

‘political, not judicial decision’.

57

It is clear that the ECtHR is unlikely to disregard the constraints imposed by limited resources if a case involving the refusal to fund a cancer, or other treatment, were presented to it. However, there is reason to believe that were a case of resource allocation to reach the ECtHR, it would demand more of PCTs than is currently expected by the UK courts. This is because under domestic laws the Wednesbury standard of reasonableness is applied, whereas under the European Convention of Human Rights decisions are made using the additional criterion of proportionality. Application of the proportionality doctrine has the potential to expose priority setting decisions to greater judicial scrutiny, allowing the courts to examine whether limiting access to a specific treatment due to resource limitations is a legitimate policy objective, when balanced against the rights of the individual seeking treatment. The possible implications of this are discussed further in Section 4.4.3 below. Whether increased judicial scrutiny of decisions will improve public understanding of the need for rationing, or increase equity in the distribution of scarce resources for cancer and other high cost drugs remains to be seen.

4.3.5 Human Rights and private providers within the NHS

The increasing use of private companies to deliver NHS healthcare in England may limit even further the already restricted ability of patients to make claims regarding access to treatment, based on the Human Rights Act. The Act only applies to public bodies, and organisations providing functions of a public nature, although a definitive list of which authorities the Act pertains to is not contained within the Act or elsewhere. If private commissioning services were to develop, it is unclear if they would be considered to be undertaking functions of a public nature, and therefore subject to the Human Rights Act. The same question arises with respect to private clinics treating NHS patients. Even if

59 Section 4.2, note 6.
60 R v Secretary of State for the Home Department, ex p Daly [2001] 2 AC 532; R (on the application of Begum (by her Litigation Friend Sherwas Rahman)) v Denbigh High School Headteacher and Governors [2006] 2 All ER 487; Sunday Times v UK (1979) 2 EHRR 245.
private commissioning services and private clinics were deemed to be public authorities for the purposes of the Act, Section 6 (5) of the Act provides that:

‘in relation to a particular act, a person is not a public authority ... if the nature of the act is private.’

There was a similar lack of clarity over whether private nursing homes providing care for state funded patients were to be considered as public bodies for the purposes of the Act. This was resolved with the enactment of Section 145 of the Health and Social Care Act 2008, which deems that such homes are exercising a function of a public nature. However, Section 145 does not apply to healthcare. In the absence of the further development of statutory law, it remains for the courts to decide which bodies within an NHS consisting of public, private and voluntary players are subject to the Human Rights Act.

4.4 Recourse to the courts when treatments for cancer and other conditions are not provided

Having established that there is no absolute right to treatment, either in domestic law or Human Rights legislation, the following section looks at how the judiciary have responded when decisions regarding resource allocation reach the courts. Attention is paid to how judicial attitudes have changed over time, and the direction in which they may evolve in future.

4.4.1 A historical perspective – the emergence of increasing transparency

It was 32 years from the inception of the NHS before the first challenge to the allocation of NHS resources arose. In the early cases to reach the courts the judiciary were deferential to the Health Authorities involved, not even requiring them to elaborate on the reasons why treatment was being denied or postponed. Bingham LJ provided guidance on the limits of judicial powers in *R v Cambridge Health Authority ex parte B*, advising:

‘Were we to express opinions as to the likelihood of the effectiveness of medical treatment, or as to the merits of medical judgement, then we should be straying far from the sphere which under our constitution is accorded to us. We have one

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61 For example, *Birmingham Area Health Authority (Teaching), ex parte Hincks op. cit. note 12; R v Central Birmingham Health Authority, ex parte Walker (1987) 3 BMLR 32; R v Central Birmingham Health Authority, ex parte Collier (1988, unreported).*
function only, which is to rule upon the lawfulness of decisions. That is the function to which we should strictly confine ourselves.”

Lord Donaldson, MR commented along similar lines in Re J (a minor), noting that:

‘resources will always be limited and on occasion agonising choices will have to be made in allocating resources to particular patients. It is outwith the scope of this judgement to give any guidance as to the considerations which should determine such allocation’.

The first hint of a change in judicial attitude had come prior to Bingham LJ’s judgment in R v Cambridge Health Authority ex parte B, when Laws J said:

‘the responsible authority must in my judgement do more than toll the bell of tight resources. They must explain the priorities which have led them to decline to fund the treatment.’

Although the Court of Appeal rejected that view within 24 hours, in subsequent cases involving the allocation of resources, the judiciary have moved from a position of passivity to being more willing to demand that the reasons for rationing be explained.

The courts have become an arena for deliberation, enhancing the transparency of rationing decisions. An example of this was the challenge brought by the pharmaceutical company Eisai on the grounds of procedural unfairness, that NICE should reveal the full details of an economic model it had used in assessing the cost-effectiveness of one of the company’s drugs. Although the challenge initially failed, it was subsequently unanimously overturned by the Court of Appeal, in keeping with the shift towards greater openness in priority setting that has been demanded by the courts. In another case involving NICE, this time in conflict with Servier Laboratories, the court once more found that NICE had neglected to comply with its obligation to be open and transparent, because it had failed to take all reasonable steps to obtain permission to release


63 Re J (a minor) (wardship: medical treatment) [1990] 3 All ER 930 at 935.


65 R v Cambridge Health Authority, ex parte B op. cit. note 62.

66 R v North West Lancashire Health Authority, ex p A, D & G op. cit. note 32; R (Ann Marie Rogers) v Swindon Primary Care Trust and the Secretary of State op. cit. note 36; R v Secretary of State for Health, ex parte Pfizer [1999] Lloyd’s Med Rep 289; R v Derbyshire Health Authority, ex parte Fisher (1997) 8 Med LR 327.


information, accepted for use in an appraisal process, as ‘academic in confidence’. However, in an intervening judicial review brought by Bristol-Myers Squibb Pharmaceuticals, which similarly challenged the failure of NICE to fully disclose the economic model it had used in assessing their drug, the courts were satisfied that the information provided by NICE was adequate to allow the drug company to run the economic calculations on their own model and did not demand that further details be released. The standard of transparency deemed necessary by the courts had already been met. The type of transparency required by the courts in these cases has been described as ‘instrumental transparency’, requiring information to be provided regarding the criteria and evidence which have informed decision making. Provision of this detail enables others to challenge and respond to the basis of decision making, potentially bringing new ideas to the debate and facilitating stakeholder participation.

### 4.4.2 Increasing transparency in IFRs

The increasing focus on openness and transparency has not been restricted to judicial involvement with priority setting decisions made by NICE, but has also spread to those decisions made at a local level, regarding IFRs. During the late 1990s, there was a shift from the early approach taken by the courts when the judiciary avoided scrutinising decision making processes and applied the Wednesbury standard of reasonableness in a conservative fashion, to a requirement that decision makers were to be more explicit about the reasoning they had used. The most recent individual funding request to undergo judicial review illustrates this well. Condliff, whose case was outlined in Section 4.3.1, sought judicial review of his PCT’s decision that he was not exceptional. He had applied for funding of a procedure on the basis that he was exceptional, and sought judicial review of his PCT’s decision when his application was declined. One of the grounds for judicial review was that insufficient reasons were provided for declining his request and that, in light of this, the decision should be regarded as irrational. Although the court did not quash the PCT’s decision on these grounds, as the reasons for the

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72 Ibid.
73 R (Alexander Condliff) v North Staffordshire Primary Care Trust op. cit. note 37.
decision had been revealed during the judicial review, Waksman J did acknowledge that there had been a breach of the duty to give reasons and considered that Condliff:

‘needed at least some kind of steer as to what might or might not prove acceptable in future.’

As discussed in Chapter 2, this expectation of greater openness on the part of the decision makers, at least in the context of IFRs, has been formalised in the NHS Constitution. In the event that an IFR is declined, the Directions underlying the Constitution place an obligation on PCTs to provide a written explanation of the reasons to the patient.

In contrast to the instrumental transparency described above in relation to NICE decision making, the form of transparency required in IFR decisions has been described as ‘non-instrumental’, necessary to respect the dignity of the individual at the centre of the decision. The need for non-instrumental transparency reflects the special moral status of healthcare. In reviewing the duty to give reasons from a philosophical perspective, Stanton-Ife acknowledges the value of reason giving in respecting patients’ autonomy and facilitating democratic deliberation. However, he expresses reservations that such a duty risks forcing:

‘an appearance of unanimity where there is diversity’

amongst decision makers. Additionally, he fears that the given reasons may subsequently be interpreted as committed generalisations by the courts, effectively hamstringing decision makers in future cases.

4.4.3 The role of the courts in scrutinising decisions

The increasing openness and transparency expected of decision makers facilitates the ability of the courts to scrutinise the reasons underlying rationing decisions. The courts have historically been limited to addressing issues arising from the procedure, rather

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74 Ibid. para 98.
75 Section 2.3.1.
77 Syrett K. The English National Health Service and the 'Transparency Turn' in regulation of healthcare rationing. op. cit. note 71.
78 Ibid.
80 Ibid.
than the substance, of resource allocation decisions. This could change if proportionality analysis were applied in cases based on individual rights, opening up rationing decisions for substantive review, as seen in other jurisdictions such as Canada and South Africa.\(^81\)

An assessment of proportionality requires the court to balance competing interests, including those of the wider community, and of the individual whose rights are at stake. This may involve reviewing previous decisions, and the impact of public policies, to evaluate whether interference with a right is justified. Unlike the judicial review process, this allows examination of the substantive content of decisions. Although the proportionality doctrine has not been applied in the judicial reviews relating to cancer drugs examined in this thesis, there has been a shift towards increased scrutiny of decisions where Human Rights are involved. This was apparent in two of the judicial reviews\(^82\) involving IFRS which cited from *R v Ministry of Defence, ex parte Smith*:

‘The more substantial is the interference with human rights, the more the court will require by way of justification before it is satisfied that the decision is reasonable’.\(^83\)

In other judicial reviews, not related to healthcare issues, reasoning analogous to the proportionality doctrine has been used even where claims to Human Rights were not involved.\(^84\) Prior to the introduction of the Human Rights Act, the House of Lords were explicit that the doctrine of proportionality should not become the standard to be


\(^82\) *R (Ann Marie Rogers) v Swindon Primary Care Trust and the Secretary of State op. cit.* note 36 para 56; *R (Colin Ross) v West Sussex Primary Care Trust op. cit.* note 36.


\(^84\) For example, in *Hall & Co Ltd v Shoreham by Sea Urban DC* (1964) 1 WLR 240 the approach of the council’s planning department was considered irrational because the court deemed that there was an alternative, and better, way for the council to achieve the aim of its planning policy. In the later case of *R v Barnsley Metropolitan Borough Council ex parte Hook* (1976) 1 WLR 1052, Lord Denning MR expressed the view that Barnsley Council could have more appropriately used less draconian bye laws to discipline a street seller who had urinated in public, rather than seeking to deprive the accused of his livelihood by revoking his licence to trade. In 2001, Lord Slynn advanced that the time had come to recognise proportionality as a full part of English administrative law, and not limit its application to Human Rights cases. See *R v Secretary of State for the Environment, ex parte Alconbury* (2001) 2 WLR 1389. More recently, Laws LJ suggested that one reason which would lawfully allow a public body to resile from legitimate expectation was when it was ‘a proportionate response when considering a legitimate aim in the public interest’. See *R v Secretary of State for the Home Department, ex parte Naderajah* (2005) EWCA Civ 1363 para 68. Subsequently, Laws LJ has described the standard of Wednesbury unreasonableness as ‘an old fashioned legal construct’ and acknowledged the increasing use of the standard of proportionality in UK law, even when the Human Rights Act is not being drawn upon. See *R (on the application of Walker) v Secretary of State for the Home Department* (2007) EWHC 1835 para 38.
applied in domestic law. There is now evidence of a creeping trend towards the use of proportionality, and as an increasing number of judicial review applications now combine claims based in Human Rights with the more usual grounds for judicial review, it is not inconceivable that the doctrine will be incorporated into domestic law in future. However, the competency of the judiciary to make substantive judgments on matters of policy and the allocation of scare resources needs to be questioned, especially as use of the proportionality doctrine potentially empowers the judiciary to overrule decisions emanating from democratic institutions.

4.4.4 What contribution can the courts make to priority setting decisions?

There is a risk that, as the courts move towards reviewing the substance of decisions, they lack the necessary expertise to address the polycentric issues at stake. Their limited familiarity with the broader business of healthcare priority setting, which spans a vast array of issues including staffing, pharmaceuticals, diagnostics, surgical interventions, computing systems and NHS buildings and estates, combined with their lack of clinical and economic expertise means they are not well placed to balance competing priorities. Further, the adversarial nature of litigation is not always best suited to facilitate decision making in this context. Hunter has claimed the courts have no place in resource allocation, asserting:

‘The law is too blunt a weapon in an area of moral and ethical choices that are heavily contingent upon the circumstances prevailing in a particular case.’

Syrett, however, has advanced a coherent case for a positive role of the courts in strengthening the legitimacy of healthcare resource allocation, and increasing the acceptability of decisions to stakeholders, ultimately a common aim of both health policy makers and public lawyers. He argues that judges can facilitate social learning and debate regarding the necessity of priority setting through their own deliberation and provision of reasons for their decisions. In this way, the transparency of resource allocation decisions is increased and priority setting agents can be held accountable for their decisions. Furthermore, Syrett contends, the role of the courts could go beyond

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85 R v Secretary of State for the Home Department, ex parte Brind (1991) UKHL 4.
89 Syrett K. Law, legitimacy and the rationing of health care. op. cit. note 81, pp 146-156.
reacting to individual cases, using public law principles to provide guidance to decision making institutions and facilitate sound public administration.\(^{90}\) Newdick identifies a more limited role for the courts, with judicial review creating procedural rather than substantive rights. He suggests the judiciary defer assessments of the public interest to those appointed to this role. Newdick advocates that decisions should be made within a ‘fair and consistent framework’, with public input to optimise the wider acceptability of decision outcomes.\(^{91}\) Aside from the central point already made, that the judiciary lack not only a democratic mandate but also the expertise necessary to pass judgment on the substantive nature of rationing decisions, another major limitation of litigation is that it primarily serves the interests of the most empowered patients, who are able to access and negotiate the legal system. If used by this group, the benefits may trickle down to those who are less empowered, as PCTs ensure their processes are legally sound and not susceptible to judicial review, but primarily the courts advantage those who are able to shout the loudest. Furthermore, litigation is expensive, draining PCTs’ funds away from providing patient care. It is also time-consuming for clinicians and other NHS staff, detracting them from clinical work. The judge in \(R\ (\text{Walker v Central Birmingham Health Authority})\), in refusing leave for judicial review, warned against using NHS resources to address patient complaints rather than for delivering clinical services as intended.\(^{92}\) In \(R\ (\text{Jean Marie Murphy})\) v Salford PCT, Salford PCT spent more money defending its actions at judicial review than the cancer treatment that Murphy was requesting actually cost.\(^{93}\) Despite the financial implications, the NHS Confederation advocates that PCTs challenge legal claims. The Confederation highlights that without confronting litigation, reasonable priority setting would not be possible. It identifies the risk of large numbers of IFRs driving the PCTs’ priorities, with resources being committed to low-priority areas, resulting in negative consequences for the wider population and leaving those without the means to threaten legal action at a disadvantage.\(^{94}\) Litigation

\(^{90}\) Ibid., pp 157-158.
\(^{92}\) \(R\ v \text{Central Birmingham Health Authority, ex parte Walker op. cit note 61.}\)
is perceived as a positive mechanism by the Confederation, through which unresolved issues can be addressed, resulting in clear legal precedent to regulate future practice.

4.4.5 Law or politics?
Ultimately, the question of which drugs should be prioritised for funding is of a political, rather than legal nature, as encapsulated by Brown LJ when he said:

‘it is inescapable to me that affordability, in the sense of choosing between competing priorities as to where funds should be allocated, must be regarded as a political decision to be taken by Government.’

However, to reduce the volume of patients resorting to judicial review when funding decisions are not in their favour, it is first necessary to increase public understanding of why rationing is inevitable. Austin advocates approaching this like any other public health programme, with the aim of improving understanding and altering attitudes, and suggests this could be achieved through proactive communication with the public on the process and outcomes of priority setting. A public health approach is a novel, but simple idea, which to the best of my knowledge has not yet been piloted. In addition, the frequency with which patients seek recourse in the courts could be reduced if the DoH were to provide greater clarity as to what constitutes exceptional circumstances in the context of IFRs. This would enable PCTs to reach decisions which are less susceptible to legal challenge. At the current time, as Paper 1 outlines, most of the guidance regarding how the concept of exceptionality should be interpreted has arisen from judicial reviews of IFRs.

4.5 Going to law as a strategy
The preceding section examined the evolving responses to judicial action within the court room. Paper 1 builds on this theme, focusing specifically on the difficulties arising from judicial review of the concept of exceptionality. However, legal proceedings can also be used as much for their impact out of the court room as in it. The law can be used indirectly, by both patients and Pharma, either purely to achieve other ends, or in the hope of collateral benefits. Patients may take advantage of the courts to obtain medicines through interim treatment orders; drug companies may strategically use legal action to strengthen their negotiating power with respect to pricing. Either group may

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resort to the law to put pressure on a third party, either directly, or via the publicity such action generates. Publicity precipitated by legal action can also be used by patients, to try to attract a private donor to fund treatment which the NHS will not provide, and by the drug industry, to stimulate demand for drugs. Although these suggestions may sound far-fetched, examples of how the courts have been used in this way are detailed below and serve to highlight that resorting to the courts can be about much more than correcting a perceived injustice.

4.5.1 The power of the media
The denial of treatment to patients by the NHS never fails to generate media publicity, and where the courts are involved the interest is greater still. It became apparent in the early cases to reach the courts that even where the judiciary did not rule in the patient’s favour, the publicity generated through the act of going to court seemed, in some cases, to help achieve a positive outcome. David Barber, for instance, a young baby with a hole in his heart, had had his operation turned down five times.97 The health authority did not wait for the outcome of the judicial review of his case, but went ahead with the deferred operation on the day that leave for judicial review of the health authority’s actions was being considered.98 Around the same time, Angela Tonge, a diabetic with end stage renal failure, sought judicial review of the health authority’s decision that no new patients were to be commenced on dialysis at her local renal unit, which had an overspend of £170,000. On the day that she was granted legal aid to take the health authority to court, the health minister released an extra £250,000 to her local renal unit. Was the timing of the health authorities’ actions in each case pure coincidence, or a result of the media focus on these patients? As discussed in Chapter 3,99 the timing of the Richards’ review was influenced by the media frenzy whipped up after several patients had had their NHS care withdrawn, whilst concurrently purchasing additional cancer care.

Health authorities in the past, and PCTs today, have not just the cost of litigation, but also their reputations to consider. Previously, at least one PCT assessed the risk of reduced confidence in primary care services created by adverse press coverage and judicial review to be significant enough to warrant entry into its corporate risk

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97 R v Central Birmingham Health Authority, ex parte Walker op. cit. note 37.
99 Section 3.1.3.
The power of the media should not be underestimated. In a survey of PCT decision making in exceptional circumstances, six PCTs admitted that local publicity and media influenced their decision making.

Perhaps with the knowledge that PCTs dislike negative press coverage, some patients have used the judicial review process as a threat. This was apparent in \( R \) (Linda Gordon) \( v \) Bromley PCT. Prior to judicial review, Gordon had made three unsuccessful applications for funding to the PCT and warned that she would seek judicial review.\(^{102}\) Ann Marie Rogers’ solicitors wrote to Swindon PCT stating that they would apply for judicial review if trastuzumab was not provided for her, before an individual funding request had even been submitted to the PCT.\(^{103}\) Both of these cases are discussed further in Paper 1. It is impossible to know how many applications for exceptional funding are conceded when judicial review is imminent, but it is likely there are some, if not many. The judicial review process in itself is costly to PCTs. If the life expectancy of the patient requesting a new drug is short, and the duration of treatment likely to be limited, the attraction of agreeing funding which may not cost much more than participation in a judicial review is obvious, even if strictly this is not the best use of PCT resources. The NHS Confederation has warned against this response, recognising that it could result in an increase in threats of legal action. Even if PCTs do not stump up the cash, private donors not infrequently come forward to cover the cost of treatment, as happened following the judicial review of \( R \) (Jean Marie Murphy) \( v \) Salford PCT.\(^{104}\) The court quashed Salford PCT’s decision not to fund sunitinib to treat her renal cancer, and after reconsidering Murphy’s request the PCT again decided against funding the drug on the basis of exceptional circumstances. However, a private donor then stepped in to


\(^{102}\) \( R \) (Linda Gordon) \( v \) Bromley NHS Primary Care Trust op. cit. note 36 para 4.

\(^{103}\) \( R \) (Ann Marie Rogers) \( v \) Swindon NHS Primary Care Trust [2006] EWHC 171 (Admin) para 33.

fund the treatment. Hope of attracting a private donor alone may motivate some patients to resort to the courts, or at least the media.¹⁰⁵

4.5.2 The benefit of interim treatment
Patients can also use judicial review as a means to obtain ‘interim treatment’. Interim treatment is provided when a judge orders that the requested drug is dispensed, pending the PCT’s reconsideration of a decision which has been deemed unlawful during judicial review. This has occurred in many of the judicial review cases involving cancer treatments to date. It would be a hard-hearted judge who did not take this approach, given the progressive nature of the disease for which treatment is being sought. For some patients the duration of interim treatment may be sufficiently long enough for them to establish whether or not a new drug will be of benefit to them. In R (Linda Gordon) v Bromley PCT the PCT was ordered to fund erlotinib, the drug in question, for four weeks, pending reconsideration of her application by the PCT.¹⁰⁶ This completed the duration of treatment for which Gordon’s oncology team were seeking funding in the first instance, as a trial of treatment to see if her lung cancer would respond. The judge made it clear his decision was pragmatic, because he could not be certain how long it would take the PCT to reassess Gordon’s application on the appropriate basis that he had outlined, rather than because he necessarily believed a trial of treatment was justified.¹⁰⁷ In cases like R (Linda Gordon) v Bromley PCT¹⁰⁸ where funding is requested, in the first instance for a trial of treatment, the honesty and the integrity of the medical team needs to be questioned. Are they really asking not for a trial, but for a definitive course of treatment? Should PCTs assume that this is behind their request? Ouseley J observed:

‘there is ‘some uncertainty..., on both sides, as to the true nature and implication of the request.’¹⁰⁹

He stated that it would be ‘disingenuous’ of Gordon’s lawyers to claim that they were solely interested in a trial of treatment, without making it clear that they would expect this to continue if it were successful.¹¹⁰

¹⁰⁶ R (Linda Gordon) v Bromley NHS Primary Care Trust op.cit., note 36.
¹⁰⁷ Ibid.
¹⁰⁸ Ibid.
¹⁰⁹ Ibid., at para 13.
Paul Bould, a 51-year-old man with lung cancer, obtained an injunction to receive erlotinib, pending judicial review of his PCT’s decision not to fund the drug, just two days before he died.\(^\text{111}\) It is doubtful whether this was in the best interest of either the patient or the taxpayer.

### 4.5.3 Pharma seek out patients to promote their own ends

Patients are not alone in resorting to the courts strategically. The drug industry, it would seem, is also keen to exploit the publicity generated by judicial review. The emotive impact of an individual patient’s story is much more effective at raising awareness of a new cancer drug than a bland scientific report. There is some evidence that the drug industry actively seeks out suitable patients to help it achieve this. As an example, after writing about her diagnosis of breast cancer, Professor Lisa Jardine was contacted by a public relations company working for Roche, and offered help in obtaining trastuzumab prior to its approval by NICE, presumably via her local PCT, using the exceptional circumstances route.\(^\text{112}\) Roche defended the approach, as part of a plan to raise awareness of accurate breast cancer diagnosis.\(^\text{113}\) Although hard to prove, PCT commissioners are suspicious that at least some of the applications they have received for the funding of cancer drugs in exceptional circumstances are funded and driven by drug companies.\(^\text{114}\) This might explain the increasing frequency of specialist medical experts being employed by patients seeking legal action, as the cost of this would be prohibitive to many without external funding.

### 4.5.4 Industry funded patient support groups

On a larger scale, pharmaceutical companies make significant donations to patient support groups. Jackson questions whether this is purely an act of corporate social responsibility and highlights how industry-funded groups may be used to lobby for increased availability of the sponsor’s drug treatments.\(^\text{115}\) Industry funded groups have,

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\(^{110}\) Ibid.


\(^{113}\) Ibid.

\(^{114}\) Personal Communication, Dr A Forrester, Clinical Advisor to North Yorkshire and York PCT, July 2009.

\(^{115}\) It was revealed in evidence presented to the House of Commons Select Committee that the drug industry refers to patient support groups as ‘ground troops’ to canvass the government. House of Commons Health Committee. *The influence of the pharmaceutical industry - Fourth report of session 2004-2005* 22 March 2005. http://www.publications.parliament.uk/pa/cm200405/cmselect/cmhealth/42/42.pdf (accessed 8 February 2013). Two patient groups set up
in the past, supported patients seeking judicial review of PCTs’ decisions not to fund the treatments they have requested. The Royal National Institute for the Blind, for example, which receives funding from Novartis, the manufacturers of ranibizumab, supported three patients with wet age related macular degeneration (AMD) in 2008 who took Warwickshire PCT to court in an attempt to obtain treatment with ranibizumab.\textsuperscript{116} Novartis must have been delighted with the outcome. Although the judge did not quash the PCT’s decision, he encouraged the PCT and Novartis to reach an agreement whereby the PCT would fund the first 14 injections for each patient, with Novartis funding additional treatments beyond this. This reimbursement scheme was ultimately rolled out nationally.

4.5.5 Undermining the use of bevacizumab in place of costlier ranibizumab
Prior to the positive NICE appraisal of ranibizumab in 2008 for use in AMD, the drug was frequently the subject of IFRs. Despite NICE approval, the funding of ranibizumab has remained controversial. There is convincing evidence from clinical trials that bevacizumab, a cheaper product belonging to the same class of drugs, is safe and as effective.\textsuperscript{117} Although bevacizumab is licensed as an anti-cancer agent, its use in AMD is considered unlicensed because its preparation for intraocular use involves dividing the licensed medicine into multiple aliquots. Altering the form of a medicine in this way is regarded as creating an unlicensed product.\textsuperscript{118} The price difference is not insignificant. Bevacizumab costs around £60 per injection, compared with £740 for ranibizumab.\textsuperscript{119} It is a strange reversal for a high cost cancer drug, belonging to a class considered worthy of special funding status within the NHS, to emerge as the bargain basement drug of choice for AMD. Bevacizumab is manufactured by Genentech, which like Novartis the manufacturer of ranibizumab, is owned by Roche. The lack of motivation in obtaining a licence for the cheaper drug in AMD is therefore perhaps no surprise. For economic

\textsuperscript{118} This differs from ‘off-label’ use, where a drug is used in its licensed form, in a situation outside its marketing authorisation.
reasons, bevacizumab is already used for AMD in 64% of Medicare patients in the US.\textsuperscript{120} For similar reasons the unlicensed use of bevacizumab in the UK has been increasing. In 2011, the SHIP PCT cluster (consisting of Southampton, Hampshire, Isle of Wight and Portsmouth PCTs) approved a policy allowing clinicians to offer patients a choice of ranibizumab or bevacizumab, with anticipated savings in the range of £4-5 million a year.\textsuperscript{121} By commissioning both drugs, the SHIP PCT cluster were therefore relying on ophthalmologists’ clinical freedom to prescribe bevacizumab over the more expensive alternative in order to achieve the anticipated savings. On this occasion, Novartis went directly to the court, to seek judicial review of the PCTs’ actions. It was thought that the drug company would cite patient safety as the grounds for judicial review,\textsuperscript{122} or possibly that the PCT had exercised their powers wrongly in commissioning an unlicensed drug. Despite the PCT cluster initially stating that they would:

‘defend their position rigorously’,\textsuperscript{123} after Novartis met with them and offered a deal which would result in a reduced price for ranibizumab, they agreed to abandon their policy.\textsuperscript{124} What would the court have concluded had the PCT cluster stood firm? NICE, when asked by the Department to Health to review the feasibility of appraisalising the clinical and cost-effectiveness of bevacizumab as a treatment for AMD within the NHS, reported that this would be possible, conditional on an assessment of the safety and quality of intraocular bevacizumab by a regulatory body, or through the involvement of such expertise.\textsuperscript{125}

Current General Medical Council (GMC) guidance states that in prescribing unlicensed medicines, doctors must:

‘Be satisfied that an alternative, unlicensed medicine would not meet the patient’s needs’.

As such an alternative, ranibizumab does exist, would ophthalmologists offering patients bevacizumab lay themselves open to charges of professional misconduct? In his advice to PCTs regarding the use of an unlicensed medicine for Sickle Cell Anaemia, Lock argues that a doctor would not be contravening the code by prescribing an unlicensed drug, where the licensed equivalent had not been made available by the PCT. Lock suggests that the duty imposed on doctors by the GMC is not absolute, because a doctor’s choice as to what he may prescribe is limited by what is available in the clinical setting. Therefore, Lock considers this to be a commissioning policy decision, not a prescribing decision accountable to the GMC. Further, he advises that if the commissioner had made this decision on the grounds of cost, a patient would have difficulty suing the commissioner directly for commissioning an unlicensed drug, given that commissioners owe no general duty of care to patients. Lock highlights that the drug industry has hinted in similar circumstances that


be breaching the marketing rules in the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994 by effectively promoting an unlicensed product. Lock believes that such a claim would be unfounded, as commissioners are not marketing drugs according to the meaning in the Regulations.\textsuperscript{128} However, in the case of ranibizumab, as the drug had been approved by NICE as a cost effective use of NHS resources, the PCT cluster were under a legal obligation to commission and fund it, and in fact continued to do so whilst promoting the use of bevacizumab.

It remains unclear on whose side the courts would have come down had the case proceeded to judicial review. For their part, the PCT cluster had difficulty implementing their policy of commissioning ranibizumab with providers in light of the pending judicial review, and ophthalmologists were not changing practice following advice from the Royal College of Ophthalmologists.\textsuperscript{129} The PCT cluster also claimed to be wary of ‘leaving an undesirable legal legacy’ to their successors, given the imminent transition from PCTs to CCGs.\textsuperscript{130} Novartis’s act of initiating judicial review may have had its desired effect in preventing ranibizumab being passed over in favour of bevacizumab, not just within the SHIP PCT cluster, but potentially throughout the NHS. Novartis could, after all, have approached the PCT cluster at the outset to offer a price reduction. Instead, Novartis increased the pressure on the PCT cluster to concede to any pricing offer it made by first taking legal action. Pursuing legal action to completeness would always have been a risky option for Novartis – had it lost it would potentially have opened the flood gates to the use of unlicensed drugs in other contexts. Irrespective of the outcome the plan could still have backfired, leaving the drug industry with an increasingly tarnished reputation as uncaring and profit driven, as happened when Pharma sued the South African government in an attempt to block the import of cheap anti-HIV drugs.\textsuperscript{131}

\textsuperscript{128} Lock does, however, recommend discussion with the NHS Litigation Authority before commissioning an unlicensed medicine, because of the theoretical increased risk arising from the lack of product liability guarantee, normally carried by the company. The NHS may nonetheless decide to accept the risk, because the cost of buying out the risk by commissioning the licensed alternative is too great.

\textsuperscript{129} SHIP PCT Cluster Board. \textit{Review of Commissioning Policy on Wet Age-Related Macular Degeneration. op. cit.} note 124. Paradoxically, it is alleged that some ophthalmologists use bevacizumab, as the more affordable option preferred by patients in private practice, yet may be required to use ranibizumab in NHS practice. Raftery J. \textit{op. cit.} note 126.


4.5.6 A pro-active response is required from PCTs

The relationship between patients, Pharma and the law is a complex one. Patients may fail to get decisions quashed at judicial review (although historically, cancer patients fare better than others), but nonetheless obtain treatment as an indirect consequence of legal action. The influence of the drug industry is immense, but even when using the law in conjunction with patient groups, drug companies remain answerable to shareholders, and motivated by profits. Both patients and Pharma can harness the power of the media. Against both parties, PCTs, which must find the cash to foot an ever increasing drugs bill, come off worse, but the real losers are those unidentified, voiceless patients who pay the opportunity cost of this bill by forgoing treatment that can no longer be afforded. To close this expanding equity gap PCTs must ensure their processes are legally robust, and accept challenges in the court room. Only by actively engaging with the law will PCTs be able to protect the interests of those who are not empowered to use the law to facilitate access to treatment, and whose illnesses and personal circumstances are such that they do not provide a sensational news story. Further, PCTs must be pro-active in engaging the media, in order to launch the public health style education programme which has been advocated to improve understanding of the necessity of priority setting.\textsuperscript{133}

4.6 The concept of exceptionality explored in the context of cancer

It is not possible to ascertain how often PCTs back down and concede IFRs when faced with the threat of judicial action. However, where PCTs have engaged in legal challenges actioned by patients, a wealth of information about the process reaches the public domain in the form of law reports. This resource has enabled me to undertake a detailed examination of how the courts have interpreted the concept of exceptionality in judicial reviews to date. The inconsistencies which arise between the different cases examined are perhaps not surprising, as most of the comments contained in the case reports are obiter dicta, and therefore not in any way binding.

4.6.1 The judicial review cases

The doctrinal analysis undertaken for Paper 1 included the case reports of the five patients who have sought judicial review of their PCT’s decisions not to fund the cancer drugs they requested, between 2005 and the present time. In addition, the case reports

\begin{footnotesize}
\textsuperscript{132} See Chapter 2, Section 2.3.2.
\textsuperscript{133} Austin D. \textit{op. cit.} note 96.
\end{footnotesize}
of two non-cancer patients who sought judicial review of their PCT’s decisions during this time period were studied. Condliff, who sought a gastric bypass, has already been discussed above in this chapter.\textsuperscript{134} Paper 1 touches again on this case because of the illumination it provides regarding the role of social factors in the assessment of exceptionality. The other non-cancer case subject to judicial review during the time frame studied, \textit{AC v Berkshire West Primary Care Trust}, involved a biological man who had undergone gender reassignment treatment but remained dissatisfied with the size of her breasts.\textsuperscript{135} AC’s request for breast enlargement surgery on the basis of her exceptionality was rejected. Although she challenged Berkshire PCT’s decision that she was not exceptional, the court deemed that this was a conclusion that the PCT had been entitled to reach. The case is not discussed in any detail in Paper 1, primarily because the judicial review focused predominantly on whether the PCT’s policies, and treatment of AC, had been discriminatory, compared with the treatment of a natal woman, rather than whether or not her circumstances should be considered exceptional.

An outline of each of the five judicial review cases, involving access to cancer drugs, which form the focus of Paper 1 is presented below. To avoid unnecessary duplication, where a particular aspect of a case is analysed in detail in Paper 1, reference to it in the following section is brief.

4.6.2 \textbf{Ann Marie Rogers v Swindon NHS Primary Care Trust}

Ann Rogers’ claim for trastuzumab in 2006 is perhaps the most well known of the judicial review cases, in part because it was the earliest challenge of a PCT’s determination of what it meant to be an exceptional patient in the context of cancer drugs, and triggered wide media coverage. 54-year-old Rogers had undergone curative surgery for breast cancer, followed by chemotherapy and radiotherapy to reduce the likelihood of her cancer reoccurring. Statistically, Rogers had a high risk of relapse, with a 57% chance of dying of breast cancer within 10 years. Her cousin had already died from the disease. Rogers learnt about trastuzumab not from her oncologist, but through her son who had read about trastuzumab on the Internet. Trastuzumab, the drug she sought, was one of the first targeted monoclonal antibody treatments, only of benefit to patients with a specific receptor on their tumour. In 2006 the drug was not licensed in

\footnotesize{\textsuperscript{134} See Section 4.3.1. \textit{R (Alexander Condliff) v North Staffordshire Primary Care Trust and the Secretary of State} (n 40) and \textit{R (Alexander Condliff) v North Staffordshire Primary Care Trust} (n 37).}
\footnotesize{\textsuperscript{135} \textit{AC v Berkshire West Primary Care Trust} \textsuperscript{[2011]} EWHC Civ 247.}
the UK, but had been evaluated in two international trials, and was estimated to halve the chance of her cancer reoccurring.\textsuperscript{136}

At the time of Rogers’ claim, over 10 PCTs were already routinely funding trastuzumab for eligible patients, but Swindon PCT was not one of them. Rogers’ NHS Trust was not willing to allow her to top-up her care by paying for trastuzumab within the NHS, so her consultant treated her at a private clinic, waiving his fees and charging only for the cost of trastuzumab. Rogers borrowed £5,000 to pay for 2 of the recommended 18 cycles of treatment, but did not have the funds to pay for any more. Her diagnosis prevented her from remortgaging her house to cover the cost of treatment.\textsuperscript{137}

Rogers did not claim to be exceptional. In fact, both her GP and oncologist agreed that she was not. Despite this, Swindon PCT decided that based on the information provided to them (regarding her family history of breast cancer, her prognosis, her potential benefit from trastuzumab and the number of other similar patients within the PCT who it was thought would also benefit from trastuzumab (about 20)), Rogers fell into ‘a grey area between unexceptional and exceptional’, but that nonetheless funding for trastuzumab would not be provided.\textsuperscript{138}

At the initial hearing, Swindon PCT’s policy was not found to be unlawful and the claim was dismissed.\textsuperscript{139} Bean J acknowledged that some PCTs had chosen to fund trastuzumab for all eligible patients, but stated that whether such policies were better was a political matter, ‘not an issue for a judge’.\textsuperscript{140} His sentiments echoed those of Brown L J seven years earlier in \textit{R v Secretary of State for Health, ex parte Pfizer}, that issues of affordability belonged in the political rather than the judicial domain.\textsuperscript{141} Rogers appealed against the decision, and the PCT was ordered to provide trastuzumab in the interim period, just as it had pending the initial hearing. On appeal, Clarke MR. found Swindon PCT’s policy to be irrational and therefore unlawful. The judge deemed the policy irrational because Swindon PCT was prepared to fund trastuzumab for some patients and explicitly stated that cost was not an issue with respect to this particular drug. Clarke MR deemed that if cost was irrelevant, as the PCT claimed, there were no reasonable grounds for providing trastuzumab to some, but not all of the clinically

\textsuperscript{136} \textit{R (Ann Marie Rogers) v Swindon Primary Care Trust and the Secretary of State op.cit.}, note 36.
\textsuperscript{137} \textit{Ibid.}
\textsuperscript{138} \textit{Ibid.}, at para 50.
\textsuperscript{139} \textit{Ibid.}, at para 76.
\textsuperscript{140} \textit{Ibid.}, at para 70.
\textsuperscript{141} \textit{R v Secretary of State for Health, ex parte Pfizer} (n 66) para 17.
eligible group who would benefit.\textsuperscript{142} Ironically, it appears that Swindon PCT had only inserted the caveat that cost was irrelevant into its policy because it had considered that a statement circulated by the then Secretary of State, Patricia Hewitt, that patients should not be refused trastuzumab ‘solely on the grounds of its cost’\textsuperscript{143} represented a legally binding Direction, rather than simply guidance. One of the important points to emerge from this case was the affirmation by Clarke MR that where a PCT is subject to financial constraints, it can legitimately decide to fund treatment for a patient in exceptional circumstances, without providing it to all patients who will benefit.\textsuperscript{144} In light of this, it was particularly interesting to learn, during the empirical element of my research, how different PCTs regard the absolute cost of IFRs. This is reported in Paper 3, where the issue of cost is revisited.

Rogers went on to receive trastuzumab, funded by Swindon PCT, but despite this her cancer reoccurred, and she died three years after the initial judicial review.\textsuperscript{145}

\textbf{4.6.3 Linda Gordon v Bromley NHS Primary Care Trust}

Linda Gordon was a 47-year-old non-smoker who suffered lung cancer. She had received traditional chemotherapy with little benefit. Gordon sought a two-month trial of a new drug, erlotinib, as this was the period of treatment which was claimed to be necessary to judge whether or not she was responding to the drug.\textsuperscript{146} Like Rogers, Gordon had not learnt about the new treatment from her NHS oncologist, but only after flying to New York for a second opinion.\textsuperscript{147} Afterwards, her oncologist said that he had not told her about the drug because it was ‘too expensive’.\textsuperscript{148} Whilst awaiting judicial review of Bromley PCT’s decision not to fund the drug in 2006, charitable donations financed four weeks of treatment for Gordon.

The judicial review was presented with evidence from the \textit{New England Journal of Medicine}, which the PCT had considered in reaching its decision. The judicial review also received a report from an oncologist, Dr Steele, who was not the treating doctor and was presumably acting in the capacity of medical expert, offering his opinion on the

\textsuperscript{142} \textit{R (Ann Marie Rogers) v Swindon Primary Care Trust and the Secretary of State} (n 36).
\textsuperscript{143} \textit{Ibid.,} at para 28.
\textsuperscript{144} \textit{Ibid.,} at para 77.
\textsuperscript{146} \textit{R (Linda Gordon) v Bromley NHS Primary Care Trust} (n 36).
\textsuperscript{148} \textit{Ibid.}
potential benefit of treatment. Dr Steele anticipated that Gordon would survive for around 10 months without treatment, and that this could be extended to up to 18 months if she responded to treatment. The PCT had not agreed with Dr Steele’s interpretation of the data. The court refrained from passing judgment on which opinion was right, emphasising that it was not the role of the court to make such decisions. This distinction echoed the view of Dobbs J in the judicial review of NICE’s decision not to approve donepezil when she stated that:

“The court has no part to play in adjudicating between the rival merits of the arguments of the experts, of whom there are many who take a view different from the Claimant’s experts.”

Nevertheless, the judge in Gordon did question the expertise of Dr Steele, as a physician, to make statistical inferences.

The PCT was ordered to reconsider its decision, on the narrow basis that it was unclear whether the PCT had considered whether to fund ongoing treatment with erlotinib, or the remaining time period needed to amount to a two month trial of the drug. An interim treatment order meant that Gordon received a further four weeks of treatment, but the PCT declined to provide ongoing treatment after reconsidering its decision. Gordon subsequently received a short supply of treatment from the relatives of a deceased patient, and self funded further treatment costing £2,500 a month. Gordon died in March 2008, 22 months after the judicial review, exceeding her predicted life expectancy of 18 months with treatment.

4.6.4 Victoria June Otley v Barking and Dagenham NHS Primary Care Trust

Victoria Otley suffered from advanced bowel cancer with liver metastasis. Having undergone surgery and two course of conventional chemotherapy, the 57-year-old initially funded five cycles of the monoclonal antibody bevacizumab, at a cost of around £15,000. Again, Otley was not initially told about the new drug by her oncologist, but instead her sister learnt about bevacizumab from the Internet. The evidence suggested

149 R (on the application of Eisai Ltd) v National Institute for Health and Clinical Excellence op. cit. note 67.
150 R (Linda Gordon) v Bromley NHS Primary Care Trust op. cit. note 36.
that bevacizumab could increase life expectancy by about two months when added to standard treatment.153

In 2007, Otley applied for judicial review when her PCT declined her application for funding of bevacizumab. The medical evidence for the requested drug was even more extensively discussed than in Gordon, and an expert opinion was provided by a professor of oncology. Somewhat unusually, Mitting J appears to have drawn his own conclusion from the presented evidence that bevacizumab could offer Otley a slim chance of cure, if it were to reduce her liver metastasis to an operable size, although it is possible that it is simply not apparent from the case report that this interpretation was provided by the expert opinion. The PCT was criticised for failing to highlight that the drug might provide a cure.154 Unlike in Gordon and Eisai, the judge in Otley evidently did feel it was within his remit to pass judgment on which medical opinion was right. Mitting J also felt able to pass comment that the case was not one in which scarce resources were a decisive feature.155 How he was able to make such a judgment regarding affordability, an issue which Bean J had previously suggested was a political rather than a judicial decision, without detailed knowledge of the PCT’s finances, or information about the number of other patients who might benefit from bevacizumab residing within the PCT’s catchment area, is unclear. The comment highlights the risk of judicial involvement with priority setting when judges lack knowledge of the polycentric issues at stake, discussed in more detail in Section 4 of this chapter.156

In comparison with Rogers, where the judge found Swindon PCT’s policy to be irrational, Mitting J approved Barking and Dagenham PCT’s policy as rational and sound, but instead deemed its decision making and reasoning to be irrational.157 The basis of his judgment included that the PCT had not accounted for the possibility that bevacizumab might offer Otley a chance of cure, despite the fact that this represented a dubious interpretation of the evidence under the circumstances. Mitting J also referred to the fact that no other treatments were available via the NHS to treat Otley. Whilst this was true, Mitting J does not appear to have thought through the implications of his

153 R (Victoria June Otley) v Barking and Dagenham NHS Primary Care Trust op. cit. note 36.
154 Ibid., paras 11-12.
155 Ibid., para 27.
156 Section 4.4.4.
157 R (Victoria June Otley) v Barking and Dagenham NHS Primary Care Trust op. cit. note 36, para 26.
reasoning. The NHS could not afford to provide high cost cancer drugs to the many patients who find themselves in this situation. Mitting J concluded that:

‘on any fair minded view of the exceptionality criteria...her case was exceptional’.  

In quashing the PCT’s decision, and expressing this conclusion, Mitting J effectively dictated the outcome of the PCT’s reconsideration of Otley’s case.

4.6.5 Jean Marie Murphy v Salford Primary Care Trust

Jean Murphy, aged 63, suffered from metastatic renal cancer, and was unable to tolerate the standard treatment of interferon because it exacerbated her depression. A new drug, sunitinib, was available to patients in nearby Cheshire and Merseyside from the NHS, but was only available to patients in Salford who entered a clinical trial. As Murphy had a previous history of breast cancer she was not eligible for the trial. Consequently, Murphy submitted a request to the PCT for funding of sunitinib. An unusually high number of reasons for Murphy’s exceptionality were advanced, including her ineligibility for clinical trials, her history of breast cancer and mental health problems, her inability to tolerate interferon and the fact that she was the main carer for her husband who had multiple medical conditions.

Burnett J found the PCT to have made an error in the decision making process, by not considering all of Ms Murphy’s potential exceptional circumstances in their totality. He did not go as far as to say that the PCT’s policy was unlawful, or that the outcome of the decision was incorrect, but simply that he could not be confident that the decision, if made again, would incontrovertibly be the same. On reconsidering its decision, the PCT again concluded that Murphy was not exceptional and should not receive funding for sunitinib. An anonymous donor subsequently provided £3,500 for Murphy to undergo two cycles of treatment. On hearing of her good response, the PCT then agreed to fund further cycles. Murphy survived for another 11 months following the judicial

158 Ibid.
160 R (Jean Marie Murphy) v Salford Primary Care Trust op. cit. note 36.
161 Ibid., para 17.
162 Ibid., para 36.
review, not achieving the maximum life expectancy of 24 months predicted for her at that point in time, if sunitinib were made available.164

4.6.6 Colin Ross v West Sussex Primary Care Trust

Colin Ross had been diagnosed with multiple myeloma in 2004. Four years later he had received a variety of treatments, and was unable to continue thalidomide, the final treatment available to him via the NHS, because of painful peripheral nerve damage, a recognised side effect.165 Ross therefore requested that his PCT fund the new drug lenalidomide for him, a drug routinely available to patients in neighbouring East Sussex.166 West Sussex PCT was explicit with its reasons for rejecting his request, stating that there was little evidence for the requested drug, and that it involved a high cost for minimal benefit.167 After his request had been considered and declined three times, Ross sought judicial review of West Sussex PCT’s decision. Once more, great attention was paid to the medical evidence for the drug, and a professor of oncology working on behalf of the patient provided an expert opinion. This was, in fact, the same doctor who had worked on behalf of Otley the preceding year. Although the PCT claimed that it could reasonably prefer the evidence of one doctor over another, as had been suggested in Gordon, Grenfell J deemed that the PCT had, in actuality, misunderstood the evidence to the extent that it amounted to a material error of fact.168

In Ross, as in Otley, the medical expert expressed the opinion that the patient was exceptional.169 The PCT took issue with this, arguing that such matters were outside the professor’s expertise.170 The judge rejected the PCT’s view on this, accepting that such a judgment was within the professor’s sphere of competence. Given the broad and multifactorial interpretation of exceptionality, which is evident from the deconstruction of the concept undertaken in Paper 1, it is somewhat surprising that the judge was prepared to accept that the clinician was in a position to provide an opinion not just on haematological issues, but also on the criteria for exceptionality.

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165 R (Colin Ross) v West Sussex Primary Care Trust op. cit. note 36.
167 R (Colin Ross) v West Sussex Primary Care Trust op. cit. note 36, para 47.
168 Ibid., paras 51-52,62,64.
169 R (Victoria June Otley) v Barking and Dagenham NHS Primary Care Trust op. cit. note 36, para 20; R (Colin Ross) v West Sussex Primary Care Trust op. cit. note 36, para 57.
170 R (Colin Ross) v West Sussex Primary Care Trust op. cit. note 36, para 72.
As in Otley, the judge was once more quite dismissive of the financial implications of funding the requested drug, and the issue of affordability, so carefully avoided by the judiciary in Rogers. Whilst accepting that the PCT could not ignore cost effectiveness in exceptional cases, Grenfell J expressed the view that the PCT should certainly take a more relaxed approach in this context and claimed that approving Ross’ application was:

‘unlikely to open any “flood gates” of further applications’. 171

The judge concluded that the PCT’s decision had been logically flawed and that its policy was unlawful. Subsequently, Ross went on to receive the lenalidomide he had requested, dying 27 months later from his disease, 9 months short of the extra 3 years of life it had been anticipated the drug might bring him. 172

4.6.7 Challenging the myths

It is striking how few of the patients discussed above learnt about the drugs they requested directly from their oncologists. The role of the Internet is prominent in facilitating access to information, and is a reason why implicit rationing, discussed in Chapter 5, 173 would be hard to sustain in current times, even if such an approach were felt to be morally acceptable. The fact that doctors were not the primary source for information about the new drugs raises questions about a doctor’s duty to inform patients about treatment which is not freely available on the NHS. This is an even more pertinent issue with the widespread acceptance of payment for additional drugs within the NHS. Whilst it has not been possible to address the question of the extent of a doctor’s duty to inform patients as part of this thesis, I hope to have the opportunity to explore the legal and ethical aspects of this duty as part of my postdoctoral work.

These five judicial reviews illustrate how hard it is for IFR panels within PCTs to both have policies, and to reach decisions, which are legally robust when subject to judicial scrutiny. Given that IFR panels very rarely have lawyers among their membership, the finding of procedural impropriety of some kind in all of these cases is not surprising. 174 However, it is a myth that the courts effectively force PCTs to concede

171 Ibid., para 8.
173 See Section 5.2.2.
to patients’ requests for cancer treatment. Although the PCTs’ decisions in all the cases reviewed were quashed, and most of the patients received interim treatment whilst the PCTs reconsidered their decisions, only Rogers, Otley and Ross then received ongoing treatment. The other myth challenged by review of these cases is the value of new drugs in prolonging life. Inevitably, anticipating life expectancy is a notoriously inaccurate science, and this brief review of cases involves only a small number of patients, but of the five, only Gordon gained the benefit predicted from the drug she requested. This is not to deny that these high cost drugs provide other advantages, such as hope, and improved quality of life, but these benefits can often be provided for a lower cost through palliative measures. PCTs are often portrayed as callous and insensitive when refusing to fund expensive cancer drugs, but the reality is that for many patients these treatments do not provide the maximum benefits predicted. It is another reason to challenge the privileged status of funding for cancer drugs within the NHS, most recently evidenced by the establishment of the Cancer Drugs Fund.

As IFRs for cancer drugs fall, and patients turn instead to the Cancer Drugs Fund, is it surprising that, in the third year of its existence, no one has challenged the outcome of a Cancer Drugs Fund decision? The number of judicial reviews of IFRs for cancer drugs demonstrates that cancer patients have a greater propensity than others to seek redress in the courts. Perhaps one of the reasons that judicial review of a negative Cancer Drugs Fund decision has yet to be seen is that the Fund has a high buy-in from oncologists, many of whom have been taken aback by the DoH’s generosity towards cancer drugs funding, and some of whom privately express reservations about the wisdom of spending so much on drugs for which there is very limited evidence and minimal benefit.\textsuperscript{175} Oncologists are also closely involved in decision making within the Cancer Drugs Fund, in a way which they have not been with IFRs at PCTs, and therefore, when an application is declined, this probably makes it easier for them to accept.\textsuperscript{176} However,

the main reason that decision making by the Cancer Drugs Fund has not been subject to judicial review is that 97% of requests are approved; the Fund does not often say no.¹⁷⁷

As the Cancer Drugs Fund has itself, up until now, been a discretionary fund, it would appear that seeking funding on the basis of exceptionality from the Fund would have been redundant.¹⁷⁸ Any appeal against a Cancer Drugs Fund decision would need to lie in the usual grounds of judicial review, or alternatively, in Human Rights legislation. Under the new arrangements proposed for a single national Cancer Drugs Fund, detailed in Section 3.2.9 of Chapter 3, the Cancer Drugs Fund will operate a national pre-approved list of funded cancer drugs, and all IFRs for cancer drugs will be made directly to the Cancer Drugs Fund, rather than to the CCGs which will replace PCTs. Whereas PCTs have previously been the focus of legal challenges from patients when IFRs for cancer drugs have been declined, the transfer of IFRs for cancer drugs from PCTs to the Cancer Drugs Fund, rather than to CCGs, will make the Cancer Drugs Fund the target of legal action if patients choose to seek judicial review of IFR decision making. It remains to be seen if this shift of responsibility for decision making will result in the emergence of legal action against the Cancer Drugs Fund, and how the courts will respond to this eventuality.

4.7 Conclusion

This chapter demonstrates how the process of judicial review and the concept of exceptionality do not sit in isolation. The NHS has never been absolutely comprehensive, but patients have become more willing to challenge priority setting decisions in the court over time. This is undoubtedly due in part to the rise of unrealistic expectations, fuelled by both the media and the DoH’s own mantra that the NHS remains ‘free at the point of delivery and available to all based on clinical need, not ability to pay’.¹⁷⁹ Just as patient attitudes have changed, so have judicial attitudes. Greater transparency has become expected of decision making bodies, and this is likely to be increasingly the position as the numbers of claims based on Human Rights grow. Although review of ECtHR cases involving resource allocation suggests that the ECtHR is no more likely to

¹⁷⁸ Since every decision by the Cancer Drugs Fund has in effect been discretionary, unless the Fund ceased to make any decisions at all it is hard to see how it could be accused of fettering its own discretion. See Chapter 2, Section 2.2.2 for a detailed analysis of the origin of the notion of exceptionality in health care funding.
¹⁷⁹ Department of Health. A consultation on strengthening the NHS constitution. op. cit. note 2.
disregard the constraints imposed by a limited budget than the domestic courts, application of the proportionality doctrine is required, which arguably requires a greater level of scrutiny than the standard of reasonableness currently used in England.

It is clear that legal action is, on occasion, used for means other than those for which it was intended. The extent to which some of these motives influence PCTs is reported as part of the empirical work undertaken in Paper 3. A brief overview of the judicial reviews which are the subject of Paper 1 reveals that reaching legally robust decisions is challenging for PCTs, and it is hard for them to avoid exposing themselves to the risk of costly legal action at the expense of clinical care. Whilst recourse to judicial review to access cancer drugs is not a common occurrence, when it does occur, interpretation of the concept of exceptionality is pivotal. This concept is the central focus of Paper 1. The paper examines how the concept of exceptionality has been interpreted from a legal perspective, with a view to establishing a set of criteria against which to determine if any given patient would be considered exceptional by the courts. It is concluded that the concept of exceptionality has been too broadly and loosely defined, and has been used to avoid addressing the need for public debate about how we decide which treatments the NHS should provide, when it cannot afford to provide them all.
5.0 Philosophical Approach: the Search for an Ethical Framework to Support Resource Allocation for Individual Funding Requests

5.1 Introduction

This chapter presents the background for the second of the papers making up the core of this thesis, ‘Accountability for Reasonableness – Why the Relevance Condition is of no Relevance’. The paper addresses the question of whether the relevance condition, one of the four conditions of Daniels and Sabin’s Accountability for Reasonableness framework,\(^1\) is fit for purpose. The pertinence of this question to IFR decision making is explained as this chapter progresses. The starting point is the recommendation by the DoH that PCTs adopt ethical frameworks for priority setting decisions.\(^2\) This advice emerged from guidance produced to support PCTs in meeting the legal requirements set out by the Directions underlying the NHS Constitution.\(^3\) As discussed in Chapter 2, the Directions were central in formalising the individual funding request process at many PCTs.\(^4\)

The DoH provided little guidance as to which ethical framework would be best suited to improving IFR decision making. The aim of this chapter is to establish which ethical framework is most appropriate for this role. First, it is necessary to examine why there is a need for an ethical framework to support decision making for IFRs. It is argued that there are two main reasons: firstly patients, especially those who are denied access to treatment, deserve to know that the determination of IFRs is morally right and fair; and secondly, it is advanced that use of an ethical framework can enhance the legitimacy of

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\(^1\) Daniels N, Sabin J. Setting Limits Fairly - Learning to Share Resources for Health. 2nd edn. Oxford: Oxford University Press, 2008. For readers not familiar with the Accountability for Reasonableness framework, an outline is provided in Section 5.5.4 below, with a fuller analysis included in Paper 2, Chapter 9, Section 9.1.


\(^3\) National Prescribing Centre. Supporting rational local decision-making about medicines (and treatments) - A Handbook of Good Practice. op. cit. note 2; Department of Health. Defining guiding principles for processes supporting local decision making about medicines. op. cit. note 2.

\(^4\) Section 2.2.3.
priority setting decisions, improving the acceptability of outcomes and therefore reducing the number of legal challenges to PCT decision making.

Having established the need for an ethical framework in IFR decision making, potential frameworks which might fulfil this role are identified and reviewed. In order to achieve this it is necessary to examine precisely what constitutes an ethical framework, and how one might assess whether it is capable of accomplishing the work expected of it.

Of the ethical frameworks identified, Daniels and Sabin’s Accountability for Reasonableness framework appears, at first sight, best suited to supporting funding requests based on exceptionality and the reasons for this choice are outlined. However, a potential problem with the Accountability for Reasonableness framework is highlighted. Despite being widely described and accepted as an ethical framework, there is some doubt as to whether it does, in fact, amount to any more than a procedural framework. Paper 2 tackles the question of whether the relevance condition is able to do the work claimed in order for the Accountability for Reasonableness framework to be considered an ethical, rather than a procedural framework, and hence fulfil the need identified for an ethical framework to support IFRs based on exceptionality. The later sections of Paper 2 review the practical difficulties of implementing the relevance condition in the context of the NHS and then tests whether funding treatment for patients on the basis of their exceptional circumstances, as occurs in IFRs, meets the relevance condition.

5.2 Why is there a need for an ethical framework in IFR decision making?

The DoH identified the need for ethical frameworks to support IFR decision making in 2009, suggesting that they could improve the consistency and quality of decision making. If an ethical framework could provide a solution to the challenge of determining exceptionality, this is an avenue worth exploring. Recommendation of the Department of Health. Defining guiding principles for processes supporting local decision making about medicines. op. cit. note 2; National Prescribing Centre. Supporting rational local decision-making about medicines (and treatments) - A Handbook of Good Practice. op. cit. note 2, pp 20, 24, 35. At present, use of ethical frameworks in IFR decision making is not universal. On reviewing the IFR policies of 20 randomly selected PCTs, to examine what role ethical frameworks played, I found that 6 PCTs’ policies made no reference at all to ethical frameworks. 3 policies mentioned ethical frameworks, but provided no detail about them. A further 3 policies explicitly included Beauchamp and Childress’ Four Principles and the remaining 8 PCTs listed the ethical principles they applied in their decision making, although only in some cases were these referred to as an
use of ethical frameworks in relation to priority setting is perhaps not surprising; ethical issues in the field of resource allocation for health are receiving unprecedented policy and academic attention.\textsuperscript{7} This has led to a marked increase in the demand for practical approaches to ethical priority setting in healthcare services\textsuperscript{8} and reflects the extent to which bioethics has come to be seen as a tool for normative policy analysis.\textsuperscript{9}

\textbf{5.2.1 Patients want to know that decisions are morally fair and just, not just legally correct}

Why is there a need for an ethical framework to support IFR decision making? I postulate that there are two reasons. Firstly, patients are increasingly aware that they are being denied care, in part because like Rogers and Otley, whose cases were discussed in Chapter 4,\textsuperscript{10} they are now able to access information about potential treatment via the Internet. Since the foundation of the NHS the public have been told that NHS care will be free at the point of delivery, and available to all based on clinical need, not on ability to pay. Even with the recent austerity measures requiring the NHS to save £20 billion by 2015,\textsuperscript{11} the message that NHS care will be universal, free and based on clinical need is not getting any quieter. It is therefore not surprising that when patients are denied care, they want to know the basis on which such decisions have been made. Learning that the policy and procedures followed by the PCT were legally correct is of little solace to the cancer patient who is told he cannot receive the only treatment with the potential to extend his life. Patients want to know that resource allocation decisions are morally right and fair, and furthermore, given that the promise held in the founding principles of the NHS has been broken, they deserve to know. Such knowledge is necessary to maintain public confidence in the NHS. The use of an ethical framework, by PCTs, is one method of reassuring the public that the decisions reached are fair and just. An ethical framework can provide clear criteria and explicit principles for decision making, which is especially important where the concept of exceptionality is involved which, as Paper 1 shows, is particularly nebulous and hard to define.

\textsuperscript{7} Kenny N, Joffres C. An ethical analysis of international health priority-setting. \textit{Health Care Analysis} 2008;16(2):145-60.
\textsuperscript{10} Sections 4.6.2 and 4.6.6 respectively.
\textsuperscript{11} Torjesen I. NHS is unlikely to meet Nicholson challenge to deliver £20bn in efficiency savings, says King’s Fund. \textit{BMJ} 2012;345:e6496.
5.2.2 The shift from implicit to explicit rationing demands greater legitimacy of decision makers

Secondly, linked to the public’s right to know that resource allocation decisions are morally right and fair, the need for ethical frameworks in priority setting has become increasingly acute because of the shift from implicit to explicit rationing, which has resulted in a greater need for legitimacy of limit setting decisions. Habermas has described legitimacy as meaning

‘...that there are good arguments for a political order's claim to be recognised as right and just...’

That PCTs limit setting decisions are not seen as ‘right and just’ is evident from the number of internal appeals and judicial reviews of PCT decisions by patients. However, it is not only patients who are challenging PCTs’ authority to make priority setting decisions. Physicians also reject limits on care which prevent access to treatments they believe will help patients. Oncologists in particular are reported to go to considerable efforts to overcome funding restrictions, in some cases ‘gaming’ the system by misrepresenting the severity of their patients’ conditions in order to facilitate access to care.

The transfer from implicit to explicit rationing came about as a result of the internal market in healthcare instigated in the early 1990s. Absolute prohibitions on the provision of some interventions were introduced. Prior to this time, theoretically at least, patients had access to all potential interventions. Whilst one might expect the legitimacy of resource allocation decisions to have increased with the transfer from implicit to explicit rationing, as a result of greater openness about decision making, this has not been the case. Previously rationing decisions were covert, often at the individual patient doctor level and passed off as decisions based on clinical judgment rather than lack of resources. Denial of care was made to appear routine. Waiting lists developed, effectively rationing care by delay, but their existence was less controversial than the

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outright prohibition of services.\textsuperscript{16} While the medical profession has traditionally been regarded as the most appropriate group to make rationing decisions,\textsuperscript{17} the increasing demand for legitimacy of limit setting decisions, which has occurred with the evolution of explicit rationing and the associated shift of responsibility for priority setting from individual physicians to PCTs, is perhaps inevitable. There is a need for ethical frameworks in priority setting decisions, such as IFRs, to bolster the moral authority of PCTs as decision makers, in order to reduce both internal and judicial challenges to their decisions.

It has been established that there are two linked reasons underlying the need for ethical frameworks. Having been promised that NHS care will be universal, free and based on clinical need, patients who are denied care deserve to know that the preference for treating another patient is based on reasons that are just and fair. In addition, there is a need for ethical frameworks in IFR decision making to bolster the legitimacy of PCTs’ decisions and reduce the number of patients challenging decisions in the courts. The next section reviews what constitutes an ethical framework and how we can assess whether a framework is capable of achieving the work expected of it.

5.3 What is an ethical framework and how can we assess if it will do the work expected of it?

5.3.1 What is an ethical framework?

To enhance the legitimacy of PCT limit setting decisions in the context of IFRs, an ethical framework cannot simply be moral ‘window dressing’ to give policies the appearance of being ethical.\textsuperscript{18} Chan and Harris have described an ethical framework as:

\textit{‘a set of ethical principles capable of being applied consistently and designed to guide our response to a particular problem or set of problems.’}\textsuperscript{19}

To be of practical use in providing guidance to decision makers, an ethical framework needs to encapsulate the criteria for decision making, and link decision making to the

\textsuperscript{16} Mechanic D. Dilemmas in rationing health care services: the case for implicit rationing \textit{op. cit.} note 14.


wider context in which it is occurring. Such a framework would help explain and justify decisions to observers. Chan and Harris contrast ethical frameworks with ethical imperatives, such as the Ten Commandments, which dictate what should not be done, as opposed to which factors need to be contemplated in determining what is to be done.\textsuperscript{20} There is also a distinction between an ethical framework and an ethical theory, such as deontology or consequentialism. An ethical theory may inform the approach of an ethical framework, but in itself does not constitute an ethical framework. It is asserted that neither identification of, nor consensus on, the underlying ethical approach is essential for the application of an ethical framework.\textsuperscript{21}

5.3.2 How do we judge successful priority setting?
How do we know if an ethical framework is capable of achieving the aim, inherent in the definition provided by Chan and Harris, of consistently and coherently being applied to guide problem solving in the context of priority setting? There is a dearth of research addressing this question and a comprehensive definition of successful priority setting is conspicuous by its absence. This is somewhat surprising given the vast amount of literature on priority setting more broadly. Sibbald \textit{et al} attempted to develop a conceptual framework to evaluate the success of priority setting through empirical research.\textsuperscript{22} However, this was based on a survey which asked a range of people what people understood successful priority setting to mean. Many of the questions were based around one specific framework for resource allocation, which is likely to have biased responses. The resulting evaluative framework produced by Sibbald \textit{et al} failed to include any objective measurements of improvements in priority setting and was effectively a summary of people’s opinions. It has not been validated and is of little practical use.

5.3.3 Three principles for appraising ethical frameworks
Attempting to establish comprehensive criteria by which to measure the success of priority setting is ambitious, and certainly requires more research to achieve it. An alternative approach to appraising the quality of ethical frameworks has been advanced, which involves evaluating the ethical framework directly, rather than the priority setting outcomes it produces. Drawing on the criteria used for evaluating clinical guidelines,

\textsuperscript{20} ibid.
\textsuperscript{21} ibid.
Heginbotham identifies three generic principles, which it is claimed are transferable to the critical appraisal of ethical frameworks. These principles, he claims, allow the reader to determine:

‘(1) where the guidance comes from, (2) what it is for, and, (3) the implications of following it.’

In practice, this would require that the origin and authors of the framework should be explicit, and that some detail of the development process should be provided, including whether this involved ethical theory, empirical research, legal guidance or stakeholder input. Clarification of the intended meaning of any key terms essential to implement the policy would also need to be apparent. As with clinical guidelines, one would expect clear detail of the instrumental role of the framework, and specific detail of how it relates to the interpretation and execution of the policy it is intended to support.

The weakness of these proposed appraisal criteria is that whilst the basic descriptive information they require would allow a critique of the framework developmental process, they would not necessarily allow an assessment of the quality of the outcomes that the ethical framework could provide. One might expect that well thought out ethical frameworks would provide better quality outcomes, but process and outcome are not intrinsically linked. Pending further research by health policy ethicists into the application of ethical frameworks, and the development of more definitive benchmarks for the evaluation of their use, these proposed criteria may be the best available to us.

5.4 Review of ethical frameworks which might be suitable for managing Individual Funding Requests

It is possible that the DoH’s recommendation that those involved with IFR policy take account of ethical frameworks is too great an expectation of PCTs. The challenge of bridging theoretical ethics with practical policy should not be underestimated. It is clearly a harder task than the development of purely abstract ethical theories, which may never need to withstand the test of implementation, and yet PCTs are being expected to integrate an ethical framework into IFR policy with little, if any, bioethical expertise. Their task would be made easier if there were an established framework,

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24 This is in keeping with Chan and Harris’ assertion that identification of the underlying theoretical approach is not absolutely necessary to apply an ethical framework, though these evaluative criteria do require at least some explanation of the basis of the framework. Chan S, Harris J. op. cit. note 19.
either generic in nature or specifically developed for priority setting issues, which could meet this need.

Historically, those PCTs which have incorporated ethical frameworks into IFR policy have used list-based frameworks. Some principle-based approaches have been developed beyond simple lists into multi-principle systems such as Beauchamp and Childress’ four principles approach, Cookson and Dolan’s pluralistic model of three principles, and the complete lives system. To date, only the first of these has proved popular with PCTs.

Around the mid 1990s, some bioethicists who had previously advocated principle based approaches started to question whether such approaches were the solution to priority setting. Klein, for example, claimed that:

‘Given the plurality of often conflicting values that can be brought to any discussion of priorities in health care, it is positively undesirable (as well as foolish) to search for some set of principles that will make our decisions for us.’

It was identified that there were problems with the quantity and quality of data available to guide priority setting, and little consensus on which ethical values should be paramount in distributing resources. There followed a shift in focus from principles to process in priority setting, in the belief that in the absence of a principled way of priority setting, transparent and accountable processes could instead provide legitimacy for these decisions. This point marked the transition to what Holm has aptly described as:

‘the second phase of priority setting in health care’.

Falling into this category of process-orientated frameworks are two established systematic approaches, which incorporate economic considerations, known as multi-criteria decision analysis (MCDA), and program budgeting and marginal analysis. The final category of ethical frameworks incorporates those with an even greater emphasis

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26 See Section 5.2, note 6 above.
on process and includes Baerøe’s framework for reasonable clinical judgments\textsuperscript{33} and Daniels’ Accountability for Reasonableness framework.\textsuperscript{34} The purpose of this section is not to provide a detailed critique of each ethical approach, as to do this task justice would require possibly several further papers. Instead, the aim is to provide an overview of the approaches outlined, drawing together in one place a summary of the possible frameworks which PCTs might consider in implementing the DoH’s recommendation to adopt an ethical framework for priority setting.\textsuperscript{35} To ensure no possible options are neglected, the approach is intentionally broad, and not restricted to frameworks already in use in IFR decision making.

5.4.1 List based approaches

List based approaches represent the most commonly used ethical approach by PCTs at present.\textsuperscript{36} Examples of the type of factors included are: health outcomes, clinical effectiveness, cost effectiveness, equity, access, patient choice, affordability, needs of the community, quality, policy drivers, exceptional need and disinvestment.\textsuperscript{37} It is not my intention to examine all the potential principles which might populate such lists, as a literature review identifying 58 such criteria, classifiable into 9 different categories has recently been published.\textsuperscript{38} However, it is worth noting that list-based approaches often include a spectrum of abstract ethical principles and more concrete objectives. As well as crossing different disciplines, the principles may include both terminal, or goal-based values,\textsuperscript{39} substantive values, and procedural values, such as transparency.

\textsuperscript{34} Daniels N, Sabin J. \textit{Setting Limits Fairly - Learning to Share Resources for Health}. op. cit. note 1.
\textsuperscript{35} Department of Health. \textit{Defining guiding principles for processes supporting local decision making about medicines}. op. cit. note 2; National Prescribing Centre. \textit{Supporting rational local decision-making about medicines (and treatments) – A Handbook of Good Practice}. op. cit. note 2, pp 20, 24, 35.
\textsuperscript{36} See Section 5.2, note 6 above.
\textsuperscript{38} The 9 different categories were health outcomes: types of benefit; disease impact; therapeutic context; economic impact; quality of evidence; implementation complexity; priority, fairness and ethics and overall context. As might be expected, principles included a mix of normative values and feasibility criteria. The 9 most frequently occurring criteria were: equity, fairness and justice; efficacy/effectiveness; stakeholder interests and pressures; cost-effectiveness; strength of evidence; safety, mission and mandate of health system; organisational requirements and capacity; patient reported outcomes; and need. Guindo LA, Wagner M, Baltussen R, et al. From efficacy to equity: literature review of decision criteria for resource allocation and healthcare decisionmaking. \textit{Cost Effectiveness and Resource Allocation} 2012;\textbf{10}(1):9.
\textsuperscript{39} Giacomini M, Kenny N, DeJean D. op. cit. note 18.
In some cases, the relationship between the principles listed and specific elements of the priority setting policy are made explicit by the provision of contextualising information for each principle, but often there is no apparent underlying ethical approach, or authority for the framework, and no justification for why some factors have been included and not others. A significant failing of list-based approaches is that it is rarely clear how the principles coherently hold together, or should be weighed against each other. Albeit in a different context, it has been observed that such a piecemeal list-based approach can result in inconsistency in the application of principles and less cogent policy outcomes.40

5.4.2 Principle based ethical frameworks

Beauchamp and Childress’ Four Principles

Beauchamp and Childress’ approach to biomedical ethics is based on four principles:41 respect for autonomy (‘the moral obligation to respect the autonomy of others in so far as such respect is compatible with equal respect for the autonomy of all potentially affected’);42 beneficence (to provide benefit); non-maleficence (an obligation not to inflict harm intentionally); and justice (‘the moral obligation to act on the basis of fair adjudication between competing claims’).43 The approach is based on the idea that irrespective of personal philosophy, religion or politics, the four principles represent a common set of moral commitments to which all can subscribe. Each principle is binding, unless it conflicts with another. In this instance it must be decided which to allow to dominate, since there is no predefined order assigned to the principles, and depending on context, different principles may take precedence.44

The four principles are linked to an established ethical theory and have the potential to be used coherently together. However, in PCT policies they are often presented as abstract principles, with no elaboration of how each principle should be interpreted, or weighed against the others.45 There is an assumption that those responsible for implementing the policy will recognise the principles as Beauchamp and Childress’

43 Ibid.
44 Ibid.
ethical framework and be familiar with its application. Crucially, there is often nothing to relate the four elements to policy, and it may be hard to see if any connection exists at all. Used in this way the four principles do not logically entail any specific policy direction, action or response. This may explain the recent finding that although people report valuing the four principles approach, they do not apply the approach to decision making. Ethicists have become increasingly critical of the four principles approach, and its potential to arrive at different and incompatible conclusions, depending on how the principles are weighted.

**Cookson and Dolan’s pluralistic model of three principles**

After undertaking empirical research examining public preferences for rationing resources between four hypothetical patients, Cookson and Dolan have proposed an embryonic model for development into a coherent theoretical position. They found that the public preferred a pluralist approach to priority setting, incorporating three commonly discussed principles of substantive justice – priority to those in immediate need, maximisation of the health of the whole community, and equalisation of lifetime health. However, it was not established whether each principle should be equally weighted, or ordered lexically, with secondary and tertiary principles coming into effect only when the preceding principle in the hierarchy failed to provide a definitive answer. The need to define the concepts inherent in each principle was recognised, given the multiple interpretations possible in each case. Cookson and Dolan also acknowledge that one reason why the three principles have yet to be developed into a theory of justice is that the public’s preference for a pluralistic approach may be simply wrong.

Although not yet elaborated on adequately enough to form an ethical framework for applied work, the pluralistic three principles approach is one of the few approaches that has evolved from research which involved choosing between individual patients, rather than population-level decisions. It therefore holds the potential to be transferred to

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46 Page K. The four principles: can they be measured and do they predict ethical decision making? *BMC Medical Ethics*; 13(1):10.
decision making in the context of IFRs, which similarly require decisions to be made at patient level, rather than population level.

The complete lives system

Having found other multi-principle allocation systems to be lacking, Persad, Wertheimer and Emanuel developed their own, which they describe as the complete lives system.\(^{51}\) As its name suggests, it considers entire lives, rather than individual episodes of illness in isolation, although somewhat fundamentally, the authors omit to detail their conception of a ‘complete life’. The complete lives system incorporates four principles in routine allocation decisions: youngest first, best prognosis, saves the most lives and the use of lottery. There is no pre-defined dominance of any of the principles. Instead, it is expected that they will be balanced to give priority to the worst off, whilst maximising benefits. Persad et al explain the rationale for the principles they have chosen on the basis that the young are the worst off as they have experienced least life. A caveat puts lower priority on very young infants, on the basis that they have not yet received the same emotional and financial investment. Prognosis is considered to avoid high expenditure on those who will only benefit for a short time, which will prevent maximisation of life years produced. Allowing for these considerations, the complete lives system aims to benefit the greatest number of people. The lottery concept is included to allow choices between similar potential recipients and is favoured for being resistant to corruption.

The complete lives system unashamedly advantages adolescents and young adults on the basis that investments in these cohorts will be wasted without fulfilment of a complete life. The authors of this framework claim that as all people age, prioritising on the basis of age does not mean they are being treated unequally. However, if men are susceptible to a specific illness, such as cardiovascular disease, at a younger age than women, then men and women with the same condition will be treated differently, with priority systematically being given to men. The complete lives system also categorically gives a low priority to those diseases which only afflict the elderly, or the very young.

The complete lives approach has been criticised on the basis that some of its component principles lack adequate moral foundations, and that its practical application is limited because it fails to provide any method for balancing principles when they conflict.\(^{52}\)

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\(^{52}\) Kerstein SJ, Bognar G. Complete lives in the balance. The American Journal of Bioethics 2010;10(4):37-45; Norheim OF. Priority to the young or to those with least lifetime health? The
complete lives system acknowledges the need for a multi-principle framework and is an admirable attempt at being explicit about what these principles should be. However, the approach needs further refinement to address the weaknesses highlighted.

5.4.3 Structured frameworks

**Multi-criteria decision analysis**

The use of multi-criteria decision analysis (MCDA) is well established in industries such as agriculture, energy and marketing. The appeal of MCDA is that it allows policy makers to evaluate several dissimilar criteria simultaneously, in a systematic and transparent fashion, before arriving at a decision. In healthcare, it holds the potential to allow the concurrent evaluation of clinical, economic and ethical principles, bringing together criteria such as cost effectiveness analyses, equity analyses, burden of disease analyses and evidence based medicine, yet still allows each to be assessed individually.

The purpose of MCDA is to allow trade-offs between relevant criteria, resulting in a rank ordering of possible interventions. In some contexts, interventions may be funded in order until the budget is depleted, but the framework is designed to aid and inform decision making, rather than prescribe a formulaic approach. There may be political, or other reasons, not fully captured by the process of MCDA, which ultimately impact on priorities for expenditure.

In order to carry out MCDA, an explicit set of objectives must initially be agreed by the decision making body, and measurable criteria established by which to gauge the extent to which each objective would be achieved by every possible healthcare intervention under consideration for funding. A performance matrix can then be created, with the rows describing the potential interventions and the columns describing the performance of each intervention against the established criteria.53

Once completed, a performance matrix can be processed either qualitatively or quantitatively. Qualitative analysis involves looking for what is described as ‘dominance’

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of one option over all others, where one intervention clearly outperforms alternative options. That intervention is normally considered a top priority for funding. In the absence of dominance, or where all other potential interventions need to be ranked, subjective interpretation of the performance matrix can be undertaken, applying holistic judgment as to which interventions will help to maximise the decision maker’s objectives. The alternative evaluation, quantitative analysis, involves converting the data within the matrix into consistent numerical values and weighting each individual criterion, following expert group consultation. Effectively the scales created represent preferences for the consequences, explicitly acknowledging that all criteria may not be of equal importance. An overall numerical score can then be given to each potential intervention, taking account of how it scored on each criterion, and the weight given to that criterion. This allows the interventions to be ranked in order of how well they achieve the original objective agreed.54

In essence, MCDA takes informal judgments regarding the potential benefits of implementing a variety of possible interventions, and attempts to quantify them. Despite the high profile Marginal Budgeting for Bottlenecks tool,55 developed by the World Health Organization, the United Nations and the World Bank, the uptake more widely of MCDA has been low. This could be because many of the common objectives in healthcare, such as reducing inequalities, and providing maximum benefit, are not easily quantifiable.

Programme Budgeting and Marginal Analysis

Originally developed for use in the defence sector, Programme Budgeting and Marginal Analysis (PBMA) is an evaluative technique which can incorporate economic principles such as cost effectiveness analysis, but, it is claimed, can also accommodate the pragmatic complexities of healthcare priority setting by integrating values such as efficiency and equity.56 One of the advantages of PBMA is that it allows analysis of historically funded services against potentially new interventions which might replace them. PBMA recognises that when making choices in the context of limited resources, funding new services will mean that others will have to be forgone. Using PBMA, an

54 Ibid.
56 Mitton CR, Donaldson C. op. cit. note 32.
expert stakeholder group systematically assesses the costs and benefits of the healthcare services under review – both historic and proposed. For each service, the benefit gained from an extra unit of resources, or benefit lost from having one unit less, is ascertained. In this way, the services to be prioritised for funding can be compared at the margin. If the marginal benefit per unit cost of intervention A is greater than that for intervention B, resources should be directed at A rather than B. Alternatively, if B is already being provided, resources should be redirected into providing intervention A and intervention B should be withdrawn. Reallocation continues until total patient benefit, or any other pre-defined criterion chosen, has been maximised using the resources available.

PBMA is primarily an economic approach, rather than an ethical framework. Its success has been found to be dependent on organisational context. The extent to which it can successfully incorporate ethical values and result in a just distribution of resources is questionable. Gibson et al undertook a study examining the implementation of PBMA in conjunction with a framework for procedural justice and found that it left unanswered the question of whether substantive justice is attainable using PBMA. In another study involving prioritisation at a PCT, Wilson et al undertook MCDA, but then calculated a cost benefit score for each intervention and carried out marginal analysis, effectively combining PBMA with MCDA. They identified a risk that, despite the apparent transparency of the process, stakeholder bias and prejudice could be internalised into the framework and that vigilance was required to prevent this.

5.4.4 Procedural ethical frameworks

**Baerøe’s framework for reasonable clinical judgments**

In theory, Baerøe’s framework should be well suited to priority setting in the context of IFRs, as it is aimed at decision making at the individual level, including instances where a patient falls outside pre-defined guidelines and consideration has to be given to whether or not a different course of action can be justified. Baerøe’s framework assumes that sole clinicians will be responsible for decision making. There is no reason that the

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process she proposes could not be followed by an IFR panel, although negotiation would probably be needed to reach a consensus on each point.

Baerøe’s framework starts from a normative basis, consisting of two components: a general goal of healthcare and principles for distributive justice. The choice of these is left to the individual clinician, but with the pre requisite that the clinician must be able to justify her choice. Baerøe does however, specify that:

‘the balancing, all-things-considered perspective on what service to provide should be seen as an issue of equity’. 60

Although Baerøe does not mandate which interpretation of equity should be adopted, the options of advantaging the worst off or equalising the distribution of resources are advanced as possibilities.

The framework itself consists of seven requirements that decision makers should follow in reaching and defending their choice of resource allocation. These are:

‘i. Self reflection: Do clinicians acknowledge the normative basis that underlies their interpretation of healthcare claims and do they reflect over the substantive content of this basis?

ii. Search for all relevant reasons for equitable healthcare: do clinicians try to discover all reasons they might find relevant?

iii. Recognition of demand for impartiality: do clinicians acknowledge the demands of impartiality?

iv. Recognition of political consequences: do clinicians recognise the political consequences of the healthcare claim they put forward?

v. Recognition of prioritised services: can clinicians justify decision as to what kinds of clinical services the healthcare service should prioritise?

vi. Recognition of the aim of justification – do clinicians try to justify the claim so that it would be acceptable to all colleagues sharing this aim of justification?

vii. Professional self regulation – are all above requirements institutionalised?’ 61

The framework aims to ensure that, in making decisions regarding individuals, decision makers consider what kind of treatment should be prioritised from a societal perspective, and justify their choice according to whichever substantive goal of healthcare they subscribe to. Similarly, decision makers are expected to recognise the effect their decision will have on the equitable distribution of healthcare and again,

60 Baerøe K. op. cit. note 33.
61 Ibid.
must strive to justify this. If a decision is made to treat a patient outside established
guidelines, all other similar patients are expected to be treated in the same manner.

The sixth requirement of the framework requires decision makers to justify their claims,
with the aim that others will be persuaded of the merits of the basis of their claims.
Baerøe contends that this ensures that decision makers deliberate regarding the
justifications of their claims, and advocates that decision makers receive education in
normative and political theory to ensure they deliberate effectively. In addition to
deliberating amongst their peers, Baerøe also champions public deliberation, to ensure
that decisions are justifiable to society. It is not expected that consensus on decisions
will necessarily be reached, but that, as a minimum, unfounded claims will be
eliminated.

The framework depends on the key assumption that decision makers will be willing to
justify their decisions as mandated by the framework. There is an inherent tension
between the lack of a principled basis for the distribution of healthcare resources and
the expectation that individual decision makers will act as though one exists. Baerøe
claims that the framework reconciles this contradiction by providing a process which
legitimises the underlying principles. To the best of my knowledge Baerøe’s framework
for reasonable clinical judgments has yet to be piloted in any real life scenarios, so it
remains to be seen whether in practice it can deliver what it promises.

**Accountability for Reasonableness**

Daniels’ acknowledges, after earlier attempts to pursue a unifying theory of distributive
justice as the basis for healthcare, that in a pluralist society we are unlikely to reach a
consensus on which principles should guide priority setting. Together with Sabin,
Daniels now advocates instead relying on a fair and legitimate decision making process,
which holds the decision makers accountable. They have used this idea to develop an
ethically based account of how resource allocation decisions should be made, known as
‘Accountability for Reasonableness’, designed as an institutional decision making

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62 Daniels’ earlier work focussed on developing a theory of just healthcare based upon the
principle of equality of opportunity. See Daniels N. *Just Health Care* Cambridge: Cambridge
63 Daniels N, Sabin J. *Setting Limits Fairly - Learning to Share Resources for Health. op. cit. note 1.*
process. Daniels and Sabin outline four essential criteria which make up this framework:\(^6^4\):

**Publicity Condition** – Decisions limiting healthcare and their rationales should be transparent and publicly accessible.

**Relevance Condition** – Decisions should be made on the basis of reasons that ‘fair minded people’ can agree are relevant to the challenge of providing high quality care in the context of limited resources.

**Appeals and Revision Condition** – There must be a mechanism to allow appeal of decisions and opportunities to revise policies in the light of new information.

**Enforcement Condition** – There should be regulation in place to ensure the above conditions are met.

Accountability for Reasonableness is clearly an institutional process, which is dependent on the organisational structure of the healthcare service for its facilitation. It requires an established forum to enable deliberation amongst fair-minded people, which Daniels and Sabin define as:

‘...people who seek to cooperate with others on terms they can justify to each other.’\(^6^5\)

The reasons on which their decisions are based must be disseminated both within the institution, and to the public, so that people can witness the coherence and consistency of policy making. Publicity about reasons allows the public to ensure that similar cases are treated similarly, at least within institutions, and Daniels and Sabin liken this to the development of case law. The appeals and revision condition strives to close the loop between policy makers and those affected by decisions, allowing people who may not have had any input into the original decision to have their voice heard, potentially reducing adversarial litigation in the courts. The enforcement condition, provided either by voluntary regulation or public regulation, aims to ensure accountability through the implementation of the other three conditions.

\(^6^4\) Ibid., p 44.
\(^6^5\) Ibid.
5.5 Selecting an ethical framework to evaluate in the context of IFR decision making – why choose Accountability for Reasonableness?

5.5.1 Which ethical framework best meets the DoH recommendations?
Having started by reviewing the need for ethical frameworks in IFR decision making, and examining how one defines and measures the success of an ethical framework, I now return to the original issue of which ethical framework is best suited to fulfil the DoH’s recommendation that PCTs should use an ethical framework in IFR decision making.

From one perspective, the choice of possible frameworks outlined above seems both vast and diverse, ranging from simple lists of principles to complex multi-criteria decision making tools. However, more than superficial scrutiny of many of the frameworks reveals that they are largely theoretically orientated, and few have even been piloted as practical applications. Whilst some, such as MCDA and PBMA, hold the potential to facilitate priority setting between services on a population level, they would not be well suited to managing IFRs, where decisions are made between treatments for individual patients. There are aspects of every framework which would be likely to cause public controversy, for it is hard to please all of the people all of the time, but Persad’s complete lives system, discriminating as it does against the very young and the very old, is unlikely to be publicly acceptable as an ethical framework for resource allocation.

Consensus support for Cookson and Dolan’s pluralistic model, arising as it does from empirical research with the public, seems much more likely. However, the public are not always right in their moral choices and, as it stands, Cookson and Dolan’s proposal is embryonic in its development.

5.5.2 The attractions of Accountability for Reasonableness as a framework to support IFR decision making
Of all the ethical frameworks reviewed so far, Daniels and Sabin’s Accountability for Reasonableness framework seems, at first sight, best suited to the task of supporting decision making regarding IFRs. Accountability for Reasonableness has been described as the ‘most important recent advance’ in the ethics of priority setting. Rather than being purely a philosophical ideal, held up as something to be aspired to but impossible to attain, Accountability for Reasonableness is, Daniels and Sabin claim, a practical

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approach.\textsuperscript{67} Decision making in IFRs necessitates a pragmatic solution. Accountability for Reasonableness is flexible enough to accommodate clinical evidence and economic analyses, as well as ethical principles relating to just distribution. The widespread acceptance of Accountability for Reasonableness by policy makers on a global level, in a variety of different settings, including the internationally respected NICE technology appraisals, suggests that the framework can provide a workable solution to the challenges of priority setting.\textsuperscript{68} It has been suggested that within health policy Accountability for Reasonableness has now become the dominant paradigm internationally,\textsuperscript{69} and the frequency of reports describing practical experience of using the framework in healthcare contexts from pandemic flu to intensive care reflect this.\textsuperscript{70}

Accountability for Reasonableness has also been subject to a considerable amount of academic research and critique.\textsuperscript{71}

Accountability for Reasonableness fulfils the criteria advanced by Heginbotham for appraising ethical frameworks.\textsuperscript{72} The authors of the framework are explicit and

\textsuperscript{67} Daniels N, Sabin J. Setting Limits Fairly - Learning to Share Resources for Health. op. cit. note 1, p 2.


\textsuperscript{69} Friedman A. Beyond accountability for reasonableness. Bioethics 2008;22(2):101.


extensive detail of the development process, and the application of the framework, is provided in Daniels and Sabin’s book ‘Setting Limits Fairly – Learning to Share Resources for Health’.  

A further attraction of choosing Accountability for Reasonableness is its alleged ability to accommodate priority setting for the kind of treatments, such as high cost cancer drugs, which are often the subject of IFRs. Daniels and Sabin dedicate a chapter of their book to the example of the model’s applicability to last chance therapies, illustrating how they perceive the framework will apply in this context.  

In addition, the four central conditions of Accountability for Reasonableness appear to accommodate other aspects of the DoH’s guidance on IFRs and transfer relatively well to the broad system used for decision making in exceptional circumstances by PCTs. The relevance condition, which is the focus of Paper 2, has the potential to be met through deliberation by the multi-disciplinary IFR panel which decides whether an IFR will be funded or not. Publicity is achieved by communication of the rationale behind decisions to both patient and clinician, a duty which is now enshrined in the NHS Constitution, although it could be argued that Accountability for Reasonableness requires publicity of outcomes to a broader public audience. The appeals and revision condition is met by the internal appeals process that PCTs are advised to provide. The enforcement condition could, to an extent, be met by the courts, through the process of judicial review, which could be used to ensure that the PCT had followed the proper processes and provided the opportunity to appeal.  

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72 Heginbotham C. op. cit. note 17.
75 Such as defining clearly and consistently applying criteria for decision making, considering precedents, communication about process, the rationale for and outcome of decisions to stakeholders and the provision of an appeals process. See Department of Health. Defining guiding principles for processes supporting local decision making about medicines. op. cit. note 2.
77 National Prescribing Centre. Supporting rational local decision-making about medicines (and treatments) - A Handbook of Good Practice. op. cit. note 2.
78 It is, however, questionable whether the courts could ensure the level of transparency about decision making that the Accountability for Reasonableness framework expects. For example, with respect to the funding of treatments restricted because of poor cost effectiveness, Daniels and Sabin suggest that the decision making body should ‘show that resources are limited in a reasonable way, that the cost and effects are as claimed, and that the comparison class of
5.5.3 Is Accountability for Reasonableness an ethical framework?

Can Accountability for Reasonableness really do all the work it claims, or has it come from the same wardrobe as the emperor’s new clothes? Although it is very widely described and accepted as an ethical framework, this representation has not gone unchallenged. Sabik and Lie argue that the framework, with its focus on procedure rather than substantive principles, is in fact a:

‘procedural account for health care priority-and limit-setting decisions.’

Does Accountability for Reasonableness meet the definition of an ethical framework, referred to earlier, as a set of ethical principles capable of being applied consistently and designed to guide our response to a particular problem or set of problems? The answer is not as obvious as one might expect, as the substantive principles in Accountability for Reasonableness are not predetermined, but arise from the relevance condition, which states that:

‘Decisions should be made on the basis of reasons that ‘fair minded people’ can agree are relevant to the challenge of providing high quality care in the context of limited resources.’

For Accountability for Reasonableness to meet the requirements necessary to be considered an ethical framework, the relevance condition needs to provide a set of principles capable of being applied consistently. If it is unable to do this, Accountability for Reasonableness cannot be considered adequate as an ethical framework.

competing technologies that we would approve are all superior in the ways claimed, and that there are not special reasons of distributive fairness that override these considerations.’ Daniels N, Sabin J. Limits to health care: Fair procedures, democratic deliberation, and the legitimacy problem for Insurers. Philosophy & Public Affairs 1997;26(4):335. As discussed in Chapter 4, Section 4.4, the courts have not, in the past, demanded this level of openness from health services limiting access to treatment. It is even more doubtful that judicial review could be used effectively to enforce the relevance condition. The judicial review cases involving access to cancer drugs, reviewed in Paper 1, Chapter 8, illustrate that the courts are more interested in how decisions are reached than in the reasons which underlie them. The limited extent to which judicial review can scrutinise the substance of decisions effectively puts the enforcement of the relevance condition beyond the reach of the courts. See Syrett K. NICE and judicial review: enforcing ‘accountability for reasonableness’ through the courts? Med Law Rev 2008;16(1):127-40. Only if a violation of Human Rights was alleged might this change. In such an event, the additional criterion of proportionality would then come into play, allowing the courts to examine the substantive content of decisions to a greater extent. See further discussion of this in Chapter 4, Section 4.4.3.

Further, Sabik and Lie challenge the idea that procedural frameworks result in any less controversy than ethical frameworks, providing three examples where priority setting decisions based on procedural frameworks have resulted in appeal, with the process being the centre of the dispute. Sabik L, Lie R. Principles versus procedures in making health care coverage decisions: addressing inevitable conflicts. Theoretical Medicine and Bioethics 2008;29(2):73-85.

Soucat A, Van Lerberghe W, Diop F. op. cit. note 55.
5.6 Conclusion

Ethical frameworks have a role to play in IFR decision making in ensuring that decisions are morally fair, and in strengthening the legitimacy of decision outcomes, hence reducing judicial challenges. To be of practical use in providing guidance to decision makers, an ethical framework needs to encapsulate the criteria for decision making, and link decision making to the broader context in which it is occurring. Methods of assessing the success of priority setting, or the quality of an ethical framework are limited, and in need of further research. Potential frameworks for supporting IFR decision making can be divided into list-based approaches, principle-based frameworks, structural frameworks and procedural ethical frameworks. Of the frameworks reviewed, Accountability for Reasonableness appeared, at least at first sight, the best suited to IFR decision making.

The second of the papers which make up the core of this thesis, ‘Accountability for Reasonableness – Why the Relevance Condition is of no Relevance’, addresses the question of whether the relevance condition, one of the four conditions of Daniels and Sabin’s Accountability for Reasonableness framework, is fit for purpose. This is necessary to ascertain whether Accountability for Reasonableness can be considered an ethical framework for resource allocation, and hence be used to meet the DoH’s recommendation that PCTs adopt an ethical framework to support IFR decision making.

Paper 2 starts by exploring the relevance condition and the constraints placed on it, before providing a comprehensive review of the theoretical limitations of the relevance condition, identified in the literature to date. Daniels acknowledges that Accountability for Reasonableness is a ‘work in progress’, and encourages others to extend it. In light of this, the final section of the paper reviews the practical problems which might arise in implementing the relevance condition within the NHS, and examines whether funding treatment for patients on the basis of their exceptional circumstances meets the relevance condition.

Ultimately, the relevance condition is found wanting, as it is unable to independently determine the reasonableness of different rationales. This leaves three options for PCTs: to reject outright the DoH’s advice to incorporate an ethical framework into IFR policy; to examine the practical application of alternative ethical frameworks; or to attempt to

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develop Accountability for Reasonableness beyond a purely procedural approach. Given the need for the use of ethical frameworks in IFR decision making which has been established in this chapter, abandoning the search for an ethical framework would seem premature. Both the practical application of an alternative framework, or the further development of the Accountability for Reasonableness framework, require further research. If the DoH is serious about improving the moral legitimacy and legal robustness of IFR decisions, it should commission and fund this research.
6.0 Empirical Approach: a Qualitative Investigation of the Assessment of Exceptionality in Individual Funding Requests

6.1 Introduction

The third and final paper which makes up the core of this thesis reports the findings of an empirical study, which complements the analysis of the concept of exceptionality already undertaken from legal and ethical perspectives. In comparison to the Legal Approach and Ethical Approach chapters, the Empirical Approach is brief. This is because the research methods used for the qualitative study are comprehensively described within Paper 3, and to avoid unnecessary duplication are not restated here. The purpose of this chapter is simply to introduce the paper ‘Individual Funding Requests in Healthcare: What Makes a Patient Exceptional?’ and explain the aim of the paper.

The empirical research was designed to explore in depth how IFR panels determine whether a patient is exceptional, in order to gain insights into if, and how, assessment of exceptionality could be improved. It was initially planned to focus this enquiry on IFR applications for cancer drugs alone. However, as discussed in Chapter 3, changes in the NHS, in particular the introduction of the Cancer Drugs Fund, have resulted in a fall in the number of IFRs for cancer drugs in many regions. The study was therefore widened to include requests for any intervention on the basis of exceptional circumstances.

Knowledge about how IFR panels determine exceptionality is needed to complement theoretical research into resource allocation, in order for a sustainable solution to priority setting to be developed. Has the omnipresent threat of legal action against PCTs impacted on processes and outcomes on the ground? Are PCTs able to envisage exceptions to policies which preclude provision of a treatment, or is it impossible to define in advance what constitutes exceptional, as the defendant in AC v Berkshire West PCT claimed?\(^1\) The empirical research aimed to provide an overview of how the concept of exceptionality is interpreted by IFR panels, what factors are considered in assessing exceptionality, and whether external factors impact on decision outcomes.

6.2 Funding for cancer drugs and other treatments in exceptional circumstances: the empirical aspect of the research

A qualitative approach was taken to the empirical research, using semi-structured interviews with IFR panel members, as it was felt that this would facilitate the

\(^1\) AC v Berkshire West Primary Care Trust [2010] EWHC 1162 (Admin) para 31.
exploratory nature of the investigation. The semi-structured approach ensured that the same broad topics were broached in every interview and the approach was flexible enough to allow probing in response to participants’ comments, whilst also allowing participants to introduce original thoughts and ideas related to exceptionality. There was openness to unanticipated issues being raised.

Whilst abundant research has been undertaken on population-based commissioning, research into the individual funding request process has been much less extensive, and predominantly quantitative in nature. To date, no published research has focussed specifically on uncovering how IFR panels interpret the concept of exceptionality and assess patients against this standard. In view of the high legal profile of the concept of exceptionality in the allocation of health resources, the time for an empirical exploration of what it means to be exceptional was overdue.

Surveys have been undertaken by both the NPC and the Rarer Cancers Foundation, regarding the number and nature of IFR requests. However, the findings of these studies were limited by differences in methods of reporting the number of IFR applications between PCTs, and overall survey response rates. The quantitative nature of the surveys also means that whilst they provide useful information about patterns of IFR applications, they reveal little about how the concept of exceptionality has been interpreted. Qualitative research on IFRs reported in the literature includes a case-based discourse analysis of decisions regarding a high cost drug at a single PCT, which concluded that individual professional judgment was likely to remain intrinsic to decision making in this context. More recently, Russell and Greenhalgh have undertaken a linguistic ethnography study examining deliberation about IFRs by decision making committees, which uncovered that discursive practices served to confer legitimacy on


3 Some PCTs operate a triage system for IFR requests, which allows applications where no clear case is made for the patient’s exceptionality to be rejected before consideration by an IFR panel. Some PCTs include these applications in their reported figures, others do not.

affordability as a guiding principle. However, very little was revealed about how PCTs interpret and apply the concept of exceptionality by either qualitative paper. The practical application of the notion of exceptionality in this complex area of decision making has remained largely unresearched.

6.3 Conclusion
During the course of the research I had the opportunity to observe IFR panel meetings at several PCTs. I was also invited to participate in a programme of regional one day IFR training events at which representatives from over half of all PCTs in England attended. Although not part of the formal data collection, these experiences were valuable in helping me to consider my empirical findings beyond the context of the five PCTs which were directly involved in the study, and have strengthened confidence in the conclusions drawn.

Without understanding the intricacies of priority setting in real life, it is hard to fully evaluate or improve upon any conjectured ethical framework for the fair and just allocation of healthcare resources. Any tool to improve resource allocation evidently needs to be more than a theoretical template; what is required is a framework with applicability in the real world. By working from the ground up and examining how the term exceptionality has been defined and applied in practice, this research is able to offer the first comprehensive insight into how PCTs interpret the concept of exceptionality in the context of IFRs.

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7.0 Outline of Submitted Papers
The focus of this thesis is the concept of exceptionality as used in individual funding requests, particularly in the context of requests for cancer drugs. The thesis has three strands of investigation: legal, ethical and empirical. The three strands, respectively investigate how the concept of exceptionality is interpreted by courts, whether the concept is relevant morally when evaluated under the relevance condition of Daniels and Sabin’s Accountability for Reasonableness framework, and finally, how the concept of exceptionality is applied in practice by PCTs.

The first paper, ‘The Concept of Exceptionality – A Legal Farce?’ analyses exceptionality from a legal perspective. It examines how the courts have interpreted the concept of exceptionality and in particular, the role of social factors in determining exceptionality. An attempt is made to construct a model against which to determine whether a patient will be considered exceptional. Two important subsidiary questions arising from the legal analysis are also addressed: firstly, whether a patient who is considered exceptional within one PCT could legitimately be considered not exceptional within another; and secondly, whether it is imperative that it must always be possible to envisage an exception to every PCT policy which states that a specific treatment will not be routinely funded. It is argued that allocating resources on the basis of exceptionality does not sit comfortably with the axiom that doctors should treat all patients with concern and respect, and that social factors should not be considered relevant unless they have direct clinical implications. Although it is possible to outline criteria against which to determine exceptionality, the manifest lack of objectivity of the criteria limit their practical application. A case is made that a patient who is deemed exceptional within one PCT should be considered exceptional within another, but that it is not reasonable to expect that an exception will be conceivable for every PCT policy. It is proposed that exceptionality should be assessed on a national, or at least supra-regional level to improve consistency of decision making. The paper concludes that exceptionality has been far too broadly and loosely defined, and that if the NHS has inadequate resources to fund all effective cancer drugs, we should have a national debate to reach a consensus on which treatments to fund, rather than hide behind the concept of exceptionality.

Paper 2, ‘Accountability for Reasonableness – Why the Relevance Condition is of no Relevance’ starts by reviewing the constraints placed on the relevance condition by the framework’s authors and then reviews the theoretical limitations of the relevance condition identified in the literature to date. Finally, the paper evaluates whether allocating resources on the basis of exceptionality meets the relevance condition. It is argued that the relevance condition may help to ensure that priority setting decisions are legitimate through due process, but does not necessarily ensure that outcomes are just. The relevance condition can only screen out obviously irrelevant reasons, which would be dismissed during any democratic deliberative process, and therefore adds little to current decision making procedures. Applying the relevance condition to the concept of exceptionality fails to determine whether or not the concept is a reasonable rationale for the allocation of healthcare resources, confirming the essentially vague nature of the relevance condition, and confirming the theoretical limitations identified with the condition. The paper concludes that, to be of real value, the relevance condition needs to do more work in determining not simply which rationales are defensible, but which are morally right. The relevance condition does not provide a method to distinguish between just and unjust reasons for the allocation of resources and is effectively redundant to the Accountability for Reasonableness framework. Deliberation is required not just for weighting reasons, as facilitated by the relevance condition, but to determine whether reasons are relevant at all.

The final paper making up this thesis, ‘Individual Funding Requests in Healthcare: What Makes a Patient Exceptional?’ reports the results of an empirical study, which endeavoured to fill the gap in knowledge about how PCTs comprehend and apply the concept of exceptionality when assessing individual funding requests. Specifically, the paper aims to provide an overview of how exceptionality is interpreted, what factors are considered in determining exceptionality and whether external factors impact on outcomes. Clinical factors were found to be of overriding importance to the determination of exceptionality. For example, having a severe form of a condition, or being unresponsive to standard treatment. Age and social factors were considered in some circumstances, but neither cost effectiveness nor absolute cost materialised as dominant considerations. This latter finding is somewhat surprising given that, in the past, the courts have suggested that where decisions to withhold treatment are based on absolute cost they are less susceptible to successful legal challenge. The media and the presence of patients at IFR meetings were identified as significant external
influences on the IFR process. The risk of legal action was reported to have resulted in positive engagement by PCTs with legal processes and principles. The paper concludes that there is an inherent difficulty in achieving consistency in the determination of exceptionality, which by its very nature requires discretional decisions. Practical challenges ensuing from the implementation of the Health and Social Care Act 2012 are identified, including the expectation of greater patient involvement with decision making, and the risk that the accumulated expertise of IFR panels may be lost in the transition of PCTs to CCGs. The DoH’s recently commissioned competency framework for local decision making is identified as a possible mechanism via which the quality of IFR decision making could be maintained, and potentially even improved, as responsibility for determining exceptionality is passed from one authority to the next.²

PART II: THE SUBMITTED ARTICLES
8.0 Paper 1: The Concept of Exceptionality – A Legal Farce?

8.1 Introduction

How should we decide which treatments are offered by the National Health Service (NHS), when we cannot afford to provide them all? Drugs that may extend the life of cancer patients have attracted much media attention. When requested by patients in the absence of a positive appraisal by NICE,\(^1\) their refusal has resulted in legal action against PCTs who, at the time of writing, are the NHS authorities to whom difficult choices about such treatments fall. Looking forward, if the proposals outlined in the recent White Papers\(^2\) and the Health and Social Care Bill\(^3\) are enshrined in law, the NHS will undergo the most radical reform instituted since its inception in 1948. PCTs may cease to exist and GP led CCGs will have to decide who receives treatments not affordable to all. However, it is important to look back and review the lessons we can learn from the past. Wherever the responsibility for commissioning healthcare services ultimately lands, the need to prioritise resources will remain.

Increasing the availability of cancer drugs is perceived as being politically popular.\(^4\) However, as the NHS operates within the constraints of a limited budget, such choices are inevitably accompanied by opportunity costs elsewhere in the system.\(^5\) The

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3 Health and Social Care HC Bill 2010-11 [132] (as introduced).

4 As an example, David Cameron, during his 2010 election campaign, unexpectedly pledged that all end of life cancer treatments would be provided without regard to cost. See Hawkes N. The political power of cancer. *BMJ* 2010;340:c2250.

5 In order to provide trastuzumab, one PCT had to cut their budget for learning disability services by £1 million/year. See *AC v Berkshire West Primary Care Trust* [2010] EWHC 1162 (Admin) 26
establishment of NICE, in 1999, was seen as an attempt to depoliticise these decisions and put an end to unequal access to treatments in different localities. NICE has undertaken technology appraisals of new drugs and treatments, to establish clinical and cost effectiveness. Generally, drugs costing below a nominal threshold of £30,000 per QALY have been considered by NICE to be cost effective, although this threshold was raised in 2009 for treatments likely to extend the life of patients with less than two years to live, by more than three months. PCTs are under a legal obligation to make available all NICE approved treatments within three months. NICE has been subject to extensive criticism, but despite its weaknesses it is an improvement on the system it replaced, when well educated and empowered patients had disproportionately greater access to many treatments, at the expense of the rest of the population. For the first time, it seemed, we had a health system which, true to its name, was providing a national health service. Every ticket in the postcode lottery was a winner. In light of this, it must have come as a surprise to Ann Marie Rogers, following her diagnosis of breast cancer, to learn that whilst Barbara Clark, living in Somerset, was able to receive trastuzumab (Herceptin) on the NHS, she, residing in nearby Wiltshire, could not. Ultimately Ann Marie Rogers sought recourse to the courts to access this new monoclonal antibody, reported to halve the risk of recurrence of breast cancer.

How did this situation arise? At the time Ann Marie Rogers requested treatment with trastuzumab, it had not been appraised by NICE. Roche, its manufacturer, had not even applied for a product licence. PCTs can legitimately refuse to fund treatments not

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11 R (Ann Marie Rogers) v Swindon NHS Primary Care Trust [2006] EWHC 171 (Admin) and R (Ann Marie Rogers) v Swindon Primary Care Trust and the Secretary of State [2006] EWCA Civ 392.
approved by NICE, save in exceptional circumstances.12 Barbara Clark’s PCT deemed her circumstances exceptional, whereas Ann Marie Rogers’ PCT did not, resulting in her seeking judicial review of the PCT’s decision. PCTs have floundered to establish a workable definition of ‘exceptional circumstances’. I will review the legal origins of the concept of ‘exceptionality’ and examine how it has been interpreted by the courts, in particular whether it is a term that should be applied solely to a patient’s clinical condition, or whether social circumstances should also be considered. I will demonstrate that based on judicial review cases to date, it is not possible to establish criteria against which to determine if a patient is exceptional.

IFRs for cancer drugs constitute the largest number of funding requests to PCTs on the basis of patients’ exceptional circumstances.13 Why have cancer drugs so often been the subject of such claims? It is in part due to their relatively low cost effectiveness, which means they are less likely to gain NICE approval, and their high absolute cost, which makes them prohibitively expensive for PCTs to fund voluntarily even for small cohorts. For many patients they also represent the ‘last chance’ of active treatment at the end of life, making access a highly emotive issue. There is anecdotal evidence that funding patients on the basis of their exceptional circumstances is resulting in different survival outcomes from cancer within different PCTs.14 From an oncologist’s perspective the concept of exceptionality appears to be a legal farce. Cancer patients should not be treated because they are exceptional, but because they are sick and have symptoms that need alleviating, for which an effective treatment is available. The concept of exceptionality has limited application clinically, morally and legally.

Acknowledging that every public authority must be careful not to fetter the exercise of its own discretion, I shall argue that exceptionality has been far too broadly and loosely defined. It is feasible that some drugs and treatments may have such low response rates, minimal benefits, and significant side effects that it would not be unreasonable to deny their provision without anticipating exceptional circumstances in which they might be funded.

12 R v North West Lancashire Health Authority, ex p A, D & G [2001] 1 WLR 977, 991. PCTs can, of course, choose to commission drugs for their local population which are not approved by NICE.
8.2 Where did the legal concept of exceptionality arise from?

It is a well established principle of administrative law that a public body is not entitled to fetter the exercise of its discretion.\(^{15}\) In the context of healthcare, this principle was made explicit in *R v North West Lancashire Health Authority, ex p A, D & G*,\(^{16}\) a case where three transsexuals were refused funding for gender reassignment treatment. Auld L J acknowledged that within limited health budgets, health authorities have to establish priorities for funding. He went on to say

> ‘The precise allocation and weighting of priorities is clearly a matter of judgment for each authority, keeping well in mind its statutory obligations to meet the reasonable requirements of all those within its area for which it is responsible. It makes sense to have a policy for the purpose - indeed it may well be irrational not to have one….It is proper for an authority to adopt a general policy for the exercise of such an administrative discretion, to allow for exceptions from it in “exceptional circumstances” and to leave those circumstances undefined’.\(^{17}\)

Auld L J emphasised that such a policy must recognise the possibility of there being exceptional circumstances, such as overriding clinical need.\(^{18}\) This was interpreted in *Rogers v Swindon PCT and the Secretary of State* as meaning that

> ‘...withholding assistance save in exceptional circumstances ...will be rational in the legal sense provided that it is possible to envisage, and the decision maker does envisage, what such exceptional circumstances might be.’\(^{19}\)

This interpretation by Clarke MR appears to raise the bar for allowing exceptions, from one where they could remain undefined, to one where it should be possible to envisage what such exceptional circumstances might be. This has resulted in a lack of clarity in the law. Exceptional cases often, by their very nature, cannot be identified in advance.\(^{20}\) Although frequently cited in subsequent cases, in practice, Clarke MR’s comments have been taken to mean that it should be possible to envisage exceptional circumstances in general rather than specific terms.\(^{21}\) The courts have made it clear that it is not sufficient for PCTs to have a policy that theoretically allows for exceptions, when in reality a

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\(^{15}\) See *R v Port of London Authority, ex p Kynoch Ltd* [1919] 1 KB 176 and *R v Secretary of State for Home Department, ex p Venables* [1998] AC 407.

\(^{16}\) *R v North West Lancashire Health Authority, ex p A, D & G* op. cit. note 12, 989 and 994.

\(^{17}\) *Ibid.*, 991.


\(^{19}\) *R (Ann Marie Rogers) v Swindon Primary Care Trust and the Secretary of State* op. cit. note 11, para 62.

\(^{20}\) This issue was highlighted by the defendant in *AC v Berkshire West Primary Care Trust* op. cit. note 5, para 31.

\(^{21}\) *R (Jean Marie Murphy) v Salford Primary Care Trust* [2008] EWHC 1908 (Admin) para 6; *R (Colin Ross) v West Sussex Primary Care Trust* [2008] EWHC 2252 (Admin) para 35 and *AC v Berkshire West Primary Care Trust* op. cit. note 5, paras 32-33.
blanket ban is being enforced. In order to accommodate this requirement of allowing for exceptions to any general policy, PCTs have established Exceptional Case Panels to consider IFRs for treatments which are not funded for the general population.

Historically there have been regional differences in the volume and outcome of individual requests for funding on the basis of exceptional circumstances, associated with a wide variation in the processes used to assess applications. There were also marked variations in the time taken to process requests. The NHS Constitution, implemented in 2010, was a missed opportunity to standardise the individual funding request process. With respect to local decision making, it did little more than clearly communicate the already well established legal right that such decisions should be made rationally after consideration of the evidence. It was a survey of PCT processes by the National Prescribing Centre which triggered guidance from the DoH, with the aim of standardising assessment of these applications. This guidance also emphasises the need to distinguish between a request for funding on the basis of exceptional

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23 In different PCTs these are known by a variety of names, including Individual Funding Request Panels, Clinical Priorities Committees, Commissioning Advisory Groups and Effective Use of Resources Groups.

24 For example, not all PCTs had written protocols for assessing funding requests, and where panels were used to consider requests, membership of the panel was not always made public. See Department of Health. Improving access to medicine for NHS patients A report for the Secretary of State for Health by Professor Mike Richards CBE. November 2008. http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_089927 (accessed 7 January 2009). I am currently undertaking an empirical study of the individual funding request decision-making process, focussing on how PCTs interpret the term ‘exceptional’ and assess claims of exceptional circumstances. I intend to publish my results in due course.

25 The Handbook to the NHS Constitution reads ‘You have the right to expect local decisions on funding of other drugs and treatments to be rationally following a proper consideration of the evidence. If the local NHS decides not to fund a drug or treatment you and your doctor feel would be right for you, they will explain that decision to you’. Department of Health. Handbook to the NHS Constitution. March 2010.http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_113614 (accessed 14 July 2011). The right of patients to receive an explanation of the outcome of decisions created a new obligation on PCTs.

26 National Prescribing Centre op. cit. note 13, Slide 28.

circumstances and multiple requests from a heterogeneous population for a new drug, the latter being more appropriately managed through the submission of a business case for a service development by the treatment provider. No specific guidance is provided on the number of patients who could plausibly be regarded as exceptional before a new policy should be formally considered. However, the NHS Confederation suggests that for highly unusual conditions, if more than one case per year is expected, a policy approach should be adopted.\(^\text{28}\)

8.3 A matter of clinical exceptions or raising expectations?

Many patients with cancer are exceptional, for a wide variety of reasons. Some are exceptional because of personal factors, such as the fortitude they demonstrate during treatment or the feats they accomplish during their illnesses.\(^\text{29}\) Others are exceptional on clinical grounds, perhaps because of the rarity of their cancer, or the age at which they presented with a particular tumour type.\(^\text{30}\) However, exceptionality is never a condition of treatment. In clinic, patients are not expected to show that their need is greater than the next patient’s, or justify their request for treatment on the basis of their domestic responsibilities, or social standing.\(^\text{31}\) Clinicians treat patients because they are ill, with the aim of returning them to full health, or improving their quality of life if this is not achievable.


\(^{29}\) Few would deny, for example, that Jane Tomlinson, CBE, whose achievements after being diagnosed with incurable cancer included completing a marathon, a full ironman race, a 4,200 mile bike ride across America and raising nearly £2 million pounds, was an exceptional patient.


The one respect in which a patient’s exceptional features might be a consideration for the treating physician is if these features are *clinical* in nature, such as being particularly fit relative to others with the same stage of cancer, or having had a response of unusual magnitude, or duration, to a previous treatment. These might lead one to offer non standard anti-cancer treatment, in the belief that they might gain more benefit from this than would normally be expected. Another small subset of patients whose exceptional features might result in them being offered non standard treatment are those who suffer intolerable side effects from conventional treatment. Additionally, patients who are ineligible for clinical trials, or who are exceptional by virtue of having a rare cancer might, in the absence of an established treatment, be offered a drug not widely available on the NHS, were there strong hypothetical reasons to believe that this treatment might be of value.

In its current form, the exceptional funding route is used to access cancer drugs which are awaiting appraisal by NICE, or have been deemed not to be cost effective, when the treating oncologist believes that the drug offers a realistic chance of benefitting the patient, usually when there are no alternative treatments available on the NHS. The trigger for requesting funding is therefore the patient’s clinical need, rather than anything about their personal or social circumstances. It is an avenue of funding which clinicians are encouraged to explore by DoH guidance, before applying to the recently established Cancer Drugs Fund\(^\text{32}\) or suggesting that the only option is private funding, through ‘top-up’ fees, or otherwise.\(^\text{33}\) It is therefore perhaps not surprising that some PCTs have been overwhelmed by exceptional funding requests, receiving up to 1,000 a year.\(^\text{34}\) Combined with a rejection rate of greater than 25%,\(^\text{35}\) the end result, on a national level, is a large number of disappointed patients. Anger is a common reaction


\(^{34}\) National Prescribing Centre *op. cit.* note 13, Slide 5. Not all of these applications are for cancer drugs, but the survey revealed that the majority of requests for funding based on exceptional circumstances are for oncological treatments.

when patients feel they are being denied treatment. Usually the responsibility for communicating a PCT’s rejection of funding is passed to the oncologist providing care. Oncologists have been reluctant to discuss unfunded drugs with patients. Clinicians are being placed in the unenviable position of raising a patient’s hopes, only to shatter them. As I will demonstrate in a later section of this paper, the legal concept of exceptionality in the context of health is so elusive that oncologists cannot use this as a basis on which to advise a patient as to whether or not it is likely to be worthwhile making an individual application for funding. A patient’s ‘exceptionality’, as far as it is applicable to clinical management at all, is very limited. Clinical factors influence the choice of treatment offered. The wide-ranging interpretation of the concept of exceptionality which has been applied by the courts bears little relevance to this.

8.4 Exceptionality – a just inequity or just inequitable?

The idea that PCT funding of cancer drugs, in some instances, hinges on whether or not a patient is exceptional does not sit comfortably with the axiom that doctors should treat all patients with equal concern and respect. GMC guidance advises doctors that the:

‘...treatment you provide or arrange must be based on the assessment you and the patient make of their needs and priorities, and on your clinical judgement about the likely effectiveness of the treatment options....You must treat your patients with respect whatever their life choices and beliefs. You must not unfairly discriminate against them by allowing your personal views to affect adversely your professional relationship with them or the treatment you provide or arrange.’

That one individual with the same cancer should be treated differently from another, as occurred with Ann Rogers and Barbara Clark, when their respective PCTs passed differing judgments on whether their circumstances amounted to being exceptional, would appear to be a distinction not embraced by this code of conduct. Both women

37 National Prescribing Centre op. cit. note 13, Slide 72.
38 Jones AL. JCCO survey on top-up payments 22 October 2008 [electronic response to Coombes, R. NHS might have to attract more private money if it is to improve standards.] BMJ 2008;336:1457.1 http://www.bmj.com/cgi/eletters/336/7659/1457#203489, (accessed 6 October 2009).
39 This includes personal views about a patient’s age, colour, culture, disability, ethnic or national origin, gender, lifestyle, marital or parental status, race, religion or beliefs, sex, sexual orientation, or social or economic status. General Medical Council. Good Medical Practice-guidance for doctors. 2009. http://www.gmc-uk.org/guidance/good_medical_practice/good_clinical_care_decisions_about_access.asp. (accessed 15 July 2010).
had breast cancer. Barbara Clark was considered exceptional by her PCT and received funding for trastuzumab, whereas Ann Rogers was not and had to seek judicial review of her PCT’s decision in order to obtain funding for identical treatment. 40 If discriminating on the basis of age, colour, culture, ethnic or national origin, gender, lifestyle, marital or parental status, race, religion, beliefs, sexual orientation or social or economic status is not permitted, are there any non-clinical ‘exceptional circumstances’ that can morally be used to distinguish between patients when choosing who should have treatment funded? It is hard to think of any factors which would not fall under the umbrella of one of the GMC’s categories. Non urgent NHS treatment can legally be withheld from patients who are violent towards NHS staff, if their behaviour is not a product of their medical condition and they are deemed competent to take responsibility for their actions. In this instance, non clinical factors are used to limit access to treatment, but this is driven by the need to ensure the safety of NHS staff, rather than the need to determine who should be prioritised for treatment when resources are limited.

In clinical practice, social circumstances are certainly a consideration in the management of medical conditions, and most clinicians aspire to providing holistic care, which inevitably encompasses social factors. In managing renal failure, for example, social considerations such as a patient’s occupation may determine the type of dialysis offered. Someone with a manual job, in an unsanitary environment, might be offered haemodialysis over peritoneal dialysis. This decision would be based on the clinical risk of infection if peritoneal dialysis were undertaken in an unclean environment. NICE guidance for the management of pregnant women explicitly considers social factors such as homelessness, domestic abuse and refugee status, but again this is because of the impact of these factors on clinical outcomes for this group. 41 However, there are also examples where social factors are considered, where there is no direct clinical relevance. Religious beliefs can influence end of life care, particularly in intensive care units. 42 Where these influence a decision to maintain active treatment, the cost

40 R (Ann Marie Rogers) v Swindon NHS Primary Care Trust op. cit. note 11; R (Ann Marie Rogers) v Swindon Primary Care Trust and the Secretary of State op. cit. note 11; Anon. Nurse wins breast cancer row op. cit. note 10.


implications can be significant. An example of where occupation influences the urgency with which treatment is provided, again not based on clinical considerations, is the DoH mandate that armed forces veterans should be scheduled for treatment faster than others of similar clinical priority. The practice is defended on the grounds that the armed forces put their lives and health at increased risk in the interests of others, though the same claim could be advanced for members of the fire service and other public sector employees. In the past, at least, social criteria were openly used to limit access to IVF, with provision on the NHS in some areas only being available to those who were married, or in a heterosexual relationship. Here, it appears, that resources were being allocated according to what kinds of families it was deemed desirable for public money to help create.

Beauchamp and Childress argue that social utility should be a criterion in priority setting, but only in emergency situations, such as pandemic flu. In this context, they advance that giving priority to health professionals and other essential workers is justified on the basis that it will increase the survival of the population as a whole. They advocate limiting judgments of social value to the specific attributes which will contribute to the protection of the community, rather than assessing general social worth. Rescher goes further, claiming that where a social investment allows scarce medical technologies to be made available, the interests of wider society should help determine who should benefit. For this reason he advocates assessing both a patient’s past and likely future contribution to society. Using social utility as a consideration in the allocation of health

43 For an example in the Canadian context, see Golubchuk v The Salvation Army Grace General Hospital 2008 MBQB 49, the case of an 85-year-old Orthodox Jew whose family’s religious beliefs led them to take legal action to prevent his life support machine being turned off. Three physicians, who maintained the man had no chance of meaningful recovery, resigned over the case. The man remained on life support for over eight months and eventually died despite this.


45 Ms Harriot was refused IVF on the grounds that she had a criminal record for prostitution offences, and had been rejected as a prospective adoptive or foster parent by social services. She challenged the decision, which was deemed lawful at judicial review. R v Ethical Committee of St Mary’s Hospital (Manchester) ex p Harriot [1988] 1 FLR 512. See also Plomer A, Smith I, Martin-Clement N. Rationing policies on access to in vitro fertilisation in the National Health Service, UK. Reproductive Health Matters 1999;7(14):60-70.

46 The ethics of this are beyond the scope of this paper. A detailed discussion can be found in Peterson MM. Assisted reproductive technologies and equity of access issues. Journal of Medical Ethics 2005;31(5):280-85.


resources creates challenges of its own. How do you rank social utility? Whose idea of social value should be adopted? Would those who could have conceivably contributed to their illness, through lifestyle choices such as smoking and alcohol consumption, be denied treatment, or given lower priority? Discrimination could easily arise. If carers were favoured over non-carers, it is likely that more women would receive preferential treatment. If treatment necessary to enable someone to function at work was given priority, the employed would be favoured over the unemployed.

Prioritising treatment on the basis of a person’s social function amounts to regarding them as a means to an end, rather than an end in themselves, contravening Kant’s widely accepted categorical imperative. Any such policy risks increasing inequity of access to healthcare and holds the potential to give rise to claims of discrimination based on Human Rights. Newdick argues that unless a person’s circumstances are ‘wholly exceptional’ the practice should be avoided. On grounds of justice, it is time to move away from the idea that some patients are exceptional, whilst others are not, on the basis of their social circumstances. Irrespective of which theory of justice one subscribes to, fundamental to all is the principle of formal justice, attributed to Aristotle, that ‘Equals should be treated equally, and unequals treated unequally.’ This principle has been widely interpreted as meaning that with regard to the respects which are considered relevant to the issue in question, persons equal in those respects should be treated equally. It follows that despite the many differences between patients, no person should be treated unequally, unless the difference between them and others is relevant to the treatment in question. Social differences between patients are not morally relevant to the allocation of expensive cancer drugs and should not, therefore, be used in the determination of exceptionality.

Furthermore, the current policy of funding patients at a local level, on the basis of their exceptional circumstances, results in the unjust consequence that similar patients may be treated differently depending on the PCT area within which they reside. Oncologists

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49 For a full discussion of the use of personal responsibility in the allocation of health resources see Buyx AM. Personal responsibility for health as a rationing criterion: why we don’t like it and why maybe we should. Journal of Medical Ethics 2008;34:871-74. Draper and Sorrell also argue that patients have an ethical responsibility to promote their own health in Draper H, Sorell T. Patients’ responsibilities in medical ethics. Bioethics 2002;16(4):335-52.

50 Kant I. Foundations in the metaphysics of morals (translator Beck L) Indianapolis: Bobbs Merrill Company, 1959 at 47 [429].


frequently review patients from several different PCTs in a single clinic. In deciding on the best treatment for their patients, the patient’s postcode and the relevant PCT’s policy on funding cancer drugs in exceptional circumstances have become considerations, for drugs which have not been approved by NICE. The reason for giving PCTs greater control of the health budget was to enable the purchasing of healthcare to be more responsive to local needs. The value of localism is in achieving more equal outcomes across heterogeneous regions. This is a valid goal where a community has a specific health problem relating to a particular population, or a local environment, but it makes a mockery of the concept of a ‘national’ health service when the management of some common cancers is determined on a local level. Postcode lotteries exist in other public services too, but given the extent to which health status impacts on life opportunities, inequality in healthcare provision is especially unjust. The current system also results in substantial inefficiencies if separate PCTs around the country have to review the evidence and cost effectiveness of new cancer drugs on an ad hoc basis, as and when individual patients request funding. Given the social insurance nature of the NHS, patients have a legitimate expectation that even if the NHS cannot provide them with every available treatment, they will at least be treated in the same way as others using the service with the same need.

8.5 The legal concept of exceptionality

8.5.1 What does it mean to be exceptional?
The discretionary powers PCTs have with respect to determining exceptionality allow them significant flexibility and the ability to be responsive to the needs of individual patients. However, given how fundamental this concept of exceptional circumstances is in assessing IFRs, to leave these circumstances undefined presents a considerable challenge for PCT policy makers and results in their decisions being vulnerable to legal...
dispute.\textsuperscript{56} Furthermore clinicians and patients are left uncertain as to patients’ eligibility for this funding. In an attempt at clarity, and perhaps also to try and establish consistency in their decision making, some PCTs have formulated their own definitions of exceptionality. West Sussex PCT, for example, had advanced that exception means ‘a person or thing or case to which the general rule is not applicable’.\textsuperscript{57} Barking and Dagenham PCT had suggested that exceptional was ‘not just “not the norm”’.\textsuperscript{58} Both of these definitions were scrutinised during judicial review. As a consequence of the lack of an agreed legal definition of what constitutes exceptional, the interpretation of this term is often pivotal when decisions regarding funding in exceptional circumstances reach the courts. However, there are strict limits on the extent to which the courts can intervene in such decisions.\textsuperscript{59} The process of judicial review limits the courts to considering whether a PCT is guilty of procedural impropriety, has acted irrationally,\textsuperscript{60} or

\textsuperscript{56} Unfortunately space constraints prohibit a full examination of what the right and proper role of the courts in the context of healthcare priority setting should be. Daniels and Sabin have argued against the involvement of the judiciary in this setting, where the focus is on the individual patient, with little consideration given to the institutional context and interests of the wider community. They highlight the lack of technical expertise of legally trained judges, who may lack knowledge of health economics and clinical medicine. See Daniels N, Sabin J. Setting Limits Fairly - Learning to Share Resources for Health. 2nd edn. Oxford: Oxford University Press, 2008 p 59. This is in keeping with Lord Bingham’s sentiment that the allocation of resources in healthcare was an issue ‘not fitted’ to the courts in \textit{R v Cambridge Health Authority, ex parte B} [1995] 1 WLR 898 at para 907. Contrary to this view, Stewart has advanced that administrative law has the potential to improve the process of decision making in resource allocation, increasing transparency and the public’s awareness of why such decisions are needed. See Stewart C. Tragic choices and the role of administrative law. \textit{BMJ} 2000;\textbf{321}(7253):105-07. Similarly, Sheldrick argues that judicial review can do more than challenge decisions with which individuals disagree, ‘leveraging access’ to policy makers and ‘opening up the system to a broader range of interests and voices’. See Sheldrick BM. Judicial Review and the allocation of health care resources in Canada and the United Kingdom. \textit{Journal of Comparative Policy Analysis} 2003;\textbf{5}(2):149-66. James and Longley also believe that the courts have a role in explaining and justifying policy choices. James R, Longley D. Judicial review and tragic choices: ex parte B. \textit{Public Law} 1995;367-73 Syrett reflects this sentiment, proposing that the courts have a role to play in enabling priority setting in healthcare to become a more deliberative process. Syrett K. Priority setting and public law: potential realised or unfulfilled? \textit{Medical Law International} 2006;7:265-79. In his book, Syrett K. \textit{Law, legitimacy and the rationing of health care}. Cambridge: Cambridge University Press, 2007, Syrett provides a thorough exploration of the facilitative capabilities of public law in this context.\textsuperscript{57} \textit{R (Colin Ross) v West Sussex Primary Care Trust} op. cit. note 21, para 28.\textsuperscript{58} \textit{R (Victoria June Otley) v Barking and Dagenham NHS Primary Care Trust} [2007] EWHC 1927 (Admin) para 9.\textsuperscript{59} \textit{Ibid.} paras 23-25.\textsuperscript{60} An irrational decision is one which is considered so demonstrably unreasonable, that no reasonable body could have reached it. This concept is commonly referred to as ‘Wednesbury reasonableness’ after the case from which it arose, \textit{Associated Provincial Picture Houses Ltd v Wednesbury Corp} [1948] 1 KB 223. Where breaches of the Human Rights Act 1998 are involved, the standard of proportionality, whereby any restriction on rights must be proportionate to the legitimate aim pursued, can instead be applied. See \textit{R v Secretary of State for the Home Department, ex p Daly} [2001] 2 AC 532.
beyond its powers. The courts cannot substitute their judgment for that of the PCT, but are limited to quashing the decision or remitting it back for further consideration.

8.5.2 Do previous judicial reviews serve to elucidate the concept of exceptionality?

An ordinary reading?
Given that the concept of exceptionality is such a source of contention, one might hope that when decisions relating to the funding of drugs in such circumstances are subject to judicial review some enlightenment as to how the term should be applied might be provided. Grenfell J, in *Ross v West Sussex PCT*, a case in which a man with multiple myeloma sought funding for lenalidomide, has been most explicit in this regard. Here, he advised that ‘an ordinary reading’ of the term exceptional should be upheld.61 Yet what constitutes an ‘ordinary’ reading? Did Grenfell J mean for PCTs to open their Oxford dictionaries and apply the definition of exceptional as ‘unusual, not typical’ found within?62 If so, in what regard? With respect to clinical features, psychological status, family circumstances, social or economic status? Many patients are unusual in one respect or another, so in itself, this definition is not discriminating enough. Rather than giving rise to a blanket ban, applying this definition could easily result in universal approval of IFRs, with all patients being considered exceptional and PCT coffers being quickly drained. PCTs would be as well to do without an exceptional funding policy and concede immediately to all patient requests for funding.

Consideration of social factors in determining exceptionality
Further examination of Grenfell J’s comments reveals that making decisions based purely on social circumstances should be avoided where possible.63 Remarks to this effect had also been passed in *Otley v Barking and Dagenham PCT*,64 the case of a 57-year-old woman with metastatic colon cancer, who having tolerated five cycles of privately funded bevacizumab, sought funding for further treatment from her PCT. This must be married with Clarke MR’s assertion in *Rogers v Swindon PCT and the Secretary of State* that a PCT facing financial limitations could, reasonably, choose to fund cancer treatment for a woman caring for a disabled child, whilst not funding it for another with

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61 *R (Colin Ross) v West Sussex Primary Care Trust* op. cit. note 21, para 82.
63 *R (Colin Ross) v West Sussex Primary Care Trust* op. cit. note 21, para 93.
64 *R (Victoria June Otley) v Barking and Dagenham NHS Primary Care Trust* op. cit. note 58, para 9.
different personal circumstances.\textsuperscript{65} This comment strongly suggests that in some instances social circumstances can be a determining factor of exceptionality. However, Clarke MR also makes clear his view in this case that where limited resources are not a consideration, the PCT should concern itself only with the clinical needs of the patient, and where these needs are equal, discrimination between patients on the basis of personal characteristics is not warranted.\textsuperscript{66}

In \textit{Murphy v Salford PCT}, one of the non-clinical factors contributing to her exceptionality submitted by Jean Murphy, who sought funding for sunitinib to treat her renal cancer, was that she was the main carer for her husband.\textsuperscript{67} In keeping with the example cited by Clarke MR, this was not dismissed by the judge as immaterial, but as a factor which should be considered in combination with all the other factors advanced.\textsuperscript{68} Clarke MR suggests that a carer of a disabled child could be deemed exceptional, but provides no clue as to where the line should be drawn in considering social factors in the determination of exceptionality, or how different social factors should be weighed against each other.

It is the very recent case of \textit{Condliff v North Staffs PCT},\textsuperscript{69} a case concerning bariatric surgery, which has finally brought clarity to this issue. Condliff was not obese enough to meet his PCT’s criteria for the funding of a gastric bypass. His doctor therefore applied for funding on the basis that he was exceptional. Various reasons to support this were advanced, including that he was housebound and could no longer attend church, or play the guitar.\textsuperscript{70} When his application was declined, Condliff applied for judicial review. One of the grounds for judicial review was that North Staffs PCT had an established policy of excluding social factors from the assessment of exceptionality.\textsuperscript{71} Condliff claimed that this contravened his Human Rights under Article 8 of the European Convention on Human Rights. Judge Waksman deemed that social factors and Article 8 private life factors are not synonymous, highlighting that whilst some private life factors may have clinical relevance, in which case they should be considered, not all social factors equate

\textsuperscript{65} \textit{R (Ann Marie Rogers) v Swindon Primary Care Trust and the Secretary of State} \textit{op. cit. note 11, para 77.}
\textsuperscript{66} \textit{Ibid., para 79.}
\textsuperscript{67} \textit{R (Jean Marie Murphy) v Salford Primary Care Trust} \textit{op. cit. note 21, para 17.}
\textsuperscript{68} \textit{Ibid., para 36.}
\textsuperscript{69} \textit{R (Alexander Condliff) v North Staffordshire Primary Care Trust} \textit{[2010] EWHC (Admin).}
\textsuperscript{70} \textit{Ibid., para 3.}
\textsuperscript{71} \textit{Ibid., para 14.}
to private life matters. However, he accepted that because the PCT’s policy of excluding social factors was capable of prohibiting considerations which might fall within the wide definition of private life under Article 8, it was imperative that he did review the lawfulness of the policy.

Judge Waksman subsequently dismissed Condliff’s claim. He concluded that it would be difficult for PCTs to investigate the credibility of patients’ social exceptionality claims, let alone objectively assess them, and that taking into account social factors would be unfair to others in the cohort against which the individual claiming exceptionality was compared, whose social circumstances were unknown. In addition, he highlighted that unfair discrimination could arise if social factors were considered and reasoned that it was consistent for PCTs to follow the same broad approach as taken by the NHS in not considering social factors in treatment decisions, when they considered claims for funding on the basis of exceptionality. However, it is noteworthy that during his judgment, Judge Waksman acknowledged that some social factors might have direct clinical implications, and he distinguished these from ‘non-clinical’ social factors.

Condliff subsequently took his case to the Court of Appeal. Again, it was concluded that the PCT’s policy of excluding social factors did not bring Article 8 into play, and furthermore, it was deemed that even if it were applicable, the PCT’s policy was within the margin of appreciation open to it, because it had reached a fair balance between meeting the needs of individual seeking treatment and the medical needs of the wider community. The judge commented that Article 8 would not require the PCT to undertake a further balancing exercise for every individual funding request application.

**Consideration of social factors awaits a European judgment**

Condliff has now lodged an application at the ECtHR, challenging North Staffordshire PCT’s refusal to approve the operation. Like the UK courts, the ECtHR has consistently held that Article 8 has a limited role in decisions allocating health resources. The cases

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72 Ibid., para 26.
73 Ibid., para 30.
74 Ibid., para 65.
75 Ibid.
76 Ibid., para 23. No examples were provided, but factors might include homelessness, domestic abuse and refugee status. These factors are recognised by NICE as impacting on the clinical outcomes of pregnant women, see note 41.
77 R (Alexander Condliff) v. North Staffordshire Primary Care Trust and the Secretary of State [2011] EWCA Civ 910.
78 Ibid., para 52.
79 Ibid., paras 31 and 54.
cited in Condliff v North Staffs PCT illustrate this. In Sentges v Netherlands,\textsuperscript{80} which concerned a person with muscular dystrophy who sought a robotic arm, Article 8 was interpreted to protect the individual, creating negative obligations on public bodies and only exceptionally, positive obligations. In the latter instance, it was advised that a fair balance must be struck between individual and community interests, with a wide margin of appreciation in cases involving the allocation of resources. It was acknowledged that national authorities are in a better position to undertake this balancing act than the ECtHR. In Pentiacova v Moldova,\textsuperscript{81} where it was claimed that the state failed to provide adequate resources for dialysis it was acknowledged that the boundaries between a state’s positive and negative obligations do not lend themselves to precise definition. The need for a fair balance between competing individual and group interests, and the margin of appreciation enjoyed by the state were re-iterated. The ECtHR has sent a strong message that in the context of allocating healthcare resources, complying with Article 8 requires the balancing of conflicting interests, best undertaken by the State, and involves a margin of appreciation.

Other relevant cases include Tysiac v Poland\textsuperscript{82} and X and Y v Netherlands.\textsuperscript{83} Tysiac v Poland concerned limited access to abortion, where the rights of eligible women were more apparent than real.\textsuperscript{84} A positive obligation on States was found, to ensure that rights provided for, and within the remit of Article 8, could be properly adjudicated upon. X and Y v Netherlands did not concern access to medical care, but is relevant, because it identified a positive obligation on states to provide a framework for the enforcement of Article 8 rights.\textsuperscript{85} These two cases were considered by the courts in Condliff v North Staffs PCT. In the first instance, the judge felt that it was nonsensical to consider a framework to either adjudicate or enforce Article 8 rights in this context, given that Article 8 rights are not generally engaged in resource allocation decisions in healthcare, and IFRs represent part of this process.\textsuperscript{86} In the Court of Appeal, Toulson L J said

\textquote{In my judgment the Strasbourg jurisprudence not only does not support, but runs counter to, the proposition that it was unlawful for the PCT to adopt a policy...}

\textsuperscript{80} Sentges v Netherlands, no 27677/02, 8 July 2003.
\textsuperscript{81} Pentiacova v Moldova, no 14462/03, 4 January 2005.
\textsuperscript{82} Tysiac v Poland (2007) 22 BHRC 155.
\textsuperscript{83} X and Y v Netherlands (1986) 8 EHHR 235.
\textsuperscript{84} Tysiac v Poland op. cit. note 82.
\textsuperscript{85} X and Y v Netherlands op. cit. note 83.
\textsuperscript{86} R (Alexander Condliff) v North Staffordshire Primary Care Trust op. cit. note 69, para 62.
that IFRs should be considered and determined exclusively by reference to clinical factors.\footnote{R (Alexander Condliff) v North Staffordshire Primary Care Trust and the Secretary of State op. cit. note 77, para 51.}

Condliff’s hopes of success in the ECtHR look slim. However, a definitive answer from the ECtHR on the role of social factors in determining exceptionality maybe a long time coming. Before the judicial review of his case by the Appeal Court had been concluded, Mr Condliff re-submitted his IFR application with additional information, and his PCT have agreed that the new clinical information provided means he now meets the criteria for exceptionally. As a result, his case is unlikely to be expedited for consideration by the ECtHR. In the meanwhile, the English judiciary is clear; in the absence of direct clinical implications social factors do not have to be considered in the assessment of exceptional circumstances.

Consideration of clinical factors in determining exceptionality

Consideration of clinical factors emerges from judicial reviews to date as less controversial, although there is little guidance as to how these should be prioritised. Reference is made to clinical need of an ‘overriding nature’,\footnote{R v North West Lancashire Health Authority, ex p A, D & G op. cit. note 12, 990-991 and R (Ann Marie Rogers) v Swindon Primary Care Trust and the Secretary of State op. cit. note 11, para 62.} but what constitutes an overriding clinical need? Auld L J, in \textit{NW Lancashire v ex p A, D & G} elaborates on this, suggesting that authorities might give priority to life threatening and other ‘grave’ diseases.\footnote{R v North West Lancashire Health Authority, ex p A, D & G op. cit. note 12, 991.} He provides the examples of cancer, heart disease and kidney failure as illnesses that one might expect to receive prioritisation over the treatment of transexualism.\footnote{Ibid., 990.} That this intervention may reasonably be considered as low priority was re-iterated in the recent case of a male to female transsexual seeking breast augmentation on grounds of her exceptional circumstances, which it was advanced were physical in nature, due to poor breast growth in response to hormone treatment. Her claim for judicial review was dismissed, despite an appeal.\footnote{AC v Berkshire West Primary Care Trust [2011] EWHC Civ 24.} However, there remains a dearth of guidance from the courts on how to prioritise between other illnesses, such as the examples of cancer, heart disease and kidney failure provided by Auld L J.

Despite Auld L J’s suggestion in \textit{NW Lancashire v ex p A, D & G} that life threatening illnesses should be ordered a high priority for resource allocation, there has been no
consensus over prognosis in subsequent judicial reviews. In *Rogers v Swindon PCT* 92 it was acknowledged that the PCT’s Exceptional Circumstances Urgent Review panel had considered whether prognosis might be a factor in determining exceptionality and concluded that it could not. This was not disputed in the course of the appeal.93 Duration of survival was also discussed in *Gordon v Bromley PCT*. Linda Gordon was a non-smoker, who developed lung cancer. She initially raised private funds to finance the drug erlotinib before applying, unsuccessfully, to her local PCT for continued funding. Although duration of survival was not considered to be applicable to the claimant, Ouseley J acknowledged that there may be instances where the need for short term survival constitutes exceptional circumstances. The example, advanced by counsel for the defence, was when someone had to make arrangements for the care of children.94 The issue of prognosis also arose in *Otley v Barking and Dagenham PCT*. Mitting J highlighted the possibility that treatment with bevacizumab, the drug at the centre of the judicial review, might shrink Victoria Otley’s liver metastases sufficiently to enable a potentially curative resection.95 He did not explicitly suggest that this factor should be determinative of exceptionality, but his repeated reference to the PCT’s failure to evaluate the possibility that the treatment might have an impact on long term survival suggests he thought that prognosis was relevant to the assessment of exceptionality.96

**Exceptional in comparison to whom?**

A more detailed analysis of judicial review of PCT decision making in exceptional circumstances elicits several further principles with respect to determining exceptionality. One of the earliest to emerge was that the index case should be compared against the cohort of people eligible for treatment when assessing exceptionality.97 This appeared to provide a clear benchmark against which comparisons of ‘unusual’ features could be determined, until the subsequent judgment in *Ross v West Sussex PCT*. The latter judicial review suggested that the index case cannot be deemed unexceptional simply because he is representative of a group of patients.98 The standard of uniqueness Grenfell J perceived West Sussex PCT to have set was considered

92 R (Ann Marie Rogers) v Swindon NHS Primary Care Trust *op. cit.* note 11).
94 R (Linda Gordon) v Bromley NHS Primary Care Trust [2006] EWHC 2462 (Admin) para 41.
95 R (Victoria June Otley) v Barking and Dagenham NHS Primary Care Trust *op. cit.* note 58, paras 11-12.
97 R (Ann Marie Rogers) v Swindon Primary Care Trust and the Secretary of State (n 11) para 67.
98 R (Colin Ross) v West Sussex Primary Care Trust (n 21) para 78.
unreasonable. Combining these two outcomes leads one to conclude that whilst the comparator is the cohort eligible for treatment, the index case does not have to be uniquely different to other members of that class to be exceptional. As a clinician, this leaves one perplexed. Exactly how different from his peers does a patient need to be for it to be worthwhile pursuing funding on the basis of exceptionality?

**Does an increased likelihood of benefit from treatment make one exceptional?**

Demonstrating features which suggest the index case is more likely to benefit from treatment than others does not invariably make the index case exceptional in the eyes of the judiciary. This is a relevant clinical consideration when prescribing some cancer drugs, as several of the new monoclonal antibodies have been shown to be more effective in specific subgroups. Erlotinib, when used for non-small cell lung cancer, for example, has been shown in clinical trials to be more effective in those of Asian origin, lifelong non-smokers and those with adenocarcinoma on histological examination. Linda Gordon possessed two out of three of these characteristics, associated with a statistically significant increase in the chance of a response, but Ouseley J was clear that possessing features which increased the likelihood of benefit did not inevitably make her exceptional. However, in *Otley v Barking and Dagenham PCT*, a case where the PCT were deemed not to have properly applied their own exceptionality criteria, the court gave significant weight to the fact that Victoria Otley was young and fit compared to other patients in her cohort, had suffered negative reactions to alternative treatment and had appeared to benefit from the new drug without common side effects. In the latter case, the increased likelihood of benefitting from the drug in question was considered a relevant factor. The inconsistency in the way this aspect was considered in these two cases is particularly incoherent from a medical perspective, as gaining more benefit from a treatment than might normally be expected is one of the few clinical justifications for treating a patient as an exceptional case.

**Considering exceptionality in the round**

One of the few very clear principles to emerge from judicial review of decision making by PCTs in exceptional circumstances is that all features that might contribute to the

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99 Ibid., para 79.
100 *R (Linda Gordon) v Bromley NHS Primary Care Trust* op. cit. note 94, para 39.
102 *R (Linda Gordon) v Bromley NHS Primary Care Trust* op. cit. note 94, para 39.
103 *R (Victoria June Otley) v Barking and Dagenham NHS Primary Care Trust* op. cit. note 58, paras 20 and 26.
determination of exceptionality should be considered in their totality, rather than individually.\(^\text{104}\) In \textit{Murphy v Salford PCT}, Jean Murphy advanced seven reasons for her exceptionality, of both a clinical and social nature. These included that she had metastatic renal cancer, that she had a history of breast cancer, which made her ineligible for entry into a clinical trial through which she may have been able to obtain the treatment she sought, and a history of mental health problems which were exacerbated by the treatment initially used to treat her renal cancer. In addition, she suffered from other side effects which prevented administration of the full dose and was the main carer for her husband who suffered with multiple health problems.\(^\text{105}\) The judicial review pivoted on the fact that the PCT had considered each of the factors individually and had found none of them on their own to be of enough significance for Ms Murphy’s case to be classed as exceptional, but had not reviewed all the factors ‘in the round’.\(^\text{106}\) Burnett J was not satisfied that had all the issues been considered together, the decision would inevitably have been the same and he therefore ordered that the decision be retaken.\(^\text{107}\) When the PCT re-evaluated Jean Murphy’s case in light of the judicial review, their decision that she was unexceptional remained unchanged.\(^\text{108}\) There was no further legal challenge.

### 8.5.3 Is it possible to establish a model of exceptionality to help to advise patients if they are likely to be considered exceptional?

The criteria for determining exceptionality, to emerge from judicial review cases to date, can be summarised as follows:

1. An ordinary reading of the term ‘exceptional’ should be applied.\(^\text{109}\)

2. Features of exceptionality should be reviewed ‘in the round’, rather than individually.\(^\text{110}\)

3. The index case should be compared against the cohort of people eligible for treatment,\(^\text{111}\) but he cannot be deemed unexceptional because he is representative of a group of patients. He does not have to meet a standard of uniqueness.\(^\text{112}\)

\(^\text{104}\) \textit{R (Jean Marie Murphy) v Salford Primary Care Trust} op. cit. note 21, para 31.
\(^\text{105}\) Ibid., para 33.
\(^\text{106}\) Ibid.
\(^\text{107}\) \textit{R (Jean Marie Murphy) v Salford Primary Care Trust} (n 21) para 36.
\(^\text{109}\) \textit{R (Colin Ross) v West Sussex Primary Care Trust} op. cit. note 21, para 82.
\(^\text{110}\) \textit{R (Jean Marie Murphy) v Salford Primary Care Trust} op. cit. note 21, para 33.
In the absence of direct clinical implications social factors do not have to be considered in the assessment of exceptional circumstances.  

Demonstrating an overriding clinical need for treatment presents a strong case for being considered exceptional.  

Demonstrating features which suggest the index case is more likely to benefit from treatment than others can, but does not necessarily, make the index case exceptional.  

The patient’s prognosis need not be a consideration, but survival for a short period of time can make one exceptional, and the example provided is where care arrangements need to be made for a young child.

How useful are these emerging principles to PCTs, either in formulating policy for decision making in exceptional circumstances, or for determining whether an individual should be considered exceptional? If we take the five cancer patients who sought judicial review of the funding decisions made by their respective PCTs, Ann Rogers, Linda Gordon, Victoria Otley, Jean Murphy and Colin Ross, and apply the criteria outlined above to them, using the information available to us in the court reports about their circumstances, the manifest lack of objectivity in the concepts that emerge, aside from the suggestion that social circumstances can be disregarded, means that each individual could be determined to be both exceptional and unexceptional, depending on how the criteria are interpreted. It is no wonder that PCTs find themselves in a conundrum when attempting to establish the existence, or otherwise, of exceptional circumstances and reach decisions that will withstand the scrutiny of the courts. All five of the cancer patients sought judicial review.

111 R (Victoria June Otley) v Barking and Dagenham NHS Primary Care Trust op. cit. note 58, para 78.
112 R (Colin Ross) v West Sussex Primary Care Trust op. cit. note 21, para 79.
113 R (Alexander Condliff) v North Staffordshire Primary Care Trust and the Secretary of State op. cit. note 77.
114 R v North West Lancashire Health Authority, ex p A, D & G op. cit. note 12, para 990 and R (Ann Marie Rogers) v Swindon Primary Care Trust and the Secretary of State op. cit. note 11, para 62.
115 R (Linda Gordon) v Bromley NHS Primary Care Trust op. cit. note 94, para 39; R (Victoria June Otley) v Barking and Dagenham NHS Primary Care Trust op. cit. note 58, paras 20 and 26.
116 R (Ann Marie Rogers) v Swindon Primary Care Trust and the Secretary of State op. cit. note 11, para 46.
117 R (Linda Gordon) v Bromley NHS Primary Care Trust op. cit. note 94, para 41.
118 Although operating against a background of different cultural values, Health Maintenance Organisations (HMOs) in Israel find themselves in a parallel situation. In Israel, the state covers the cost of a minimum package of healthcare, referred to as the basket of services. Patients wishing to access treatments not included in the basket can claim that their exceptional circumstances warrant the provision of additional services. If these claims are rejected by the HMOs, patients may seek judicial review. Similar challenges in defining exceptionality as...
patients who resorted to judicial review were successful in getting their PCT’s decisions quashed.\textsuperscript{119} On a national level, around half of patients who appeal their PCT’s decision on exceptional funding are successful in reversing a negative outcome.\textsuperscript{120} It is possible PCTs concede to avoid costly court proceedings, which they are unlikely to win.\textsuperscript{121} The actual processes of applying for exceptional funding, appealing decisions and seeking judicial review have become mechanisms of limiting access to drugs in themselves, with only the most empowered patients being able to pursue these avenues. Patients are often dependent on the Internet to obtain information about new drugs\textsuperscript{122} and many are not aware of the existence of the judicial review process, or the availability of pro bono legal assistance for those not eligible for legal aid.

\textit{An attempt at uniformity}

The NHS Confederation suggests the following definition of exceptionality to aid PCTs in understanding the meaning of exceptionality within the IFR process:

\begin{quote}
The patient is significantly different to the general population of patients with the condition in question and the patient is likely to gain significantly more benefit from the intervention than might normally be expected for patients with that condition.\textsuperscript{123}
\end{quote}

described in the English context have been encountered. Attempts at creating criteria against which to consider exceptionality have been made and assessment is limited to objective medical criteria. However, disagreement between judges still exists and there is regional variation in the outcomes of similar cases. Gilbar and Bar-Mor argue that the use of the concept of exceptionality is appropriate despite its difficulties, but that more just outcomes could be achieved by including all life prolonging treatments in the basket of care, taking into consideration social and personal circumstances in the assessment of exceptionality, and limiting the discretion of HMOs. See Gilbar R, Bar-Mor H. Justice, equality and solidarity: the limits of the right to health care in Israel. \textit{Medical Law Review} 2008;16(2):225-60.

\textsuperscript{119} Subsequently, all received approval for funding of the requested drug by their PCT. Jean Murphy initially received two months funding for sunitinib from a private benefactor. She then reapplied to Salford PCT for funding, on the basis that she had responded unusually well to the drug. On this occasion her IFR was approved. Anon. Cancer patient wins drug battle. \textit{BBC News}. 22 October 2008. http://news.bbc.co.uk/1/hi/england/manchester/7685071.stm (accessed 2 January 2013).


\textsuperscript{121} This is illustrated by \textit{R (Ann Marie Rogers) v Swindon Primary Care Trust and the Secretary of State op. cit.} note 11, para 4 and \textit{R (Victoria June Otley) v Barking and Dagenham NHS Primary Care Trust op. cit.} note 58, para 2. Both Rogers and Otley gained their knowledge about the new treatments they sought from the Internet.

The first part of the definition is in keeping with Rogers v Swindon PCT\textsuperscript{124} and Ross v West Sussex PCT\textsuperscript{125} in that the patient needs to be different from the cohort of patients with the condition, but not uniquely so. However, its usefulness is limited by the absence of guidance as to how the patient should be ‘significantly different’. The latter half of the definition is consistent with Otley v Barking and Dagenham PCT\textsuperscript{126} which suggested that increased likelihood of benefitting from a drug was a relevant factor. This case was subsequent to Gordon v Bromley PCT when Ouseley J passed comment that possessing features which increased the likelihood of benefit did not inevitably make her exceptional\textsuperscript{127}. Whether this definition can withstand legal scrutiny will not become apparent until a PCT which has adopted it is subject to judicial review.\textsuperscript{128}

8.6 Can there be more than one lawful answer to a policy question?

As judicial review is essentially an assessment of procedural, rather than substantive correctness, \textit{prima facie} it appears that there could be more than one lawful answer to a policy question. This suggestion was advanced by Bean J in Rogers v Swindon PCT\textsuperscript{129}. He was making reference to the fact that some PCTs had chosen to fund trastuzumab for the entire eligible group, whilst others had not. Although his ultimate judgment in this case was subsequently overturned by Clarke MR\textsuperscript{130}, Bean J raises an interesting possibility. If there can be more than one lawful answer to a policy question, how would this apply to the funding of cancer drugs in exceptional circumstances? It would follow that a patient could legitimately be considered exceptional within one PCT, but not within another, as effectively happens at the moment with the so called ‘postcode lottery’. Why should the same person potentially be treated differently in two PCTs?

One possibility is that X might appear exceptional in PCT A when compared to the cohort of patients with the same disease and living in that region, but not when compared to the cohort of patients in PCT B. Thus, that X could be treated differently is based on the

\begin{footnotesize}
\textsuperscript{124} R (Ann Marie Rogers) v Swindon NHS Primary Care Trust \textit{op. cit.} note 11, para 67.
\textsuperscript{125} R (Colin Ross) v West Sussex Primary Care Trust \textit{op. cit.} note 21, para 79.
\textsuperscript{126} R (Victoria June Otley) v Barking and Dagenham NHS Primary Care Trust \textit{op. cit.} note 58, paras 20 and 26.
\textsuperscript{127} R (Linda Gordon) v Bromley NHS Primary Care Trust \textit{op. cit.} note 94, para 39.
\textsuperscript{128} It is noteworthy that in R (Alexander Condliff) v North Staffordshire Primary Care Trust and the Secretary of State \textit{op. cit.} note 77, paras 19-25, the judge quoted extensively from the NHS Confederation document containing this definition. Although reference was not made to the definition itself, the document was clearly regarded as an authoritative source.
\textsuperscript{129} R (Ann Marie Rogers) v Swindon NHS Primary Care Trust \textit{op. cit.} note 11, para 68.
\textsuperscript{130} R (Ann Marie Rogers) v Swindon Primary Care Trust and the Secretary of State \textit{op. cit.} note 11.
\end{footnotesize}
evidence that there are significant differences between two groups with the same disease but who live in different PCT regions. The existence of such factors is not implausible, and may relate, for example, to the genetics of the local population. These factors would seem most credible when the number of patients in each cohort is small; i.e. the disease in question is relatively rare. However, if the number of patients in each cohort is large, for example those with breast cancer, then it would seem unlikely that there would be significant differences between the populations with the disease in PCT A and B. Under these circumstances, if Patient X is considered exceptional against the comparator pool in PCT A, she should, logically, also be considered exceptional against the comparator pool in PCT B, which will consist of like patients to the comparator pool in PCT A. So, if Bean J is right, and the cohort against which exceptionality should be measured is those patients with the same condition, it follows that, at least with respect to determining exceptionality for the funding of cancer drugs, there should only be one policy answer to the policy question: a patient who is considered exceptional within one PCT should be considered exceptional within every PCT. This deduction presents a strong case for the determination of exceptionality on a national level, if the concept is to be used as the basis on which to allocate funding.

8.7 Must an exception be envisaged for every individual drug?

As discussed earlier in Section 8.2, the principle that it must be possible to envisage circumstances in which a drug might be funded when declining applications on the basis of exceptional circumstances, was established in R v North West Lancashire Health Authority and re-affirmed in Rogers v Swindon PCT. The first suggestion that this principle might be deviated from appeared in Gordon v Bromley PCT. In response to the question of whether Bromley PCT had imposed a blanket ban on the provision of erlotinib, Ouseley J suggested that:

‘The claimant might well go too far in saying that an exception must be capable of being envisaged for every drug in order for refusal in an individual case to be lawful.’

He proceeded to give the example of a drug that

‘...may simply not have sufficient proven routine clinical benefit...’

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131 R v North West Lancashire Health Authority, ex p A, D & G op. cit. note 12, 991.
132 R (Ann Marie Rogers) v Swindon NHS Primary Care Trust op. cit. note 11, para 62.
133 R (Linda Gordon) v Bromley NHS Primary Care Trust op. cit. note 94, para 39.
134 Ibid., para 39.
However, in *Murphy v Salford PCT*, which was decided subsequent to *Gordon v Bromley PCT*, it was strongly re-affirmed that this original principle not only still held, but was not controversial.\(^{135}\) It was also considered in *Ross v West Sussex PCT*\(^{136}\) and *AC v Berkshire West PCT*.\(^{137}\)

Ouseley J’s remark that it might not be imperative to envisage an exception for every drug is worthy of exploration. Are there some drugs and therapies for which there is so little evidence of benefit that it would be preposterous for a PCT to be expected to envisage exceptional circumstances when they might be funded?\(^{138}\) If a PCT denied funding of Chinese herbal medicine, or Gerson Therapy,\(^{139}\) would they be expected to envisage circumstances in which they would be provided? It may be that in the future there will be licensed cancer drugs which are so expensive, and with such low response rates, which even when they do work provide very limited extension of life, accompanied by such significant side effects, that it would be reasonable to deny

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\(^{135}\) *R (Jean Marie Murphy) v Salford Primary Care Trust* op. cit. note 21, para 6.

\(^{136}\) *R (Colin Ross) v West Sussex Primary Care Trust* op. cit. note 21, para 35.

\(^{137}\) *AC v Berkshire West Primary Care Trust* op. cit. note 5, paras 32-33.

\(^{138}\) Assessing the clinical effectiveness of new treatments is a common challenge for exceptional case panels, as the treatments requested are often in early clinical use, or for rare conditions where little evidence exists. The traditional hierarchy of evidence places well conducted meta-analyses of randomised controlled trials (RCTs) at the top, followed by individual RCTs, observational studies (such as cohort and case control studies) and finally case studies and expert opinion. See Greenhalgh T. *How to read a paper: the basics of evidence-based medicine*. 3rd edn. Malden, Mass.: Blackwell Publishing, 2006. p 16. In the absence of RCTs, PCTs must rely on forms of evidence lower down the hierarchy. Even when RCTs and meta-analyses exist, results may be conflicting. It is usual for Exceptional Case Panels to have at least one or two people specifically responsible for researching and presenting the evidence for requested treatments, often with a Public Health background. It is much less common for panels to include a hospital consultant, although supporting evidence is usually sought from the requesting physician. See National Prescribing Centre, *op. cit.* note 13, Slide 11. In *R (Colin Ross) v West Sussex Primary Care Trust* op. cit. note 21, para 91 confusion over the outcome of some of the relevant trials was apparent. The limited information available in law reports may not reveal the true extent of this problem. Although there is no formal role for a medical expert ‘witness’ in the judicial review process, both parties can submit written evidence from a medical expert to support their position. Given the relatively low position of personal opinion in the evidence hierarchy, the weight which has been given to individual expert’s views during judicial review is surprising. This is particularly apparent in *R (Victoria June Otley) v Barking and Dagenham NHS Primary Care Trust* op. cit. note 58, para 20 and *R (Colin Ross) v West Sussex Primary Care Trust* op. cit. note 21, paras 57, 71 and 72. In the latter case, the defendant challenged the claimant’s medical specialist of straying into territory beyond his expertise, by commenting on the PCT’s application of their exceptionality policy, but this objection was dismissed by the judge. It would appear that the limits of medical opinion in cases concerning exceptionality have yet to be defined.

provision without being able to envisage exceptions where they would be funded. This is not to refute that the cancer patients whom they are designed to treat have an ‘overriding clinical need’, but unfortunately in many cases it is a need for which no effective magic bullet exists. If resource constraints were not an issue, it could be argued that little would be lost by trying drugs even with low effectiveness. However, in a social insurance health system, every treatment carries an opportunity cost. Providing an expensive cancer treatment with low effectiveness means that another patient, and possibly many other patients, will be deprived of treatments with better effectiveness. It is neither a rational nor ethical use of limited resources to spend money on very high cost, low benefit, treatments. Whilst it would be an appropriate and logical action for a self interested patient approaching the end of life, when funding is provided by a social insurance system, it makes no sense from a societal perspective. That patients who apply for funding on the basis of their exceptional circumstances are identifiable makes these decisions harder, especially when individual’s stories are sensationalised in the media, but statistical patients treated are of no less value than identified patients. A preference for identified lives is irrational and the heart wrenching tales in the court must be subject to dispassionate analysis, so that unknown patients without a voice do not suffer.

8.8 An end to local exceptionalism?

Lord Darzi proposed to end the postcode lottery three years ago and Andrew Dillon, Chief Executive of NICE, has also called for consistency in PCT decision making. In the absence of clear legal criteria on the determination of exceptionality, reaching decisions which are robust enough to withstand judicial review is challenging and PCTs are exposed to the risk of costly legal action. Furthermore, money and time spent by PCTs on defensive legal action cannot be invested in improving clinical care. Clinicians are left bewildered as to why some seemingly very similar patients are deemed exceptional,

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140 Brock DW. Ethical and value issues in insurance coverage for cancer treatment. *Oncologist;* 15(suppl_1): 36-42.
141 Ibid.
144 This point was acknowledged by the judiciary in *R v Central Birmingham Health Authority, ex parte Walker* (1987) 3 BMLR 32, one of the early judicial review cases involving the allocation of resources for infant cardiac surgery.
when others are not. The process of applying for funding on the basis of exceptional circumstances creates unrealistic expectations for patients, fuelled by media hype and indirect marketing by pharmaceutical companies. Seeking recourse in the courts is not an option easily accessible to all, further increasing inequities between patients.

If there are inadequate resources to fund all effective cancer treatments, we should not hide behind the concept of exceptionality, but should have an open and honest debate as to how we reach a consensus on which drugs to fund, and how we are prepared to pay for those treatments it is agreed should be provided. The Cancer Drugs Fund has widely increased access to oncological treatments, although evidence of regional

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146 Pharmaceutical companies are governed by strict guidelines with respect to direct marketing to patients, but human interest stories of individuals ‘fighting’ to obtain cancer drugs help raise public awareness and stimulate demand. Of 361 national news stories reviewed between 1998 and 2006 focusing on trastuzumab, 65% named breast cancer patients. See Wilson P, Booth A, Eastwood A, et al op. cit. note 145. There is suggestion that the drug industry actively seeks out suitable patients to support through public relations companies. For example, after writing about her diagnosis of breast cancer, Professor Lisa Jardine was contacted by a public relations company working for Roche, and offered help in obtaining trastuzumab prior to its approval by NICE. See Berg S. Herceptin: Was patient power the key? *BBC News*. 9 June 2006. http://news.bbc.co.uk/1/hi/health/5063352.stm (accessed 7 February 2010). Pharmaceutical companies also have a close relationship with patient advocacy groups, providing significant financial sponsorship. Given their common interest in increasing access to cancer drugs they are not uneasy bedfellows, but there is a risk that the association may result in a lack of objectivity on the part of patient groups. For a more detailed discussion see Jones K. In whose interest? *Sociology of Health & Illness* 2008;30(6):929-43 and Ferner R, McDowell S. How NICE may be outflanked. *BMJ* 2006;332(7552):1268-71. The House of Commons Health Select Committee has recommended that steps should be taken to restrict the influence of drug companies on patient support groups, see House of Commons Health Committee. *The influence of the pharmaceutical industry – Fourth report of session 2004-2005* 22 March 2005. http://www.publications.parliament.uk/pa/cm200405/cmselect/cmhealth/42/42.pdf (accessed 8 February 2013).

147 As Sheldrick highlights, multiple factors influence patients’ access to the courts, including the existence, or not, of legal aid and the organisational capacity of interest groups. (Sheldrick BM. Judicial Review and the allocation of health care resources in Canada and the United Kingdom. *Journal of Comparative Policy Analysis* 2003;5(2):149-66.) For example, in her attempt to access trastuzumab from Bristol North NHS PCT, Elisabeth Cooke, a psychiatric nurse, was supported by the trade union Unison. Thompsons Solicitors. Thompsons and trade union campaign for Herceptin. 12 June 2006. http://www.thompsons.law.co.uk/ntext/thompsons-trade-union-campaign-herceptin.htm (accessed 7 January 2011).
variations in access is already beginning to emerge,\footnote{148} and there has been no evaluation of the opportunity cost to other health services of financing the Fund. With the introduction of value-based drug pricing, planned for January 2014,\footnote{149} and CCGs, there is a risk that access to drugs could become an even bigger postcode lottery. Unlike PCTs, CCGs will not operate at arm’s length from patients, and GPs may be more vulnerable not only to pressure from patients and their families, but also to the external influences which arise in funding requests on the basis of exceptionality, including those from the media, patient support groups and the pharmaceutical industry.\footnote{150} The decision for the outcome of NICE technology appraisals to remain mandatory will help reduce this.\footnote{151}

When a drug is not nationally approved, there will, on occasion be reason to treat one cancer patient differently from others with the same condition, on clinical grounds. For example, if there is reason to believe they may benefit more from a treatment than usually expected, or if they suffer intolerable side effects from standard treatment. From a medical perspective, these patients could be considered exceptional. The restructuring of the NHS presents a perfect opportunity to start assessing these patients on a national, or at least supra-regional basis, to enable standardisation of the concept of


\footnote{150} In a survey of PCT decision making in ‘exceptional circumstances’, 10 PCTs admitted that local publicity and media influenced their decision making. Macmillan Cancer Support, Press release, 29 October 2008. \textit{Cancer patients facing exceptional difficulties to get funding for cancer drugs} http://www.macmillan.org.uk/Abotus/News/Latest_News/Cancer_patients_facing_exceptional-difficulties_to_get_funding_for_drugs.aspx (accessed 22 March 2011).

\footnote{151} This decision to change the status of outcomes of NICE technology appraisals from mandatory to advisory was reversed during the Government’s ‘listening exercise’ on the Health and Social Care Bill, when many GPs said they were not happy to effectively have the power to ration treatments. Removing NICE’s mandatory powers would have moved the NHS from a position where local funding of the relatively few cancer drugs not approved by NICE was at the discretion of PCTs, to a position where the funding of all cancer drugs was at the discretion of CCGs. See Gulland A. \textit{NICE confirms its role in new NHS after government U turn.} 2011 \textit{BMJ;} 343 and Department of Health, Press Release, 14 June 2011. \textit{Government changes in response to the NHS Future Forum} http://www.dh.gov.uk/en/MediaCentre/Pressreleases/DH_127577 (accessed 9 October 2011).
exceptionality and consistency in the determination of exceptionality.\textsuperscript{152} This would be more just, ensuring that like patients are treated in the same manner, irrespective of their place of residence. A nationally ring fenced pot of money to fund those patients deemed to be exceptional would also prevent destabilisation of the budgets of the proposed new CCGs from the need to find funds to finance expensive treatments at short notice.

The misconception that all new cancer treatments emerging onto the market are wonder drugs must be challenged. This myth serves only to provide false hope and defer conversations about the end of life, a topic which both the healthcare profession and wider society need to learn to address more comfortably. This is not to say that the pharmaceutical industry should not be rewarded fairly for innovation. Drug research and development is expensive, but pharmaceutical companies spend twice as much on marketing as research.\textsuperscript{153} Patient access schemes\textsuperscript{154} and regulation of drug pricing may go some way towards making new cancer drugs affordable, but with the pace of development of medical technologies it is inconceivable that we will ever be able to afford every available treatment. Even if the health budget were to be increased, we would still need a fair and just way of deciding which treatments should be financed. Funding patients on the basis of exceptionality, determined locally, is not the answer.

\begin{footnotesize}
\textsuperscript{152} Consistency of decisions could be improved, if, for example, the individual funding decision process were to be run by clusters of CCGs, covering larger populations. In Wales, it has already been suggested that the appeals process for exceptional funding requests should move to a single national system. Health Commission Wales. \textit{A Review (A report on the findings and conclusions, including recommendations, for Mrs Edwina Hart AM MBE, Minister for Health and Social Services, Welsh Assembly Government)}. June 2008.


\textsuperscript{154} Patient access schemes involve either the supply of a limited amount of free drugs, or drug rebates. Whilst having the potential to save the NHS money, such schemes have been criticised because of their high administration costs and the failure of the NHS to reclaim all monies due. For sunitinib alone, a drug used to treat kidney cancer, it is alleged the NHS has failed to reclaim nearly £4 million. For more detail see Williamson S, Thomson T. A report into the uptake of patient access schemes in the NHS. \textit{Clinical Pharmacist} 2010;2:268-70.
\end{footnotesize}
9.0 Paper 2: Accountability for Reasonableness – Why the Relevance Condition is of No Relevance

9.1 Introduction

Daniels and Sabin’s Accountability for Reasonableness framework has been hailed as the ‘most important recent advance’ in the ethics of priority setting in health.¹ It has rapidly gained popularity worldwide and some claim that, within health policy, Accountability for Reasonableness has become the dominant international paradigm.² Daniels and Sabin acknowledge that in a pluralist society we are unlikely to reach a consensus on which principles should guide priority setting. They instead advocate relying on a fair and legitimate decision making process to promote the accountability of decision makers. The framework consists of four essential criteria:³

Publicity Condition – Decisions limiting healthcare and their rationales should be transparent and publicly accessible.

Relevance Condition – Decisions should be made on the basis of reasons that ‘fair-minded people’ can agree are relevant.

Appeals and Revision Condition – There must be a mechanism to allow appeal of decisions and opportunities to revise policies in the light of new information.

Enforcement Condition – There should be regulation in place to ensure the other three conditions are met.

Rather than a purely philosophical ideal, held up as something to be aspired to but impossible to attain, Daniels advocates Accountability for Reasonableness as a practical tool to improve the fairness and legitimacy of resource allocation decisions within healthcare.⁴ In England, the Accountability for Reasonableness framework has been adopted by NICE⁵ and the numerous qualitative studies of the framework in the academic literature reflect the popularity of the Accountability for Reasonableness framework.

Framework globally.\textsuperscript{6} Despite widespread adoption of the framework, use of the relevance condition remains conspicuous by its absence. It has been highlighted that no institution has publicly adopted this condition in decision making.\textsuperscript{7}

Why, unlike the other three conditions, has the relevance condition not been utilised? Is it able to do the work claimed, or is it not fit for purpose? In this paper I will address this question. I will start by exploring the relevance condition and the constraints placed on it, before providing a comprehensive review of the theoretical limitations of the relevance condition, identified in the literature to date.\textsuperscript{8} Daniels acknowledges that Accountability for Reasonableness is a ‘work in progress’, and encourages others to extend it.\textsuperscript{9} The final section reviews the practical difficulties of implementing the relevance condition in the context of the National Health Service (NHS) and tests whether funding treatment for patients on the basis of their exceptional circumstances meets the relevance condition. This is a well-established reason for the allocation of resources by PCTs.

\textbf{9.2 The relevance condition explored}

In this section I will examine precisely what Daniels and Sabin have outlined about the relevance condition and how they have suggested it should be used in practice. The relevance condition states:

\begin{quote}
‘The rationales for limit-setting decisions should aim to provide a reasonable explanation of how the organization seeks to provide “value for money” in meeting the varied health needs of a defined population under reasonable resource constraints. Specifically, a rationale will be reasonable if it appeals to the evidence, reasons, and principles that are accepted as relevant by fair-
\end{quote}


\textsuperscript{7} Friedman A. \textit{op. cit.} note 2, p 112.

\textsuperscript{8} Although not without their critics, the other three conditions of the Accountability for Reasonableness framework are not as controversial, and are less challenging to apply in practice. Limits of space prevent me from examining them, or the role of procedural frameworks in priority setting more broadly. For a discussion of the latter issue see Sabik L, Lie R. Principles versus procedures in making health care coverage decisions: addressing inevitable conflicts. \textit{Theoretical Medicine and Bioethics} 2008;\textit{29}(2):73-85.

\textsuperscript{9} Daniels N. Just health: replies and further thoughts. \textit{Journal of Medical Ethics} 2009;\textit{35}(1): pp 36, 38.
Reasons which meet the relevance condition will not necessarily form the basis of limit setting decisions. The aim of the relevance condition is to determine which reasons are admissible considerations in resource allocation. Decision makers may subsequently decide to dismiss them or assign greater weighting to other relevant reasons.

9.2.1 What is reasonable?
What is meant by a ‘reasonable explanation’? The Oxford English Dictionary defines reasonable as meaning ‘fair and sensible’. Given the basis of Daniels’ work in Rawls’ philosophy, it is logical to interpret the idea of a fair and sensible explanation as one which is consistent with Rawls’ principle of fair equality of opportunity. Daniels uses this principle to ground the special moral importance of health in his book ‘Just Health’. This interpretation of the relevance condition is explicitly confirmed by Daniels’ statement that the role of this condition is:

‘to search for mutually justifiable reasons for thinking that a particular resource allocation is an acceptable way to aim at fair equality of opportunity.’

However, Daniels acknowledges that the principle of fair equality of opportunity alone is too general and indeterminate to solve the challenge of allocating healthcare resources. He indicates that it was the lack of consensus on the ‘fine grained principles’ of how to best protect fair equality of opportunity which triggered the creation of the Accountability for Reasonableness framework.

9.2.2 The need for fair-minded people
The relevance condition assigns much significance to the role of fair-minded people which makes the notion of fair-mindedness worthy of further exploration. Limited clarification of the concept of fair-mindedness is provided, beyond likening the qualities of fair-minded people to athletes who comply with the rules of a game because they value teamwork and ability above gaining advantage through inflicting injuries on their

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10 Daniels N, Sabin J. op. cit. note 3, p 45.
12 Daniels N. op. cit. note 4, p 47. See also Sachs B. Lingering problems of currency and scope in Daniels’s argument for a societal obligation to meet health needs. Journal of Medicine and Philosophy 2010;35(4):402-14.
13 Daniels N. op. cit. note 9, pp 36-41.
14 Daniels N. op. cit. note 4, pp 24, 103, 107.
15 Daniels N. op. cit. note 9, p 38.
There is no acknowledgement of the significant difference between competitive sports, where rules have been universally established, and priority setting, where they have not. Daniels and Sabin advise that the rules sought should ‘shape a conception of the common good’. With regard to priority setting, they limit the search for rules to those accepted by fair-minded people in order to narrow the scope of disagreement, although they concede that the application of the rules may well be contested.

9.2.3 Determining rationales for limit-setting decisions

Daniels is explicit that the rationales for limit-setting decisions are not pre-determined, nor does the relevance condition require the pursuit of fair equality of opportunity to solve any given priority setting problem in only one given way. It is suggested that in many situations there may be more than one tenable answer, but the choice of rational solutions is not infinite. Consensual decision making should be achieved through argument and deliberation over individual cases, and it is stipulated that reasons which form the basis of limit-setting must be acceptable to all fair-minded people. For this reason aggregation through voting is not supported by Accountability for Reasonableness, because aggregation would result in a minority being forced to abide by reasons which they believe to be irrelevant. If even one person believes a factor to be extraneous, the terms of the relevance condition mean that the factor must be unreasonable. Such a situation is distinguished from a deliberation where all fair-minded people agree that the reasons under discussion are relevant, but cannot reach an agreement, for example, on the weight or priority that should be accorded to them. In this circumstance, Accountability for Reasonableness permits a vote. It is claimed voting is justified because:

‘the minority is not being compelled to do something for reasons it thinks irrelevant or inappropriate ... the preference of the majority rests on the kind of

\[\text{\textsuperscript{16}}\text{Daniels N, Sabin J. op. cit. note 3, p 44.}\]
\[\text{\textsuperscript{17}}\text{Ibid.}\]
\[\text{\textsuperscript{18}}\text{Ibid., p 45.}\]
\[\text{\textsuperscript{19}}\text{Daniels N. op. cit. note 9, p 38.}\]
\[\text{\textsuperscript{20}}\text{Daniels N, Sabin J. op. cit. note 3, p 65.\text{They do not, however, exclude outright the possibility of substantively correct answers. See Daniels N, Sabin J. \textit{Ibid.}, p 64.}}\]
\[\text{\textsuperscript{21}}\text{Daniels N. op. cit. note 4, p 112; Daniels N. op. cit. note 9, p 38}\]
\[\text{\textsuperscript{22}}\text{Daniels N. op. cit. note 4, p 113.}\]
\[\text{\textsuperscript{23}}\text{Ibid., p 112.}\]
\[\text{\textsuperscript{24}}\text{The voting procedure to be used is not specified by the Accountability for Reasonableness framework, but left to the discretion of the institution, see Daniels N. op. cit. note 9, p 38.}\]
view that even the minority must acknowledge appropriately plays a role in the deliberation.’ 25

Notwithstanding the acknowledgement that the relevance condition can give rise to more than one valid solution, some limits are set on outcomes. On grounds of fairness, comparable cases must be treated in the same manner, unless dissimilar treatment can be justified.26 It is envisaged that a body of ‘case law’ will develop, establishing a set of reasons and rationales that can be applied to future cases. Deviation from this is only sanctioned if a new case can be shown to be materially different from a previous case, or if deliberation over a new case reveals errors in preceding rationales. In the latter eventuality, public admission of a change in policy is encouraged, to avoid the impression of inconsistency.27 However, Daniels and Sabin are clear that the relevance condition does not preclude different institutions reaching divergent decisions about similar, or even identical, conditions. The possibility of arriving at divergent outcomes is defended on the grounds that two institutions may reason about an identical case in different ways, placing greater weight on some reasons than on others, hence reaching different decisions. It is argued that in the climate of moral pluralism in which these decisions are reached, neither set of rationales can be endorsed independently of the fair process engaged. The weight given to principles by both institutions may be reasonable. It is this lack of moral certainty about what amounts to a just outcome which leads Daniels to a procedural approach and his claim that, provided the reasons used by both institutions are relevant, the different outcomes are both arguably fair.28

9.2.4 Constraints on reasons

Specific constraints are placed on reasons that may be considered as relevant. Explicitly, reasons based in religious faith are not admissible under the relevance condition, on the grounds that they are of no relevance to those not sharing that faith.29 In addition, reasons applied in decision making under the relevance condition must be seen as ‘relevant and appropriate’ by those affected by the decisions, as well as being considered relevant by fair-minded policy makers.30 A further constraint of the relevance condition is that decisions should not disadvantage anyone more than they would need to be disadvantaged under an alternative distribution of resources. It is

26 Ibid., p 48.
27 Ibid.
28 Ibid., p 80.
29 Ibid., p 53.
30 Ibid., p 52.
claimed that if any of us were the person disadvantaged more severely than was necessary, each of us would wish to use this as a basis of a complaint. Avoiding disadvantage more than is necessary is a reason that all people would therefore consider relevant. Daniels and Sabin distinguish this situation from others where decisions will lead to relative disadvantage for some people, but resources have been distributed so as to minimise the resulting disadvantage. They describe this as 'mere disadvantage' and accept this as an inevitable consequence of priority setting decisions.

9.2.5 What are relevant reasons?
Daniels and Sabin give little detail about exactly what might constitute relevant reasons under the relevance condition, although they do suggest that institutions may generate lists of essential aspects of limit-setting decisions. An example of an aspect which might be included in such a list is patient selection criteria for treatment, accompanied by the rationale underlying the criteria, such as trial evidence or acceptable risk benefit ratios.

Relative cost effectiveness and opportunity costs are also outlined as meeting the relevance condition. Inclusion of these reasons is justified by claiming that people who are aiming to meet the medical demands of a population with limited resources:

‘would be interested in a reason that a particular intervention had fallen below some defensible threshold of cost effectiveness.’

It is implied that cost effectiveness is a factor that all ‘fair-minded’ people would find relevant. However, Daniels and Sabin stress that unmodified cost effectiveness analysis

31 Ibid., p 54.
32 It is implicit here that Daniels and Sabin are referring to an alternative distribution of resources within the healthcare budget. They do not address whether the current distribution of resources between health and other public needs is fair. See Daniels N, Sabin J. op. cit. note 3, pp 2, 54. Harris and Regmi have advanced the idea that medical treatment should only be deemed unaffordable if other national budgets, which would have to be reduced to fund healthcare, are protecting interests of comparable importance. Harris J, Regmi S. Ageism and equality. Journal of Medical Ethics;38(5):263-66.
33 Daniels N, Sabin J. op. cit. note 3, p 48. In addition, they describe the criteria used by the Blue Cross/Blue Shield Medical Advisory panel, as examples that ‘all stakeholders should accept as relevant and appropriate – if not sufficient’ for making decisions regarding the coverage of new technologies. These are; the technology must have final approval from the appropriate government regulatory body; the scientific evidence must permit conclusions concerning the effect of the technology on health outcomes; the technology must improve net health outcomes; it must be as beneficial as any established alternative and the improvement must be attainable outside investigational settings. (see ibid., p 53.)
34 Ibid., p 56.
35 This is not universally accepted. Harris, for example, argues that what matters is that every individual gets an equal chance of accessing treatment, irrespective of cost effectiveness. See
provides an insufficient basis for limit-setting decisions, and that incorporation into a deliberative process, such as Accountability for Reasonableness, is imperative to ensure that potentially unjust distributive concerns are addressed.36

9.3 The relevance condition – fit for purpose?
In this section, I review the numerous conceptual shortcomings of the relevance condition highlighted in the academic literature to date, before proceeding to examine the relevance condition from a practical perspective in the subsequent sections of the paper.

9.3.1 The goal of equality of opportunity
A fundamental objection to the relevance condition is that its goal of increasing equality of opportunity implies that reasons that do not contribute to this aim are inevitably unreasonable and irrelevant. What may matter more than striving for equality of opportunity is providing people with an opportunity to improve their lives, though not inevitably in equal shares.37 The relevance condition also fails to consider other criteria for social justice and equity, beyond equality of opportunity. Daniels and Sabin claim that Accountability for Reasonableness provides a solution for morally pluralistic societies.38 However, it is not morally neutral as it endorses the goal of equality of opportunity as the prime moral principle. Incorporating moral values into a framework which is able to accommodate pluralistic values may be perceived as a strength of Accountability for Reasonableness. However, in trying to square the circle, the relevance condition has arrived at a compromise so morally bland that it fails to do any real work in determining which reasons are morally right.

9.3.2 Legitimacy, fairness and consistency

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36 Daniels N, Sabin J. op. cit. note 3, p 39. Further guidance as to what constitutes relevant reasons is contained within a qualitative case study of healthcare priority setting (Singer PA, Martin DK, Giacomini M, et al. Priority setting for new technologies in medicine: qualitative case study. BMJ 2000;321(7272):1316-18). The study cites factors which the authors found were being considered in practice, including benefit, evidence, side effects, cost and cost effectiveness. In an accompanying editorial, Daniels confirms that the reasons reported are the kinds of reasons that meet the relevance condition. (Daniels N. Accountability for reasonableness. BMJ 2000;321:1300-01.)


38 For an exploration of the implications of moral pluralism see Wolf S. Two levels of pluralism. Ethics 1992;102(4):785-98.
Daniels claims that Accountability for Reasonableness facilitates the making of legitimate and fair limit setting decisions. Whilst some accept legitimacy is achieved through providing a due process, Rid challenges the latter claim of fairness, arguing that the substantive component of the framework, the relevance condition, is not adequately specific to provide a well defined, independent benchmark of a just outcome. Rid shows that the relevance condition verifies, as a minimum, that decision outcomes are consistent with the principle of fair equality of opportunity, for example, by prohibiting discrimination on the grounds of race or gender. In her account, Rid describes Accountability for Reasonableness as constrained pure procedural justice, a description with which Daniels concurs in his response to Rid’s paper.

Rid proposes the addition of two further conditions to the Accountability for Reasonableness framework to help ensure just outcomes. The first of these is a consistency condition to ensure congruent outcomes in decisions about similar cases by an individual health provider, to address fears that the publicity condition will not be adequate to ensure that similar cases are treated equivalently. Secondly, the addition of an impartiality condition is suggested, to reduce the risk of decisions makers allowing self-interest to influence their ability to balance competing claims, when choosing between two equally just options. Rid does not accept that the requirement for the relevance condition to allow only reasons accepted by fair-minded people to be used will ensure that consistency and impartiality are inherent in decision making. She argues that the concept of fair-mindedness as presented in the relevance condition is circular, open-ended and unhelpful. Beyond acknowledging that Rid is correct that more work needs to be undertaken to establish a fair deliberative process, work that Daniels

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39 Daniels N. op. cit. note 4, pp 46, 170, 117.
41 Ibid., p 14.
42 Rid defines it as a process with: ‘an independent, but indeterminate, criterion of justice that is consistent with more than one possible outcome’, which enables a fair choice to be made between these equally just outcomes. (Rid A. op. cit. note 40, p 15.)
43 Daniels N. op cit. note 9, p 38.
44 Daniels proposes that the public accountability ensuing from the publicity condition, which requires policy makers to be explicit about the rationales behind priority setting decisions, will help to ensure that the formal requirements of fairness are met. See Daniels N, Sabin J. op. cit. note 3, p 49.
45 Rid A. op. cit. note 40, p 15.
46 Ibid., p 16.
considers should be done at different institutional levels, Daniels does not respond specifically to the other weaknesses which Rid highlights in the relevance condition.48

Hasman and Holm raise a similar concern regarding the ability of the Accountability for Reasonableness framework to ensure consistency not only of which reasons are accepted as relevant over the course of time, but also constancy in how they are balanced against each other.49 They call for the weights assigned to each relevant reason to be made explicit to improve uniformity in decision making.50

9.3.3 False assumptions
Friedman has two different objections to the relevance condition. On a pragmatic level, he argues that the relevance condition is based on three false assumptions: that most moral disagreements relating to priority setting in healthcare are related to the weights that should be attributed to considerations that everyone agrees are relevant; that arguments about weights are more easily resolved than disagreements about which factors are relevant; and that there is a relatively straightforward method to distinguish between legitimate and illegitimate reasons which are relevant to decisions involving the allocation of resources.51 Friedman rebuts these assumptions in turn.52 The relevance condition, he asserts, requires us to grapple with contentious debates in political philosophy, prior to even considering the moral principles at stake.53

9.3.4 The rejection of faith based reasons
Friedman’s second objection to the relevance condition is that the categorical rejection of faith based reasons is unjust.54 He rejects the notion that decision making can be simplified by excluding some kinds of reason from the debate in advance of democratic deliberation, and advances instead that all reasons should be judged on their substantive merits rather than on their genealogical origins.55 Friedman argues that differences between reasons grounded in religious faith and those grounded in moral

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48 Daniels N. op cit. note 9, pp 36-41.
49 Hasman A, Holm S. op. cit. note 37, pp 261-273.
50 Ibid., pp 265-273.
51 Friedman A. op. cit. note 2, p 104.
52 Ibid., p 105-107.
53 In addition, Friedman reminds us that people can be right about something, even if their reasoning is misguided, and therefore failing to give consideration to poorly reasoned ideas may risk dismissing ideas which are nonetheless of value. Friedman A, op. cit. note 2, p 107.
54 Ibid., p 108.
55 Ibid., pp 101-112.
theories, which many people find ‘misguided, confused, or incoherent’ as non-believers might so find the major religions, are differences of magnitude rather than class.

Daniels and Sabin’s assumption that reasons based in religious faith will always be considered irrelevant by others not sharing that faith is, in any case, flawed. It is quite possible that those not sharing the faith of Jehovah’s Witnesses would nonetheless support their request for more expensive non-blood products over blood products, just as those who are not followers of Islam might support the request of Muslims to receive non-porcine derived treatments. The relevant reason is not the religious faith on which the request is based, but the shared conviction that a person’s strongly held personal beliefs, whatever their source, should be respected.

9.3.5 The black box

Hasman and Holm criticise the process of decision making in Accountability for Reasonableness as a ‘black box’, due to the absence of detail on how to determine the reasonableness of reasons under the relevance condition, and the lack of guidance regarding the form and nature of the actual process of deliberation. To illustrate their criticism, and also how the assessment of reasonableness may be influenced by cultural, social, political and historical factors, Hasman and Holm use the example of the concept of social solidarity in Northern Europe. They conclude that it is far from apparent as to whether or not solidarity based reasons are reasonable under the relevance condition.

But are they expecting the relevance condition to do more work than Daniels and Sabin ever intended? It could be argued that whether or not these factors are considered reasonable under the relevance condition will rightly be determined by the socio-political and cultural setting, and that it is a strength of the Accountability for Reasonableness model that it can be adapted for use in different contexts. The framework is intended to be broad enough to be used in countries at all stages of economic development, irrespective of the mode of healthcare delivery.

57 There may be reasons, relating to the principle of fair equality of opportunity, for regarding religious beliefs as a reasonable consideration under the relevance condition. These are discussed in Section 9.3.4. See also Savulescu J. The cost of refusing treatment and equality of outcome. Journal of Medical Ethics 1998;24(4):231-36.
58 Hasman A, Holm S. op. cit. note 37, pp 261-273.
59 Ibid., pp 271-272.
60 Daniels N. op. cit. note 4, p 104.
Accountability for Reasonableness explicitly permits institutions to give different weights to the reasons that people agree are relevant. What is less clear is whether the fair-minded people at one institution could legitimately arrive at an entirely different set of reasons from a fair-minded group of people at another. The alternative, which Hasman and Holm appear to interpret from the framework, is that there are a universal ‘core set’ of relevant reasons, consistent with the principle of fair equality of opportunity, which all fair-minded people will agree exist, even if they weight them differently in priority setting decisions. If Daniels and Sabin envisage this alternative, then it follows that if enough fair-minded people were gathered together, a comprehensive list of relevant reasons could be compiled, even if no consensus could be reached on how they should be weighted. However, if even a single person believes a factor to be irrelevant, the terms of the relevance condition imply that the factor cannot be reasonable. On these grounds, it would not take a high level of disagreement amongst a large group to inhibit the growth of a list of relevant reasons. When objections were raised to the inclusion of reasons as relevant, it would also raise the question of whether the reason was truly irrelevant, or whether the person raising the objection was not fair-minded. In the absence of criteria for establishing fair-mindedness, there would be no clear way of making a distinction between these two possibilities. This impracticality is incongruent with Daniels and Sabin’s intention that Accountability for Reasonableness would have real world applicability, from which one can infer that Daniels and Sabin must have envisaged that not only could different groups of fair-minded people legitimately place different priority on different relevant reasons, but that the substance of the relevant reasons themselves would vary between institutions, depending on context. Further, had Daniels and Sabin envisaged a universal list of relevant reasons, as opposed to a range of tenable rationales, one would have expected them to have published a more exhaustive list than provided in their most recent monograph.  

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61 Daniels N, Sabin J. *op. cit.* note 3, p 80.  
62 Hasman A, Holm S. *op. cit.* note 37, p 261.  
63 Daniels N. *op. cit.* note 4, pp 112-113.  
64 Daniels N, Sabin J. *op. cit.* note 3, p 2.  
9.3.6 Deeper into the black box

Lauridsen and Lippert-Rasmussen\(^{67}\) identify similar failings in the relevance condition. They assert that in the absence of systematic account of a method to distinguish between relevant and irrelevant reasons, in advance of democratic deliberation, the framework cannot achieve its aims. By exploring whether it is possible to construct a methodology to distinguish between relevant and irrelevant reasons, they advance that such a methodology would necessitate the existence of a domain of reasons acceptable as relevant to all fair-minded people within the field of healthcare, to which decision makers have epistemic access.\(^{68}\) This is not dissimilar to the ‘core set’ of relevant reasons postulated by Hasman and Holm. Lauridsen and Lippert-Rasmussen’s argument is developed by demonstrating that, even if such a domain of reasons does exist, no mechanism allows their identification by policy makers prior to democratic deliberation.\(^{69}\) Although it was not explicit whether Daniels envisaged that this should be possible in *Just Health*,\(^{70}\) work published since suggests this is not what Daniels and Sabin are advocating.\(^{71}\) If I am mistaken in this interpretation of accountability of reasonableness, Lauridsen and Lippert-Rasmussen illustrate convincingly that in any case, it is not possible to identify the reasons which fair-minded people will find relevant, in advance of democratic debate.\(^{72}\)

The alternative to this, advanced by Lauridsen and Lippert-Rasmussen, is to accept that deliberation under democratic conditions is the only mechanism of determining the relevance of reasons.\(^{73}\) The relevance of reasons cannot, therefore, be established prior to the deliberative democratic process. Although the idea inherent in the relevance condition, that the reasons accepted as relevant by fair-minded people can constrain the democratic process, may hold true, these reasons can only be uncovered through deliberation. This leaves the relevance condition with virtually no role to play as the condition does not enhance our existing ideas of how democratic political institutions should be regulated. On the basis of these arguments, Lauridsen and Lippert-Rasmussen

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\(^{68}\) Ibid., p 64.

\(^{69}\) Ibid., pp 63-64.

\(^{70}\) Daniels N. *op. cit.* note 4.

\(^{71}\) Evidence to support this view can be found in N. Daniels & J. Sabin. *op. cit.* note 3, p 45 which refers to ‘the fair-minded search for mutually acceptable rules’, suggesting an element of discussion in reaching agreement on which reasons will be considered relevant. This is reiterated in N. Daniels. *op. cit.* note 9, p 38 which states ‘The point behind insisting on what we call the relevance condition is to search for mutually justifiable reasons.’

\(^{72}\) Lauridsen S, Lippert-Rasmussen, *K. op. cit.* note 66, pp 63-64.

\(^{73}\) Ibid., pp 64-65.
conclude, similarly to Rid,\textsuperscript{74} that the relevance condition can only independently screen out obviously irrelevant reasons, such as racial identity, which would, in any case, have been screened out in the democratic process.\textsuperscript{75}

### 9.3.7 Where does that leave us?

The theoretical analysis of the relevance condition to date suggests that the relevance condition, as part of the Accountability for Reasonableness framework, may legitimise priority setting decisions through providing a due process, but that the outcomes are not necessarily just. Rather, the relevance condition amounts to constrained pure procedural justice.\textsuperscript{76}

A fundamental objections to the relevance condition is that it is based on three false assumptions regarding; the causes of moral disagreement; the ease with which disagreements can be resolved; and the preconception that there is a simple method to distinguish between legitimate and illegitimate reasons.\textsuperscript{77} It has also been argued that reasons arising from religious beliefs should not be rejected outright.\textsuperscript{78}

It is proposed that further measures are needed to ensure consistency and impartiality of the relevance condition,\textsuperscript{79} including being explicit about the weights given to different reasons in decision making.\textsuperscript{80}

Finally, it has been established that there is no epistemologically accessible core set of relevant reasons, and that relevant reasons cannot be established prior to democratic debate.\textsuperscript{81} The relevance condition can only screen out obviously irrelevant reasons, which one would expect to be dismissed during deliberative democratic process.\textsuperscript{82} Consequently, the relevance condition adds little to our current democratic decision making processes.

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\textsuperscript{74} Rid A. \textit{op. cit.} note 40, p 15.
\textsuperscript{75} Lauridsen S, Lippert-Rasmussen, K. \textit{op. cit.} note 66, p 65.
\textsuperscript{76} Rid A. \textit{op. cit.} note 40, p 15.
\textsuperscript{77} Friedman A. \textit{op. cit.} note 2, p 104.
\textsuperscript{78} \textit{Ibid.}, pp 101-112.
\textsuperscript{79} Rid A. \textit{op. cit.} note 42, p 15-16.
\textsuperscript{80} Hasman A, Holm S. \textit{op. cit.} note 39, pp 265-273.
\textsuperscript{81} \textit{Ibid.}, pp 63-64.
\textsuperscript{82} Rid A. \textit{op. cit.} note 42, p 15.
9.4 Implementing the relevance condition – a case study

9.4.1 Applying the relevance condition within the NHS: the exceptional case

Priority setting in healthcare is a real problem requiring a practical solution, and few have been forthcoming. Daniels and Sabin advance Accountability for Reasonableness as a functional approach to addressing resource allocation. They appear to recognise that the framework is not flawless when they reflect that:

‘imperfect processes can improve our grasp of what better processes would be.’

Their acknowledgement that Accountability for Reasonableness cannot be tested without being applied to different contexts invites experimental application of the relevance condition to real world settings. It therefore seems a worthwhile exercise to evaluate the challenges of implementing the relevance condition within the NHS, despite the theoretical shortcomings identified. I propose to use the funding of medical treatment for patients, on the basis of their exceptional circumstances, as a case study for this purpose.

Within the NHS in England, regional PCTs are under a legal obligation to fund all treatments approved by NICE. PCTs can legitimately refuse to fund treatments not approved by NICE, save in exceptional circumstances. This has given rise to a situation where patients, or their representatives, can apply to their local PCTs for the funding of treatments not otherwise provided on the NHS, on the basis of a patient’s exceptionality. PCTs have established processes for managing these requests, whereby applications are assessed by a multi-disciplinary panel, of the kind which Sarah Palin might refer to as a ‘death panel’, to assess if an individual case is indeed exceptional.

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83 Daniels N, Sabin J. op. cit. note 3, p 2.
84 Ibid., p 170.
85 Ibid., p 183.
87 See R v North West Lancashire Health Authority, ex p A, D & G [2001] 1 WLR 977 990. They can, of course, also choose to commission drugs for their local population which are not approved by NICE.
89 National Prescribing Centre. Supporting rational local decision-making about medicines
What constitutes ‘exceptional’ in these circumstances has not been defined by law and how PCTs assess patients’ claims of exceptionality varies across the country. However, the NHS Confederation has produced a definition of exceptionality which has been adopted by many PCTs. The definition suggests that exceptionality is demonstrated when:

‘the patient is significantly different to the general population of patients with the condition in question and the patient is likely to gain significantly more benefit from the intervention than might normally be expected for patients with that condition.’

PCT decision making in exceptional circumstances is an ideal candidate for evaluating the relevance condition, as exceptionality is a well-established and legally recognised reason for allocating resources. In addition, the other three central conditions of the Accountability for Reasonableness framework transfer relatively well to the broad system used for decision making in the context of requests for funding on the basis of exceptionality. The appeals and revision condition is potentially met by the internal appeals process that PCTs are advised to provide, and subsequently by recourse to judicial review should the need arise. Publicity is achieved, though perhaps only in part, by communication of the rationale behind decisions to both patient and clinician, an obligation now enshrined in the new NHS Constitution. The regulative requirement is met by statutory obligations on the PCT.

I will first examine the difficulties of applying the relevance condition within the NHS. Following this I will assess whether the concept of exceptionality meets the criteria of the relevance condition, including considering whether ‘fair-minded’ people would
agree that this concept is relevant to the pursuit of healthcare when resources are limited, if exceptionality forms part of a rationale which provides a reasonable examination of how ‘value for money’ will be achieved, whether it meets the requirement that similar cases are treated similarly and, finally, whether the concept of exceptionality avoids anyone being more disadvantaged than anyone need be under the alternative limit-setting options. This question can only be addressed if the policy which excludes NHS funding of the treatment in question is itself fair and reasonable. If the exclusion criterion for funding is itself arbitrary, or blatantly discriminatory, claiming exceptionality against the excluded cohort may itself depend on differences based on arbitrary and irrelevant reasons. In examining whether exceptionality meets the relevance condition, I will therefore start from the assumption that the exclusion criteria for treatment are fair and reasonable.  

The relevance condition’s pre-requisite that relevant reasons seek to provide ‘value for money’ is not controversial, given the extent to which such an objective is necessary to enable healthcare funded through taxation to remain free at the point of delivery. Assessment of the cost effectiveness of new technologies has already become well established within the NHS, even if the methodology used is disputed.  

In order to identify relevant reasons under the condition, a group of:

‘fair-minded people who are disposed to finding mutually justifiable terms of cooperation’

must be found, or at the very least, a method developed to establish what evidence, reasons and principles would be accepted as relevant by such a group. Despite the efforts of Rid, Hasman and Holm, and Lauridsen and Lippert-Rasmussen, it has not proved possible to develop such a method. With little guidance as to what constitutes ‘fair-minded’, we might broadly translate the concept in this context as being

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95 Clearly, in practice, this may not be the case, but time and space do not allow me to address this issue here.
96 Daniels N, Sabin J. op. cit. note 3, p 45.
98 Daniels N, Sabin J. op. cit. note 3, p 45.
99 Rid A. op. cit. note 40, pp 12-16.
100 Hasman A, Holm S. op. cit. note 37, pp 261-273.
demonstrated by people with an interest in the common good of the PCT’s population, rather than a desire to push forward their own agendas.102 Applications for funding to PCTs on the basis of exceptionality are usually assessed by a panel of people, typically including public health consultants, general practitioners, pharmacists, medical directors, PCT commissioners, non-executive directors of the PCT and less commonly, a lay member. In the absence of any objective way to assess fair-mindedness, the relevance condition effectively requires us to take a leap of faith to believe that none of those people entrusted with policy making brings vested interests to the table. It could be argued that another of the conditions of the Accountability for Reasonableness framework, the publicity condition,103 would enable independent monitoring of whether policy makers were being fair-minded in their reasoning, but publicity alone might not be sufficient to expose the presence of a devious self-interested decision maker.

Daniels and Sabin specify that reasons used in decision making under the relevance condition must be seen as ‘relevant and appropriate’ by those affected by the decisions.104 Although this statement is not explicitly qualified, one assumes they are not applying this expectation to actual patients who have had their treatment denied, but are referring to the population affected by priority setting decisions, prior to the need for treatment arising, as is commonly accepted in the broader philosophical literature on collective prioritisation.105 It could be argued that the involvement of lay people in the decision making process would at least ensure that the reasons used in decision making are ones which the wider public would consider relevant, which is perhaps a more realistic aim. However, lay panel members do not tend to be democratically elected and cannot be considered representative of the general population.106

102 Mark Sheehan has advanced his own interpretation of what is required of a reasonable person in this context, namely someone who understands (a) the nature of the decision, (b) that the decision needs to be made, (c) that there is reasonable disagreement to be had and someone (d) who is disposed to reach a decision. Sheehan M. Rare and exceptional: Dealing with difficult healthcare resource allocation decisions, Lent Lecture, Kings College London, 27 February 2001.
103 Daniels N, Sabin J. op. cit. note 3, p 45.
104 Ibid., p 52.
Providing unsuccessful applicants with a right of appeal, a further condition of the Accountability for Reasonableness framework, allows people to challenge PCTs’ decisions when they are perceived to be unfair. However, at the present time, both internal PCT appeals and judicial review are only permitted to challenge the process of decision making, rather than the content of decisions themselves. Although existing appeals process can quash outcomes and mandate that a decision be reconsidered, they cannot specify what the outcome of the decision should be.

The relevance condition would reject claims of exceptionality based on religious reasons, as irrelevant. Outside the context of exceptionality based decisions, the NHS accepts religious grounds as justification for differential treatment. The NHS has a duty to respect a patient’s religious beliefs, although whether this duty extends to an obligation to provide costlier alternative treatments has yet to be tested in the courts. Failure to provide an alternative treatment, acceptable to a patient’s religious beliefs, may result in under utilisation of a specific healthcare service by a particular religious group, leading to health inequalities. However, it could also be argued that the opportunity cost of providing a costlier alternative treatment, sanctioned by religious beliefs to one patient group, will result in disadvantage to another group of patients whose treatment will be unaffordable as a result. Given that the principle of fair equality of opportunity underlies the relevance condition, this makes the condition’s outright rejection of religious reasons as a basis for allocating resources troublesome. Like other grounds advanced for being exceptional, claims based on religious reasons need to be considered on a case-by-case basis to ensure that the impact of decisions on equity is evaluated.

A further pragmatic difficulty arises in meeting the requirement that resource allocation decisions, under the relevance condition, should not disadvantage anyone more than they need to be under an alternative distribution of resources. Admireable though the aim of avoiding unnecessary disadvantage is, even if it were possible to easily measure

107 Daniels N, Sabin J. op. cit. note 3, p 45.
108 Judicial review limits the courts to considering whether a PCT is guilty of procedural impropriety, has acted irrationally, or beyond its powers.
112 Daniels N. op. cit. note 9, pp 36-41.
113 Daniels N, Sabin J. op. cit. note 3, p 54.
the level of disadvantage under any given resource allocation, the vast number of possible permutations would make such a calculation a practical impossibility. Mandating that PCTs consider issues of equity and health inequalities when allocating resources, which is already required by the principles underlying NHS policy,\textsuperscript{114} may be the closest to minimising unnecessary disadvantage that can be achieved in practice.

Even when resources have been distributed so as to minimise disadvantage, it will be difficult in some cases to establish whether those who meet the criteria of exceptionality by being significantly different from the population with the condition in question, and who stand to gain significantly more benefit from an intervention, are suffering from what Daniels and Sabin describe as ‘mere disadvantage’.\textsuperscript{115} This would make enforcing the rule that mere disadvantage should not be a consideration under the relevance condition impractical.

9.4.2 Does the concept of ‘exceptionality’ meet the relevance condition?

Fair-minded people could argue that considering patients’ exceptionality when allocating resources is a relevant concept, because the concept recognises patients as individuals and allows for dissimilar treatment where there is a valid reason for treating one patient differently from another.

The NHS Confederation definition of exceptionality includes an increased likelihood of benefitting from treatment as a relevant consideration.\textsuperscript{116} This is an admissible consideration under the relevance condition. An increased likelihood of benefit from treatment might be expected to be associated with improved cost effectiveness, another factor advanced as applicable under the relevance condition.\textsuperscript{117}

There is no reason to think that similar exceptional cases would not be treated similarly under the relevance condition in this context, although if there were many similar cases, one would have to question how exceptional these cases in fact were.\textsuperscript{118} Although those


\textsuperscript{115} Daniels N, Sabin J. \textit{op. cit.} note 3, pp 54.

\textsuperscript{116} Ibid., p 48.

\textsuperscript{117} Ibid., p 56.

\textsuperscript{118} This issue was raised in the case of \textit{R (Ann Marie Rogers) v Swindon Primary Care Trust and the Secretary of State} [2006] EWCA Civ 392 para 42. Rogers sought Judicial Review of her PCT’s decision not to fund the cancer drug Trastuzumab. Her oncologist said she was one of about twenty patients he treated who would benefit from the drug, and was therefore not exceptional.
patients deemed to meet the exceptionality criteria would receive treatment which was not universally available, the rest of the population would have the security of knowing that if they were to find themselves in exceptional circumstances, they would also be considered on an individual basis and, in this respect, treated similarly.

From the perspective outlined, it appears that a group of fair-minded people could conclude that the concept of exceptionality meets the requirements of the relevance condition. However, an opposing view could just as easily be advanced. It could be argued that the concept of exceptionality does not meet the requirement of the relevance condition to provide ‘value for money’, because providing a system which allows for IFRs on the basis of exceptionality is time consuming and expensive. Internal appeals of decisions and defending decisions taken to judicial review can add significantly to that cost.¹¹⁹ In the context of limited resources, providing a system to examine whether differences between individuals warrant differential funding is a luxury that cannot be justified, and to meet the ‘value for money’ requirement, this money should be spent directly on healthcare, not on the administration of a system for the benefit of a few.

This alternative fair-minded perspective could claim that allocating resources on the basis of exceptionality means that patients suffering from identical diseases receive different treatments, and that well-informed patients claiming exceptionality can take advantage of media and legal pressure to obtain costly treatments which are not widely available to all. Under such a system, which permits large amounts of money to be spent on a relatively small number of people, some people will inevitably be disadvantaged more than they need to be, as this money could otherwise provide cheaper treatments to a greater number of people.

Attempting to apply the relevance condition to the concept of exceptionality fails to determine whether or not the concept is a reasonable rationale on which to allocate healthcare resources. It is unable to tell us what fair-minded people would conclude regarding the use of the concept of exceptionality in healthcare priority setting and reveals the essentially vague nature of the relevance condition. Factors meeting the terms of the relevance condition are not inherently the morally correct rationales to

determine resource allocation within healthcare. The relevance condition sanctions the use of all rationales which meet its terms as defensible in setting priorities in healthcare. To be of real value, the relevance condition needs to do more work in determining not simply which rationales are defensible, but which are morally right. Unsurprisingly, the problem with the relevance condition which emerged from the theoretical analysis persists. The condition does not avoid the disagreements between underlying substantive principles arising in principle-based approaches.

9.5 Conclusion – the irrelevance of the relevance condition

The relevance condition makes up one of the four cornerstones of the Accountability for Reasonableness framework. Its purpose is to ensure that the rationales on which healthcare resources are allocated are reasonable, where reasonableness is determined on the basis that reasons meet with the approval of ‘fair-minded’ people and appeal to the principle of fair equality of opportunity. Reviewing the theoretical limitations of the relevance condition, the condition’s inability to independently determine the reasonableness of different rationales prior to democratic deliberation is a major failing. Daniels has publicly welcomed a wider community effort to uncover aspects of the framework which need further modification, so despite the shortcomings identified, the relevance condition was examined in the context of the NHS, using PCT funding of patients on the basis of their exceptional circumstances as a case study.

Practical limitations were identified by the case study, including the difficulty of objectively appointing ‘fair-minded’ people, ensuring that the reasons on which decisions are based are considered relevant and appropriate by those affected by the decisions, and not disadvantaging anyone more than they would be under an alternative distribution of resources. It is also clear that the relevance condition is unduly restrictive, excluding, for example, reasons on the basis of their genealogical origins.

Attempting to determine whether the concept of exceptionality meets the relevance condition has served to confirm the theoretical weaknesses identified with this condition. The relevance condition does not provide a method to distinguish between legitimate and illegitimate reasons on which to allocate resources for healthcare, and it is unlikely that any procedural approach alone could make such a distinction. Given the complexity of such decisions, and the conflicting values involved, deliberation would appear to be an essential component of determining not only the weight to attribute to

120 N. Daniels. op. cit. note 9, p 36.
different reasons, but also in deciding whether they are relevant to the decision in question at all. It is likely that such discussions will be influenced by context and culture, with no globally universal solutions. Despite its superficial attractiveness, the relevance condition is not fit for purpose and is redundant to the Accountability for Reasonableness framework.

10.1 Introduction

There is ongoing international debate about how we decide which healthcare services to fund, when we cannot afford to fund them all. In England, PCTs are mandated to fund all drugs approved by NICE within three months of a positive appraisal.¹ No such obligation exists with respect to other treatments, but English law dictates that any PCT policy of not funding a treatment must allow for the possibility of exceptions to that policy.² In order to accommodate applications from clinicians who have reason to think a patient should be treated as an exception to a funding policy, PCTs have established processes whereby such requests are reviewed by a multi-disciplinary panel to assess if an individual case is indeed exceptional.

Applications may be based on the grounds that the patient should be considered exceptional to an existing commissioning policy, or they may be requests for a treatment for which no policy exists, often because the disease in question is rare or the efficacy of the therapeutic intervention requested unproven. This research focuses on those requests based on the former criterion, namely that of being exceptional. The challenge faced by PCTs in determining whether a patient meets the requirement of being exceptional is well illustrated by several high profile judicial reviews of PCT decisions not to approve IFRs. Earlier studies revealed wide variation in the processes used to assess IFRs.³ In response, the DoH produced guidance to standardise processes across the country.⁴ The concept of exceptionality has never been expressly defined by

the DoH or the courts. The NHS Confederation has produced a definition of exceptionality which has been adopted by many PCTs. The definition suggests that exceptionality is demonstrated when:

‘the patient is significantly different to the general population of patients with the condition in question and the patient is likely to gain significantly more benefit from the intervention than might normally be expected for patients with that condition.’

In contrast to population based commissioning, research on IFRs has been limited and often quantitative in nature, which has precluded deeper insight into the dimensions contained within the concept of exceptionality. Russell et al have reviewed the role of public and patient participation in IFR decision making. Hughes and Doheny undertook a case based discourse analysis of individual funding decisions regarding a single high cost cancer drug at one PCT, concluding that individual professional judgment was likely to remain intrinsic to decision making in this context. However, little is known about how the idea of exceptionality is actually interpreted and applied by PCTs in this complex area of decision making. This qualitative study endeavours to fill this gap in knowledge by exploring in depth how Individual Funding Request panels determine exceptionality, in order gain insights into if, and how, this could be improved; specifically the study aims to provide an overview of how the concept of exceptionality is interpreted, what factors are considered in assessing exceptionality, and whether external influences impact on decision outcomes. Other European countries operate similar systems of providing interventions to selected individuals, which are not provided to all. It is therefore likely that healthcare systems elsewhere face similar decision making/resources/handbook_complete.pdf (accessed 23 March 2009).

5 Ford A. op. cit. note 2.
7 National Prescribing Centre. A Comprehensive Survey of PCTs to Evaluate Local Decision-Making Processes for Funding New Medicines .op. cit. note 3; Rarer Cancers Forum. Taking Exception: an audit of the policies and processes used by PCTs to determine exceptional funding requests.op. cit. note 3.
challenges of determining the basis on which one individual is treated differently from the wider population.

10.2 Research methods

A qualitative approach was taken to the research, which involved individual semi-structured interviews with IFR panel members. In addition, the researcher was invited to observe IFR panel meetings on multiple occasions, at different PCTs, and took the opportunity to make field notes. Although not part of the formal data collection, observation at these meetings has strengthened confidence in the conclusions drawn.

10.2.1 Sampling and recruitment

PCTs were purposively selected from all PCTs in England, to incorporate a mix of population size, deprivation levels, proportion of urban versus rural inhabitants and regional location. Screening was then undertaken of PCTs’ IFR policy documents, to ensure that the final study sample included a spectrum of decision making approaches, at least as described within the written policies.

Access to IFR panels was generally negotiated through the panel Chair, who forwarded the study information leaflet to panel members via email. All panel members were offered the opportunity to participate. Individual appointments were made, to explain the study in more detail, with those panel members who expressed an interest.

The sample size was not predetermined and it was not easy to anticipate how many IFR panel members from each PCT might be willing to participate. Because local research governance approval can take many weeks, twelve PCTs were initially approached, to avoid the risk of unnecessary delays arising from the need to obtain additional governance approvals once interviewing was underway. Data saturation was reached after conducting interviews at five PCTs, and interviewing then ceased in keeping with the qualitative methodological approach.

10.2.2 Data collection

Semi-structured interviews were recorded between May and July 2011, at PCT premises. NHS research ethics committee, and local research governance approval was obtained. Individual participants provided written consent.

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A topic guide, listing key issues, was used to allow similar issues to be explored across the sample. This included: background information about the participant; the broad approach to decision making; interpretation of the term exceptional; the factors considered in determining exceptionality; and influences on decision making. The topic guide was flexible enough to allow probing in response to participants’ comments, and there was openness to unanticipated issues being raised. The interviewer aspired to maintain a neutral role. Individual in-depth, semi-structured interviews were chosen over focus groups to avoid answers being influenced by peer pressure to conform to certain viewpoints, and to allow exploration of individuals’ meanings and interpretations of the subject matter. Interviews were transcribed verbatim. In addition field notes were made to document the context of interviews.

10.2.3 Data analysis
Interview transcripts were imported into NVivo 9, which was subsequently used to manage the study data. Analysis was conducted using Framework Analysis. Framework is an iterative approach, developed for applied policy research, which does not originate from any single epistemological background. This analytical method is recognised as being well suited to research which has specific questions and a limited time frame. The initial analytical step is familiarisation with the data, which was achieved through reading and re-reading a range of transcripts selected from participants with a variety of roles, collected during different time periods of the research. This enabled identification of emergent concepts and recurring themes. These were used to construct an index that was then systematically applied to the whole data set. Effectively, this allowed the data to be labelled, sorted and compared under the key ideas and themes that had been identified.

Once the data had been indexed, a thematic chart was created, with each theme occupying a column, and each study participant a row. Some of the themes replicated those used in the index, others were split to create two or more sub-themes, and a few were collapsed into one theme, where it was felt two index headings were strongly connected. The original data was then summarised into each cell, maintaining as far as possible the essence of its raw format, by retaining key terms and keeping interpretation to a minimum. Relevant verbatim texts were not included in the cells, but remained

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12 QSR International, Cambridge, MA.
linked via the software. Each transcript was worked through systematically, until all the
data was synthesized within the thematic chart. The charted data was then repeatedly
examined, with reference to the original transcripts, for higher order conceptual
categories to describe the data.

To guard against selectivity in the use of data, the analysis which emerged was discussed
with members of the supervisory study team, who were familiar with a sample of
original transcripts. Illustrative quotations were linked to themes at each stage of the
analysis, and with the end results, to ensure that the analysis remained rooted in the
respondents’ accounts. The researcher also reflected on her own preconceptions of
exceptionality, and used this self-awareness to attempt to minimise bias during data
collection and analysis. Finally, member checking was undertaken, with several
participants reading the paper to ensure that their views had not been misinterpreted,
and there were no gross errors of fact. Minor amendments were made as a result.

10.3 Findings

10.3.1 Sample characteristics
30 IFR panel members were interviewed, from 5 different PCTs. Of the PCTs invited to
participate, 1 declined due to work pressures created by the transition to CCGs. The
maximum number of people from any single PCT was 11, and the minimum 3. The
professional background and other characteristics of the participants are shown in Table
1 overleaf. Non-executive directors were distinguished from lay members, although
some of the PCTs without lay representation considered the non-executive directors to
fulfil the role of a lay member.

10.3.2 Explanatory framework
The results reported in this paper focus on three higher order core conceptual
categories which emerged: the concept of exceptionality; factors considered in
determining exceptionality; and external influences on decision making. Although
analysis of the data set revealed other themes which do not relate directly to this focus,
limits of space prevent their inclusion here.
Table 1: Characteristics of study participants

<table>
<thead>
<tr>
<th>Professional Background (Number of Panel Chairs in parenthesis)</th>
<th>Gender</th>
<th>Length of time involved in IFR decision making (Years)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Male</td>
<td>Female</td>
</tr>
<tr>
<td>Public Health Consultant</td>
<td>8 (2)</td>
<td>5</td>
</tr>
<tr>
<td>General Practitioner</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>Non-Executive Director</td>
<td>4 (3)</td>
<td>2</td>
</tr>
<tr>
<td>Lay Member</td>
<td>4 (1)</td>
<td>3</td>
</tr>
<tr>
<td>Commissioning Manager</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Nurse</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Pharmacist</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>IFR Manager</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>TOTAL</td>
<td>30 (6)</td>
<td>18</td>
</tr>
</tbody>
</table>

10.3.3 The concept of exceptionality

It was expressed that the concept of exceptionality is difficult to articulate to both patients and healthcare professionals. All of the participating PCTs used a definition of exceptionality broadly based on that provided by the NHS Confederation, cited earlier in the paper, which requires the patient to be significantly different from others with the condition, and likely to gain more benefit than usually expected. Application of the definition was widely acknowledged to be a hard task. A few participants, clinicians as well as lay members, were unclear whether the variation of the definition in use by their PCT required patients to meet one, or both, of the conditions listed. The extent to which the exceptional patient had to be different from the general population of patients with the condition in question was also perceived differently. At one extreme, different in the dictionary definition sense, as in ‘not the norm’, was applied. At the other extreme an expectation that the patient should effectively be unique was expressed. In the middle of the spectrum was the view that there should be something about the circumstances of the individual which was overlooked by those writing the baseline commissioning policy.
'is there something about the circumstances of this patient which means that this patient wasn’t in the mind of the people who made that [baseline commissioning] decision ... so had this patient been in their mind there might have been a different decision?’ Public Health Consultant

The paradox of attempting to define exceptionality was alluded to. Some participants articulated that, by its nature, exceptionality was not definable.

‘if you could define exceptionality with relation to a particular condition then by definition it should be seen as part of the original commissioning policy.’ Public Health Consultant

It was expressed that the difficulty of defining exceptionality was poorly understood, especially by the legal profession.

Inherent to determining exceptionality, using the NHS Confederation definition, is the need to establish the cohort of patients against which an individual is being compared. The focus given to this was not consistent across PCTs, although at some PCTs the cohort identified as the comparator was specifically recorded in the minutes for each decision made. The challenge of establishing whether a patient with specific key features was exceptional, or simply part of a smaller cohort, was conveyed.

Some interventions were identified by participants where it would be attractive to implement a blanket ban on access, for example, reflexology, homeopathy and vasectomy reversal. The advantage of disallowing any exceptions to non-funding policies was seen as a way of preventing well-informed, empowered patients from gaining preferential access to treatments not widely available to all. The alternative perspective was that it would be difficult for commissioning policies to envisage every eventuality, and that permitting exceptions was a humane way of allowing for individual circumstances to be considered.

‘We’re not dealing with sets of cans where we might be able to cover every eventuality ... I think we always need something in place to ensure that people who don’t fit the norm get the appropriate treatment.’ Non-Executive Director

The question of whether the right definition of exceptionality was in use was raised, although alternatives were not proposed.

10.3.4 Determining exceptionality

During the course of the interviews it emerged that some factors were considered to be strongly relevant to the determination of exceptionality. Other factors were mentioned to be of less, or no importance. These issues are reviewed below.
Clinical factors
It was universally expressed that clinical factors were a predominant consideration in assessing exceptionality. The kinds of reasons provided, which might make a person exceptional, included having a severe form of a condition, having failed standard treatment, co-morbidities or extreme side effects preventing the use of standard treatment, significant risks if treatment was not given, or an unexpected course of disease, for example, surviving much longer than the usual cohort of patients. In some instances, exceptionality was perceived to be so grounded in the clinical context that participants needed to look to clinicians on the panel for advice on determining exceptionality, although their ideas would not necessarily go unchallenged.

‘it is really quite difficult if you’re not a clinician to be able to say, yes, they’re definitely clinically exceptional...’ Non-Executive Director

In stark contrast to this was the minority view that exceptionality was something intrinsic to the patient, rather than the disease.

‘there’s something that’s happened within them that’s made them exceptional ... I think that’s, for me, that’s what I’m looking at and listening to.’ Nurse

Social factors
At some PCTs it was mentioned that clinicians submitting IFR requests frequently cited patients’ social circumstances as the basis of their exceptionality, although others remarked that this trend was decreasing. Claims of exceptionality which incorporated social factors were reported to include caring responsibilities of the patient, the existence of a young family, single parent status, the wish to witness events such as a child starting school and information about employment status and role. Some PCTs had a formal policy of not considering social factors and routinely censored this information from the panel to prevent it from inadvertently influencing decisions.

There was a division of opinions on the role of social factors in determining exceptionality, across and within panels. At one extreme were participants who asserted that social factors were irrelevant to exceptionality. Reasons given for this included that incorporating social factors into the assessment of exceptionality inevitably meant making value judgments about people’s lives, which respondents felt was morally wrong. It was also perceived that considering social factors in the assessment of exceptionality had the potential to exacerbate inequities in the way that patients were treated.
‘I just feel really strongly that you don’t judge someone’s life against another, and so we have to be very clear that we don’t take [social circumstances] into account.’ Public Health Consultant

At the opposite end of the spectrum were those participants who freely admitted to considering social factors.

‘there are social factors taken into account at times, as I say with the lady who wanted to be alive for her child’s wedding, that’s a good example.’ Lay Member

In between these polar views were three further perspectives. There were those who followed their local IFR policy guidance, which allowed consideration of social factors on a case-by-case basis. In some instances, this was at the discretion of the chair.

‘there may well be circumstances in which the non- clinical factor is taken into account and that is done on a case by case basis, at the discretion of the Chairman of the Panel…’ Public Health Consultant

A further cohort admitted that they would consider, and had in the past considered social factors, although they felt that strictly they should not. Often, respondents in this group viewed patients claiming to be exceptional in a holistic manner, and found it difficult to consider clinical factors independently of social and broader life factors.

‘We shouldn’t do really, but we do, because they do affect the whole lifestyle of a person.’ Nurse

The third group of participants again expressed the belief that they should not let social factors sway their decision making, but felt that, despite their best efforts, it was inevitable that these factors impacted on their decision making. They felt an emotional response to a patient’s circumstances which influenced their decision making.

‘Being human, we can none of us ignore the social. We’re supposed to…’ General Practitioner

One area which participants raised as being a difficult territory were claims of exceptionality based on the need to restore or maintain functions essential for the role in which applicants were employed. Examples given were a nurse who needed ophthalmic intervention to maintain her vision and a professional pianist in need of treatment to his hand so he could continue to play. Such patients universally elicited a strong sense of sympathy from panel members, but contrasting opinions were expressed on how such claims should be handled. One line of reasoning presented was that maintaining functional ability was more important for the individual in question
than the general population, and therefore the applicant could gain greater benefit from the intervention than others in their cohort. Others argued that applying a narrow definition of exceptionality which excluded employment related reasons, along with domestic related social reasons, felt instinctively wrong. An opposing view was also presented, reasoning that approving such requests discriminated against the unemployed. To some, the question of whether the importance of a particular ability to a person’s social or employment role should contribute to their exceptionality remained unresolved. Many participants stated that more guidance on the parameters of exceptionality in this context would be useful.

**Age**

IFR policies concerning exceptionality universally excluded discrimination on the basis of gender, race and sexual orientation, and this was reiterated by comments from the research participants. In contrast, age was raised as a factor which might be clinically relevant, and which should be considered in determining exceptionality if, for example, a disease was particularly rare in a certain age category, or evidence for efficacy of treatment existed only for a discrete age group.

Additionally, several participants expressed that age was a consideration in determining exceptionality, irrespective of its relation to clinical outcome. Amongst this group, younger patients were viewed more favourably. Some holding this opinion expressed reservations about whether preferential treatment of the young in the absence of supporting clinical reasons was an acceptable stance, but nonetheless admitted it influenced their perspective. Although lay members articulated this view more frequently, it was also expressed by some non-lay members.

‘One factor that perhaps you shouldn’t take into account, but I do, is age. Your decision is influenced, must be influenced, by the fact that if a person is maybe 25 and you can prolong his or her life, then that’s a very different matter to somebody who is, say, 85...I think you have to take that into account.’ Lay Member

There was a suggestion that consideration of the age of the patient had been more prevalent in the past, with a shift in attitude away from this following the introduction of the Equality Act 2010. In pursuit of being more objective, some PCTs removed all demographic information from applications before they reached the IFR panel, although one PCT had reversed its decision to remove the patient’s age from applications on the basis that it could be clinically relevant.
Clinical effectiveness
Clinical effectiveness of a requested treatment was universally agreed to be important, though it was acknowledged that for some treatments good quality evidence of effectiveness might be scanty or absent. Some IFR panels considered clinical effectiveness of a proposed treatment prior to assessing a patient’s exceptionality; others only considered clinical effectiveness if a patient was first determined to be exceptional. Where a treatment was claimed to be more effective in the applicant than for others in the same cohort, consideration of clinical effectiveness was inherent in determining exceptionality.

Private treatment
The practice of funding treatment privately, and subsequently applying for provision of NHS treatment on the grounds of exceptionality, was reported to be increasingly common. It was not clear whether this is a strategy used by patients to try to prove their ability to benefit from treatment, a last ditch attempt to continue treatment once private funds have been exhausted, or simply that patients only learn about the route of funding on the basis of exceptionality after commencing private treatment. The efficacy of privately funded treatment has usually been established, but these are treatments not routinely provided on the NHS either because they have not been deemed cost-effective, or have not yet been appraised by NICE.

Evidence of benefit from private treatment was perceived as a particularly difficult facet of assessing exceptionality, and several participants commented on the lack of legal guidance on if, and how, response to privately funded treatment should be incorporated into the assessment of exceptionality. Concern was expressed that including evidence of benefit from privately funded treatment in the assessment of exceptionality would result in disadvantage to those who could not afford to fund a trial of treatment. Many participants reported that judgments in this area were ultimately made on a case-by-case basis.

‘it’s fuzzy territory and there are judgements that need to be made...just as clinical judgements need to be made at the level of patient–clinician; these are the same kind of territory.’ Public Health Consultant

Accessing treatment after clinical trials
Accessing treatment not funded on the NHS, through participation in a clinical trial, is particularly common for new drugs or those being used for new indications. The efficacy of these treatments may not always have been established, but an individual may claim
anecdotal evidence of benefit after trial participation. Evidence of this kind, used to support a claim of ability to benefit more from treatment than others, was widely, though not universally, rejected as being irrelevant to the assessment of exceptionality. In comparison to the consideration of benefit from privately funded treatment, panel members felt they were on much firmer ground, with many citing the obligation on those responsible for managing the trial, arising from the Medicines for Human Use (Clinical Trials) Regulations\(^\text{14}\) and the Declaration of Helsinki to ensure post trial access to effective treatments.\(^\text{15}\)

**Patient responsibility for illness**

It was widely expressed that causation of the disease requiring intervention was irrelevant to the assessment of exceptionality. Exploring this idea in more depth revealed that many of the research participants felt that, as in the NHS more broadly, a patient’s responsibility for causing his own illness was only an admissible consideration in selection for treatment if continuing the causative behaviour was likely to impact on the success of the proposed treatment. Comparison was made, for example, with the lower priority given to those in need of a liver transplant who continue to drink heavily.

A deviation from this view emerged in relation to bariatric surgery. A minority of people commented that in relation to weight management, the patient’s responsibility for their condition was a consideration. This view was more frequently, but not exclusively, held by lay members. Some acknowledged that their perspective would not be regarded as acceptable by other panel members. It was perceived that obesity was a condition which patients could take action to reverse themselves, and this differentiated fatness from other conditions where the patient’s behaviour was a contributory factor.

‘*Patients overfeeding – yes, I think the reality is that that is part of our decision making. I’ll probably get sacked for saying that.*’ Commissioning Manager

**Patient choice**

Patient preference for an intervention not routinely funded on the NHS, over one that is provided, was recognised as the trigger factor for some applications for treatment on the basis of exceptionality. It was universally felt to be irrelevant to the assessment of whether or not someone could be classed as exceptional. Perspectives on this included that the requesting clinician’s assessment of what treatment a patient needed was more

\(^{14}\) Medicines for Human Use (Clinical Trials) Regulations 2004 SI 2004/1031.

important than the patient’s personal choice, and that personal choice could not extend to allowing one patient preferential access to treatment at the expense of others.

**Cost effectiveness and absolute cost**

Cost effectiveness was frequently mentioned in the IFR policies of the participating PCTs. Most IFR application forms also provided a specific section for provision of this information. One PCT was unambiguous that cost effectiveness was integral to the ethical and legal framework underpinning its decision making, and affordability was also a fundamental consideration. However, at the remaining PCTs, cost effectiveness had a much less dominant role in the assessment of exceptionality than suggested by the policy documents, with most participants expressing that it was a separate consideration from the determination of exceptionality. If it was considered, it was generally after the exceptionality of the patient had been established.

‘We make commissioning decisions based on cost effectiveness. We rarely, if ever, make exceptionality decisions based on cost effectiveness because that’s the whole point of exceptionality. It’s not a cost effective treatment that’s why the NHS doesn’t fund it...’ Public Health Consultant

In many cases, accurate cost effectiveness data was not found to be available. Similar difficulties with calculating the absolute cost of a requested treatment were also highlighted, often depending on the patient’s response to treatment and the duration of effect. Many IFR panels did not consider the absolute cost of treatments requested on the basis of exceptionality, to an extent that the cost of requests was not calculated or recorded. Some participants admitted they had been surprised to learn of the financial implications of some of the decisions they had made. Where absolute cost was considered, this, like cost effectiveness, was only reviewed after exceptionality had been established. No participant could recall an intervention for a patient who had been determined to be exceptional which had subsequently been turned down on the grounds of cost.

**10.3.5 External influences on decision making**

Although IFRs were decided by panel members, it became apparent during the course of interviewing that external influences impacted on the decision making process, in both positive and negative ways. The external influences identified are reported on below.

*Patient participation in decision making*
Patient attendance at the IFR panels involved in the study was the exception rather than the norm. Only one of the panels had a policy of allowing patients, or their representatives, to attend panel meetings, if they asked. The policy was not publicised. Decisions were only made after patients had left the meeting. Some participants felt that the presence of a patient’s representative at the panel meeting significantly changed how they viewed a case. It was expressed that panel members were gaining a degree of insight into patients’ lives, and the impact of funding decisions, which did not occur at the level of population based commissioning. There was concern that this brought with it pressures of a different magnitude. Participants were in favour of transparency and openness around the decision making process, but feared that decisions could be coloured by an individual’s personal, non-medical circumstances, and the associated pressure which resulted from possession of this knowledge.

The effect of the media

The media were perceived as having considerable power in influencing the public’s understanding of why access to treatments were sometimes denied by the IFR process. It was felt that the media’s understanding of the concept of exceptionality was largely based on the psycho-social model, reflecting their failure to grasp how the concept was applied by PCTs. Panel members were aware that full details of the patient’s circumstances, and the limitations of the intervention requested, were often omitted by the media.

‘that [case] was reported as just a straight refusal … none of the background … people didn’t know the whole story.’ Lay Member

Reporting was criticised for not covering the issue of opportunity costs.

‘new treatments are pronounced on the media and everybody thinks they’re entitled to them and we can afford them and often we can’t. Or if we can it’s at the expense of something else and that’s what I don’t think the general public understand.’ Commissioning Manager

Some PCTs had communication departments which responded to media coverage, but it was acknowledged that they were restricted by issues of data protection and patient confidentiality.

‘We’re quite defenceless in the sense that the boss wouldn’t want to reply to that article to say, but don’t forget [the requested treatment] doesn’t really work.’ Public Health Consultant
Frustration was expressed at how quickly patients resorted to using the media, in some cases before a decision had even been reached, and in many before the appeals process had been exhausted. However, the direct benefit of media publicity to patients was also recognised, with numerous examples provided of patients who had subsequently had treatment funded via private donors, or charitable campaigns co-ordinated by local newspapers.

‘We’ve had a massive Facebook campaign trying to get us change our mind on funding a patient…as a result we had 2,000 letters saying, ‘Give this patient the treatment,’ before we’d even considered whether to give him it or not.’ Public Health Consultant

IFRs were clearly perceived as a high risk area in terms of publicity. Views on the impact of the media on the decision making process were broadly divided into four kinds. One group acknowledged the presence of media pressure, but maintained that decision making should, and could, be conducted independently of its influence, to ensure that patients who did not access the media were not disadvantaged.

‘I think that can be difficult at times, particularly if you know somebody who’s dashing off to the press if you make this decision or that decision…sometimes it’s about trying to insulate the decision making panel from some of that sort of pressure.’ Pharmacist

The second group also felt that the media should not influence decision making, but feared that it had some impact, even if it were at a subconscious level, despite their best efforts not to let it. Another group acknowledged that the media did affect the decision making process, largely in a positive way, but not decision outcomes. They expressed the view that media attention ensured that the issues of a case were thoroughly debated and documented. The final group offered an entirely different perspective. They argued that there were some occasions, albeit rare, where determination of exceptionality requests in the face of widespread publicity warranted specific consideration of the PCT’s reputation.

‘There are other reasons for making decisions other than just the pure public health approach … to lose a whole lot of negative publicity for the PCT politically, with a small p, that might be an entirely rational thing to do. It actually may be entirely rational broadly for the health of the population as well because it’s quite important that the population has some faith in the structures that manage its health service.’ Public Health Consultant
The risk of legal action

The numerous judicial reviews of PCT decision making in exceptional circumstances over recent years had not gone unnoticed by IFR panel members, most of whom were familiar with what the process involved, the outcomes of previous judicial reviews, and their implications. This awareness was regarded as an essential component of a public health doctor’s knowledge base. A few participants also made reference to the relevance of European Human Rights legislation.

The risk of judicial review of PCT decisions was felt to be ever present. Some perceived that being subject to judicial review, at some point in the future, was inevitable for most PCTs. It was also expressed that should a judge choose to, he would almost certainly be able to find flaws in any decision making process. Rather than influence individual decisions, the impact of this risk was reported to make PCTs focus on ensuring their processes were as robust as possible. Minuting of decisions and reasons was seen by many to be of paramount importance. The high calibre of the discussion within IFR panels, which in turn was felt to result in high quality decision making, was directly attributed to the omnipresent risk of judicial intervention.

‘it [judicial review] just sharpens everybody’s thinking in terms of adherence to the process and the quality of the decision making...’ Public Health Consultant

The availability of legal advice in difficult cases was frequently referred to. Few individuals worried personally about the risk of judicial review, reflecting that decisions were group based.

Those panel members who had been party to court action felt that as a consequence they now had a much better understanding of the importance of process in decision making, and some felt that they had been able to develop more robust definitions of exceptionality within their organisations. Rather than feeling fearful of judicial review, those who had been through the process expressed that they had acquired new knowledge and skills, both on a personal and organisational level, which left them feeling more adequately prepared to manage any future legal challenges.

Pressure from Members of Parliament (MPs)

Letters from MPs supporting patients’ requests for treatment were reported to be a common occurrence, and responding to them was said to constitute a significant burden of work. As they rarely contained new clinical information, they were not routinely
passed to IFR panels. Unlike media pressure, the impact of MPs was nearly universally felt to be negligible.

The influence of other PCTs
IFR panels tended to have an awareness of decisions being made in neighbouring PCTs, but the influence was greatest where PCTs within a region had formally collaborated to reach consistent policies, for example, regarding in-vitro fertilisation or bariatric surgery. In one instance, a panel member from another PCT had observed a panel meeting and commented on differences in process, which was felt to have been a positive influence.

10.4 Discussion
This research offers the first comprehensive insight into how PCTs interpret the concept of exceptionality in the context of IFRs. Amongst the PCTs studied, there was evidence of consistency in the written definition of exceptionality in use, based on that issued by the NHS Confederation.\textsuperscript{16} This is a shift in practice from 2008, when a spectrum of definitions was in use.\textsuperscript{17} In practice, the overriding considerations in the determination of a patient’s exceptionality were clinical factors, relating either directly to the patient, or their response to treatment. This is in keeping with findings from earlier research on IFRs.\textsuperscript{18} It was identified that in some circumstances the age of the patient could be clinically relevant. Once exceptionality was established, evidence of clinical effectiveness of the treatment sought was a pre-requisite of approval, although it was accepted that the standard of evidence might not equate to that used in NICE technology appraisals.

Perspectives on the role of social factors in determining exceptionality revealed the greatest range of views, ranging from those members who thought that they should be absolutely excluded, to those who felt that a holistic view of the patient should be taken in assessing exceptionality. However, most of the interviews were undertaken before the judicial review of a case in which the appellant claimed that the PCT’s policy of excluding social factors in determining exceptionality breached his rights under Article 8 of the European Convention of Human Rights.\textsuperscript{19} The judge deemed that this was not the

\textsuperscript{16} The NHS Confederation. \textit{Priority Setting: managing individual funding requests}. op. cit. note 6, p 4.

\textsuperscript{17} Rarer Cancers Forum. \textit{Taking Exception: an audit of the policies and processes used by PCTs to determine exceptional funding requests}. op. cit. note 3.

\textsuperscript{18} Hughes D, Doheny S. \textit{op. cit.} note 9. 2011;73(10):1460-68.

\textsuperscript{19} R (Alexander Condliff) v North Staffordshire Primary Care Trust and the Secretary of State [2011] EWCA Civ 910
case, and that PCTs were not obliged to consider social factors which did not have direct clinical implications. As the outcome of this judicial review has brought clarity to the legal position regarding social factors in IFR decisions, greater consistency in how social factors are regarded may now exist between panel members.

Patients who had accessed a trial of treatment privately to provide evidence that they could benefit created a moral dilemma for panel members. There was concern that giving the outcome of private treatment any weight in assessing exceptionality unfairly disadvantaged those without the financial means to purchase treatment. Whilst the recent clarification of policy which permits the use of ‘top-up’ payments to purchase non-funded drugs within the NHS makes this option more accessible, it remains far from universal.20 However, given that privately funded treatment is one of the few ways in which patients can demonstrate the requirement that they could benefit more from treatment than others, excluding evidence resulting from private treatment penalises those who might choose to prioritise their spending on health, and exacerbates the difficulty which patients face in proving exceptionality.

Although attitudes towards patient responsibility for illness were fairly consistent in being non-judgmental, an exception to this emerged in relation to bariatric surgery. A similar pattern in professional behaviour has been previously observed in a study on rationing, which noted that healthcare workers were less prepared to act as advocates for the morbidly obese than for cancer patients.21 The underlying reasons for this warrant further exploration, to allow this issue to be addressed.

In contrast with population based commissioning decisions, neither cost effectiveness, nor absolute cost of treatment, was often a dominant consideration in deciding to approve treatment in exceptional circumstances. Whilst it might be expected that the cost effectiveness thresholds for population based commissioning are likely to be exceeded by interventions requested on the basis of exceptionality, there is some suggestion that where decisions to withhold treatment are based on absolute cost they are less susceptible to successful legal challenge.22 Further evidence for this comes from

21 Owen-Smith A, Coast J, Donovan J. ‘I can see where they’re coming from, but when you’re on the end of it … you just want to get the money and the drug.’: explaining reactions to explicit healthcare rationing. Social Science & Medicine 2009;68(11):1935-42.
judicial comment to the effect that it made no sense for PCTs to ignore cost effectiveness once an exceptional case had been established. In light of the relative reluctance of the judiciary to interfere with decisions to limit access to treatment on financial grounds, the relative lack of attention paid to costs is puzzling and warrants further investigation. As PCT budgets tighten to achieve the efficiency savings required by the current economic climate, it is possible that cost will become a more significant consideration in exceptional decision making.

Patient choice played virtually no role in decision making based on exceptionality, yet frequently requests were perceived to be driven by patient demand. This is illustrative of the growing chasm between what the NHS can afford to provide and the expectations created by the government’s mantra of patient choice. The language of choice is omnipresent throughout health policy, including more recently in the NHS Constitution and the Health and Social Care Act 2012. Patients have been unreservedly encouraged to take the role of consumers. Until the illusion of unfettered choice is dispelled, through greater transparency in policy and practice, pressures on the IFR system are likely to grow.

Similar disparity was evidenced between the government’s rhetoric of ‘no decision about me without me’ and the practice of decision making in IFRs. Only one panel
allowed patients to attend meetings, and this policy was not publicised. Whilst the sample in this study was not statistically representative, the finding that patient attendance at IFR panels is not commonplace is accordant with other reports. National guidance regarding patient attendance at IFR panels remains ambivalent and it is not clear whether patient involvement results in better decision making. This study revealed that personal contact with patients, or their representatives, altered the perception of some panel members, and created additional stresses. Another study has shown that patients also find the process distressing.

The reported influence of the media on the decision making process varied hugely, from those members of the panels who felt strongly that steps should be taken to insulate the panel from the impact of publicity, to those who argued that, in unusual circumstances, it might be in the wider public interest to take account of media pressure and the subsequent risk to the reputation of the PCT. This is consistent with an earlier survey which found that 9% of PCTs ‘definitely or probably’ took local media publicity into consideration when determining IFR requests.

The study revealed some gaps in participants’ knowledge. For example, not all panel members were aware of the obligations on those organising clinical trials to provide ongoing access to drugs with evidence of continued benefit to trial participants, even when this information was contained within the PCT’s IFR policy document. If screening systems are in place to ensure that applications on the grounds of exceptionality from such patients do not reach the IFR panel, then this would have no repercussions for decision making. The limited recall of the definition of exceptionality demonstrated by some participants has the potential to have greater impact. A minority were not sure if the definition in use by their PCT required the patient to be both significantly different from the cohort of patients with the condition, and to have the ability to benefit significantly more from treatment, or whether it was only necessary to meet one of these requirements. The reasons for this warrant further investigation. It is possible that...
it reflects unmet training needs, lack of clarity in the policy, or the possibility that someone with in-depth knowledge of the policy, or a copy of the policy guidance itself, is readily available for reference at panel meetings, so that there is no need for panel members to retain this information.

10.5 Limitations

It was anticipated that using PCTs operating within a range of demographic contexts would enable inferences to be drawn through comparison between cases, and between professional groups across cases, but the participants’ accounts were more homogenous than expected, with no clear pattern to the differences which were encountered. Four lay members, and four non-executive directors were interviewed as part of the research, but no consistent differences emerged in their attitudes compared with those of other panel members.

It is possible that in addition to the factors which participants reported using in the assessment of exceptionality, there are other values which they chose not to articulate, or which influence decisions at a subconscious level. The researcher attempted to overcome this by maintaining a neutral stance, a non-judgmental attitude to responses and by probing respondents’ answers. Saturation was achieved, suggesting that all relevant issues were discussed, but the possibility that this study represents an incomplete picture of the values used in determining exceptionality should not be overlooked.

The nature of the individual interviews meant that it was not possible to obtain a consensus view across a whole panel regarding why some of the decisions discussed had been reached. For example, some participants described that social factors had been considered in certain cases. It is possible that the perception of the participants as to the grounds of these decisions was not entirely accurate, due to poor recall, or misunderstanding at the time of the decision. Focus groups would have allowed these issues to be explored in a group context to confirm the accuracy of the accounts. Although time and resources did not allow for this, the relatively large sample size, and the existence of corroborating accounts from multiple participants has increased confidence that a relatively accurate picture of decision making practices has been obtained.
The willingness of the PCTs which agreed to participate, and the voluntary, self selecting nature of participants from within each panel, may have introduced an element of bias to the study. Those PCTs with more robust processes, or panel members holding particular perspectives, may have been more willing to engage in the research. This should be borne in mind when considering the generalisability of the findings.

The IFR panels also make decisions regarding the funding of treatments where no funding policy exists, for example for rare diseases. However, the findings of this study are not transferable to that context, as the focus on this study was specifically on decision making in exceptional circumstances.

10.6 Conclusion

This study represents the first significant qualitative research into the factors which IFR panels consider in determining exceptionality. The framework analysis suggested that clinical factors were of overriding importance in the determination of exceptionality, with cost effectiveness generally only being considered once exceptionality was established, in those cases where it was considered at all. Absolute cost was infrequently a consideration. Age and social factors were considered in some circumstances, and there were mixed responses regarding the relevance of evidence of benefit from a trial of private treatment and the patient’s responsibility for their illness. Some participants expressed the view that even when they thought these factors were irrelevant considerations, it was difficult not to let them influence decision making.

This study identified several external influences on the decision making process, most significantly the media and patient presence at panel meetings. The risk of legal action by patients against the PCT, was reported to have resulted in positive engagement with legal processes and principles, leading to the development of well-structured decisional processes.

The variation in weight given to different factors by different participants may in part reflect the inherent difficulty of trying to achieve consistency within a policy, which by its very nature involves discretionary decisions. However, it may also reflect unmet training needs amongst some panel members. The DoH has recently commissioned a competency framework for local decision making.\(^{33}\) Of particular relevance to the

findings in this study, it describes specific competencies required for deliberation, reasoning and ethical judgment. The framework identifies the need to challenge personal assumptions, to show a willingness to explore a personal moral position in relation to the organisation’s ethical framework, and to recognise the impact of emotion on ethical engagement with an issue and subsequent judgments. Training to ensure these competencies are met will be particularly important if the body of people responsible for IFR decision making changes with the transition of PCTs to CCGs, as the accumulated shared experience and knowledge of current panels will be lost. It is also clear that if the government is serious about involving patients in this kind of decision making, adequate support will be needed not only for patients, but also for panel members, to ensure that the specific pressures arising from patient contact in individual exceptional funding requests do not unduly distort the decision making process.

Individual commissioning decisions are not unique to England.\(^{34}\) It is likely that other healthcare systems face similar difficulties in determining when population based commissioning decisions should not apply to an individual. Although in different cultural contexts the factors considered may differ, the need to establish what these are, and apply them consistently, will prevail.

PART III: CONCLUSION

‘...the debate about priorities will never be finally resolved. Nor should we expect any final resolution.’

11.0 Conclusion

11.1 Introduction

The central theme of this thesis is the concept of exceptionality as a basis on which to allocate healthcare resources. The analysis has primarily, but not exclusively, been undertaken in the context of cancer. The life-threatening nature of cancer and the high cost of new drugs available to treat the disease make resource allocation decisions in this domain particularly acute.

Whilst much has already been written on the subject of resource allocation in healthcare this thesis represents, as far as I am aware, the most substantial piece of research undertaken to date on allocating resources on the basis of exceptionality, drawing together perspectives from law, ethics and practice, to illustrate the tensions that arise between the three.

I have questioned the ongoing use of the concept of exceptionality in its current form as a just basis on which to allocate scarce resources. In this concluding section, I argue that it is time to acknowledge that the founding principles of the NHS, namely that the NHS will meet the needs of everyone on the basis of clinical need, rather than ability to pay, are no longer achievable. We cannot continue to maintain the fallacy that all treatments are available, if only a patient can establish that their circumstances are different enough from those of the man in the next bed. The time has come to have a national debate about which treatments we would like the NHS to provide, and how we will afford to pay for those services. This will enable the concept of exceptionality to be restored to its original function, of permitting discretion in unforeseen circumstances on the rare occasions they arise. Examples might include when a patient has an unusual adverse reaction to standard treatment, which means that the standard treatment cannot be tolerated, or where standard treatment is contra-indicated because of the presence of a specific co-morbidity.

The novel aspects of this thesis have been to review how the concept of exceptionality has been interpreted by the courts,\(^1\) to use the concept of exceptionality as a case study for the application of the relevance condition,\(^2\) to undertake an empirical study of how the term exceptionality is interpreted in practice by IFR panels\(^3\) and finally, to combine

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2. See Paper 2, Chapter 9.
these three approaches to evaluate exceptionality from legal, ethical and empirical perspectives.

11.2 The submitted articles – ethical, legal and empirical perspectives

11.2.1 Exceptionality, as it is presently used, is not an appropriate basis for the allocation of scarce resources

As a clinician, I am troubled by the idea that some patients are deserving of treatment, on the basis that they are in some way exceptional, when others are not. It does not sit comfortably with the axiom that doctors should treat all patients with equal concern and respect. The legal analysis of the concept of exceptionality undertaken in Paper 1 demonstrated that the term lacks clarity. It is very difficult to ascertain in advance of an IFR application whether a patient will be considered exceptional or not, and what range of factors are pertinent to this decision. More recently, it has emerged from judicial review that unless social factors have direct clinical implications, they do not have to be considered by PCTs in their assessment of a patient’s exceptionality. However, PCTs are not precluded from considering social factors if they feel it to be appropriate, and during the empirical research it became apparent that some IFR panel members are swayed by a patient’s social circumstances, even when they report that rationally they do not consider that such factors are relevant to decision making.

Paper 3 revealed that, in practice, a lack of objectivity exists in how the concept of exceptionality is understood and applied. Although many common factors, such as severity of disease, response to standard treatment and clinical effectiveness of the requested treatment were used in the determination of exceptionality, there was nonetheless considerable variation in how the concept of exceptionality was interpreted both within and across PCTs. It was also apparent that the existence of an identifiable patient, who stood either to benefit or to suffer as a result of the assessment of exceptionality, impacted on the objectivity of decision making. This was particularly apparent if the patient, or their relatives, met with the IFR panel. Similarly, the media,

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5 Ford A. *The concept of exceptionality: a legal farce?* op. cit. note 1.
7 See Chapter 10, Section 10.3.4
either consciously or subconsciously, influenced those responsible for determining exceptionality in some cases.\textsuperscript{9}

These findings confirm that exceptionality, as it is presently used, is not an appropriate basis on which to allocate resources. The term is too loosely defined, and inconsistently applied. Whether or not a patient is assessed as exceptional is overly influenced by many factors beyond their actual circumstances, and may vary not only between different PCTs, but even within PCTs, depending on the panel members present for decision making.

11.2.2 The relevance condition is unable to do the work claimed
Despite the shortcomings of exceptionality identified above, the relevance condition, one of the four cornerstones of the Accountability for Reasonableness framework, was applied to the concept of exceptionality and was found to lack the capability to determine whether or not the concept of exceptionality is a morally relevant criterion for resource allocation.\textsuperscript{10} The critical analysis of the relevance condition, undertaken in Paper 2, found unsurprisingly that the theoretical limitations of the condition identified persist when the relevance condition is applied in practice. The relevance condition is unable to do the work claimed by Daniels and Sabin. It does not avoid the disagreements between the underlying substantive principles arising in principle based approaches. The relevance condition is unable to determine whether or not any given rationale is a reasonable basis on which to allocate healthcare resources, in advance of democratic debate.\textsuperscript{11} It is apparent that deliberation is needed not only to determine the weight to be given to any one reason in setting priorities, as promoted by the relevance condition, but also in determining whether a reason is relevant to the decision in question at all. The relevance condition therefore adds little to current decision making processes within the NHS.\textsuperscript{12} The analysis of the relevance condition confirms that Accountability for Reasonableness amounts to a procedural, rather than an ethical framework and is insufficient to meet the need identified by the DoH for an ethical framework to support IFR decision making.

11.2.3 Cancer as an exception in itself

\textsuperscript{9} See Chapter 10, Section 10.3.5.
\textsuperscript{10} See Paper 2, Chapter 9.
\textsuperscript{12} See Chapter 9, Section 9.4.2.
During the course of this research a new theme of exceptionality emerged, which has been termed ‘cancer exceptionalism’. The special status of cancer, within NHS funding, has become increasingly apparent. The first indication of this was the lowering of the cost effectiveness threshold for end of life drugs by NICE. Though theoretically applicable for any end of life drug meeting the specified criteria, in reality all treatments so far approved under this special measure have been cancer drugs. The lowered NICE cost-effectiveness threshold was followed by the Richards’ review of top-up payments within the NHS. Again, the guidance which materialised is, in theory, applicable to any disease, but the review was triggered over the furore which arose when several cancer patients had their NHS treatment withdrawn for concurrently purchasing private cancer treatment. That the review was headed by the National Cancer Director reflects that this was primarily regarded as an issue concerning access to cancer drugs. A change of government further increased the priority of cancer within the NHS budget, with the establishment of the £200 million Cancer Drugs Fund. Despite suggestions by the DoH that society may have a preference for prioritising the treatment of severe conditions, no evidence to support this claim has been uncovered during the course of this research. Rather, there is evidence that the Cancer Drugs Fund is releasing downward pressure on drug pricing in England and serving the interests of Pharma over patients.

The prioritisation of funding for cancer drugs disadvantages not only non-cancer patients, but also those cancer patients not in need of high cost treatments. Both groups

19 See Chapter 3, Section 3.2.2.
suffer through paying the opportunity costs of the Cancer Drugs Fund, and other special measures for cancer.21

The differential treatment of expensive cancer drugs makes more pressing the need to address the question of how we decide which drugs are to be funded on the NHS, when we cannot fund them all. Singling out high cost diseases for special funding is not sustainable, either nationally or on an individual level, on the basis of exceptional circumstances.

11.3 Looking backwards to find a new way forwards

11.3.1 Framing exceptionality in terms of clinical benefit and difference

During the course of this research, I looked to the courts to help elucidate the concept of exceptionality in the absence of any other source of authority on the issue. The notion of exceptionality arose from the principle of public law that public bodies are not at liberty to fetter the exercise of their own discretion.22 Following *R v North West Lancashire Health Authority, ex p A, D & G*, this principle came to be understood in the context of healthcare as meaning that PCTs must allow for departures from any policy precluding funding of a treatment to the general population, in exceptional circumstances.23 Whilst it was made explicit in *R v North West Lancashire Health Authority, ex p A, D & G* that those exceptional circumstances could remain undefined,24 *Rogers v Swindon PCT and the Secretary of State* raised the bar with respect to what was required of PCTs by stating that for polices on funding in exceptional circumstances to be rational, it must be possible to envisage what such exceptional circumstances might be.25 Although the idea that PCTs should be able to envisage what might amount to exceptional circumstances has since been interpreted in general, rather than specific terms, there was a shift in PCT policies to frame exceptionality in terms of clinical difference and, in particular, the potential to gain differential benefit from treatment, in comparison with other similar patients. This is exemplified by the NHS Confederation definition of exceptionality, which states that to be considered exceptional, a patient should be:

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21 See Chapter 3, Section 3.2.3.
23 *R v North West Lancashire Health Authority, ex p A, D & G* [2001] 1 WLR 977
24 *Ibid.*, 998
25 *R (Ann Marie Rogers) v Swindon Primary Care Trust and the Secretary of State* [2006] EWCACiv 392 para 62.
As discussed in Paper 1, the courts have been reluctant to express what should or should not constitute exceptional, and have provided little guidance to IFR panels to help in determining whether or not a patient should be regarded as exceptional. In the judicial review cases to date, the courts have stuck largely to procedural territory deeming, for example, that factors contributing to exceptionality should be ‘weighed in the round’ and that the index case should be compared against the cohort eligible for treatment. Such an approach is not surprising, as what constitutes exceptionality amounts to a substantive judgment, and this has not traditionally been the domain of judicial review. However, Paper 1 revealed that some substantive ideas relating to exceptionality are emerging, relating for example to clinical need, ability to benefit from treatment and prognosis. As discussed in Chapter 4, claims based in Human Rights are also starting to alter the courts’ traditional procedural based approach, and in the most recent judicial review involving access to treatment it was established that PCTs are not obliged to consider patients’ social circumstances when assessing exceptionality. It is possible that, if the courts increasingly adopt a substantive approach in reviewing funding decisions, greater clarity regarding what constitutes exceptionality will emerge with time. However, even if this were to develop, there is a risk that the judicial approach to exceptionality may be as varied as that of individual IFR panel members, as revealed by Paper 3, which would not be helpful.

11.3.2 Problem one: the focus of equity is lost

The development of the framing of exceptionality in terms of factors such as clinical difference, benefit from treatment, clinical need and prognosis has resulted in two problems. The first problem is that it has resulted in confusion about the question

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28 *R (Jean Marie Murphy) v Salford Primary Care Trust* [2008] EWHC 1908 (Admin) para 33.
29 *R (Ann Marie Rogers) v Swindon Primary Care Trust and the Secretary of State* *op. cit.* note 25, para 67.
30 Chapter 8, Section 8.5.3.
31 See Chapter 4, Section 4.4.3.
32 *R (Alexander Condliff) v North Staffordshire Primary Care Trust and the Secretary of State* [2011] EWCA Civ 910.
33 Paper 3, Chapter 10.
underlying the concept of exceptionality. The principle of public law that public bodies are not at liberty to fetter the exercise of their own discretion, from which the concept of exceptionality originated, indicates that the concept exists to permit the exercise of discretion in unforeseen circumstances. In a social insurance system, with limited funds, the question to be answered when assessing patients who claim to be exceptional is actually a question of equity - on what grounds can funding for this patient be justified when funding has not been made available to other apparently similar patients? Framing the question in terms of clinical difference and benefit detracts from the central question of equity, and leads IFR panels to look for ways in which patients are significantly different from others, rather than focussing on issues of equity, though the latter is undoubtedly harder to achieve. Although in determining exceptionality IFR panels are faced with a named individual, funding for patients based on grounds of exceptionality ultimately comes out of the same pot of money used for population based commissioning, and if the principles used for population based commissioning are to be diverted from, this needs to be justified. IFRs create a tension between doing the best for the individual patient in front of the IFR panel and making equitable resource allocation decisions for the population as a whole. Considerations of cost effectiveness and affordability cannot be put aside, as appeared to be the practice at some of the panels which participated in the empirical research.

11.3.3 Problem two: everyone is different

The second problem arising out of framing exceptionality in terms of clinical difference and the potential to benefit from treatment is that most patients are able to perceive themselves as having different needs, or different potential benefits from others. Patients’ expectations are raised. Messages filtering down from the DoH have exacerbated this situation, such as the letter from Bruce Keogh, NHS Medical Director which contained this extract:

‘Any decision to restrict access to a treatment or intervention must be justified in relation to a patient’s individual circumstances, and any individual affected must be able to challenge such decisions through an exceptional case review process … there will be patients for whom their individual clinical circumstances mean an intervention is likely to be of higher value in their case in comparison to others with similar conditions. This means that decisions should not be made solely on the basis of cost … individuals should always be entitled to argue that their

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34 Personal Communication, Dr Daphne Austin, Consultant in Public Health, March 2012.
35 See Paper 3, Chapter 10.
treatment is likely to be of such exceptional benefit that it deserves to be funded by the NHS..."\(^{36}\)

Keogh’s letter reinforces the idea that all patients are potentially exceptional with respect to any treatment. As argued in Paper 1, there are some treatments that are so ineffective that it would reasonable to deny provision without being able to envisage exceptions where they would be funded.\(^{37}\) Although no reference was made to \(R\) v Sheffield Health Authority, ex parte Seale in any of the judicial reviews regarding access to cancer drugs, this was the rationale behind Sheffield Health Authority’s policy in 1994 of not providing fertility treatment to women over the age of 35.\(^{38}\) Seale, a 37-year-old, contested the policy, but the court held that it was not irrational of the health authority to apply the age of 35 as a blanket cut-off, taking no account of individual circumstances, given that the authority was acting on the advice that the fertility treatment was likely to be less effective after this age and the health authority was operating in the context of limited resources. It was not even considered relevant by the court that other medical opinions existed regarding the effectiveness of fertility treatment in older age groups. This case is evidence that there are treatments that can be considered so ineffective that the decision to restrict them does not have to be justified in relation to the patient’s individual circumstances, contrary to Keogh’s advice.\(^{39}\)

The idea that all patients have the right to request virtually any treatment on the grounds of exceptionality has resulted in many PCTs receiving large numbers of IFRs. Current application rates are not published, but the most recent figures from 2009 report that 12% of PCTs had received more than 200 IFRs in the preceding financial year, and one had received 1,000.\(^{40}\) Is it really possible that all these requests warranted discretionary decisions? How many of these requests represent patients who were not envisaged, at the time at which the policies to which they claim to be exceptions were written? There is a risk that the number of IFRs, at some PCTs at least, is becoming


\(^{37}\) Ford A. \textit{The concept of exceptionality: a legal farce?} \textit{op. cit.} note 1.

\(^{38}\) \textit{R v Sheffield Health Authority, ex parte Seale} (1994) 25 BMLR 1.

\(^{39}\) Department of Health. \textit{Dear SHA Medical Director letter from Professor Sir Bruce Keogh.} \textit{op. cit.} note 36.

unsustainable. Assessing IFRs requires multi-disciplinary panels, and takes doctors away from clinical work. The process is costly and further expense arises if legal action is initiated. The money spent on managing IFRs cannot be invested in clinical care.\footnote{Welsh P. Sutent battle cost more than drug. \textit{Manchester Evening News}. 3 December 2008 http://menmedia.co.uk/news/s/1083449_sutent_battle_cost_more_than_drug (accessed 22 July 2010).} One wonders if these consequences were anticipated by Auld LJ, when he established the concept of exceptionality in healthcare. The comments of Hooper LJ, in \textit{AC v Berkshire West Primary Care Trust}, suggest otherwise.\footnote{The case has been discussed earlier, in Chapter 4, Section 4.6.1.} Although the case was cast primarily as a discrimination case, with little reference to the notion of exceptionality, Hooper LJ provided illumination on the concept when he said:

\begin{quote}
‘The use of the phrase “exceptional circumstances” tells the decision maker that the number of persons who will succeed under the proviso is expected to be a small minority. It does not otherwise provide a helpful legal test for the decision maker.’\footnote{\textit{AC v Berkshire West Primary Care Trust} [2011] EWHC Civ 247 para 64.}
\end{quote}

If the number of patients expected to successfully gain access to treatment on the grounds of exceptionality is small, why is the number of applications so high? The fundamental problem is that people’s expectations of the NHS have grown to exceed a level that the NHS can fulfil. As mentioned earlier in this thesis, the founding principles of the NHS, that care will be ‘\textit{free at the point of delivery and available to all based on clinical need, not ability to pay}’,\footnote{Department of Health. \textit{A consultation on strengthening the NHS constitution}. November 2012. http://www.wp.dh.gov.uk/publications/files/2012/11/Consultation-on-strengthening-the-NHS-Constitution.pdf (accessed 18 December 2012).} have been re-iterated with every new policy and initiative in the NHS, since 1948. Despite the national austerity measures, as recently as November 2012, at the launch of the consultation on the revised NHS Constitution, Health Minister Norman Lamb said:

\begin{quote}
‘With this Government, the founding principles of the NHS – \textit{free at the point of delivery to all, regardless of their ability to pay – will not only be supported, but reinforced ... This government will always make sure it is free to all, no matter your age or the size of your bank balance...we are strengthening this Constitution, which enshrines the right of everyone to have first class care, now and in the future.}’\footnote{Ibid.}
\end{quote}
At the same time as expecting the NHS to make savings of £20 billion, the then Secretary of State for Health peddled the myth that:

‘we will move to an NHS where patients will be confident that, where their clinicians believe a particular drug is the right and most effective one for them, then the NHS will be able to provide it for them.’

The sums do not add up. The government continues to make claims for the NHS which are simply not capable of being met with the resources available. It was apparent in Chapter 3 that the NHS can no longer deliver a universal, free and comprehensive service. The public’s expectations have been raised beyond what is reasonably deliverable. This has resulted in a sense of entitlement to treatment, with patients seeking IFRs on the basis of exceptionality when no other route to access NHS treatment remains open. When this fails, the most determined patients resort to the courts.

11.3.4 The end of exceptionality, or a new beginning?

It is time to acknowledge that the founding principles of the NHS are no longer being fulfilled. The mantra that care will be provided on the basis of clinical need, irrespective of ability to pay must be relinquished. A national debate is needed regarding what the NHS should provide, and how we afford to pay for those services, for example through increased tax or national insurance contributions. It seems unlikely that the British public would be prepared to increase contributions to the Treasury to a level that would enable the NHS to provide all available care. In the absence of comprehensive and universal care, the best alternative would be a defined basket of care, to ensure that people are aware of the level of care that will be available to them at their time of need. This would avoid the scenario, as currently occurs, where people may pay a lifetime of tax and national insurance contributions to find subsequently that the only drug available to treat their cancer is not provided by the NHS. If a well-defined basket

48 Chapter 3, Section 3.1.
of care were established, those who wished to purchase insurance to provide additional cover would be free to do so. A national basket of care would also end the local variations in care which currently exist, and ensure equity of access to services. It would also avoid the current duplication of priority setting processes which occur at every PCT.

To determine what should be included in a basket of care would require discussion on a national level. Having reviewed the relevance condition of the Accountability for Reasonableness framework, it is apparent that no procedural framework alone will provide answers regarding the optimum allocation of healthcare resources. Such a task will require democratic deliberation to determine which values are relevant and how they should be weighted. This could be facilitated through discussion forums, public hearings, community meetings and telephone surveys. Such an approach would serve simultaneously to meet the public health campaign type of approach advocated by Austin, to increase awareness of, and the need for, priority setting. Whilst facilitating collective argument will not be an easy task, this is preferable to people resorting to the courts with increasing frequency to access healthcare. Chapter 4 highlighted the limitations of the courts in adjudicating on healthcare priorities. As has been re-iterated by numerous judges, choosing between competing priorities is a political not a judicial question, and the time has come for the government to grasp the issue. Other countries have held government sponsored reviews of national healthcare priority setting and such a debate is now overdue in England. In the longer term, ongoing discourse would be required as new technologies emerge, regarding whether or not they should be included in the basket, and sustainable political structures would be needed to facilitate debate.

The grounds of exceptionality, as a discretionary route to funding should remain, because there will always be unforeseen circumstances where the inability to exercise discretion would result in harsh and inhumane consequences. However, it is anticipated that with clearer boundaries on what is not included in the health basket, and a degree of consensus on how this was arrived at, patient expectations would be more realistic.

50 See Chapter 9, Section 9.5.
51 See Chapter 4, Section 4.4.5.
52 See, for example, the comments of Brown LJ in R v Secretary of State for Health, ex parte Pfizer [1999] Lloyd’s Med Rep 289 para 17 (cited above in Section 4.4.5) and Bean J in R (Ann Marie Rogers) v Swindon NHS Primary Care Trust [2006] EWHC 171 (Admin) para 70 (cited above in Section 4.6.2).
53 For example, Norway and the Netherlands. For more detail see Ham C. Priority setting in health care: learning from international experience. Health Policy 1997; 42: 49 - 66.
As a consequence, IFR applications would be fewer, or in Hooley LJ’s words, consist of ‘a small minority’. Exceptionality should be assessed on a national, or at least supra-regional basis to enable standardisation of the concept and consistency of decision making. This may require new legislation because, at least prior to the Health and Social Care Act 2012, this statutory duty fell to the PCT and could not be delegated. Under the planned reconfiguration of the NHS, the NHS Commissioning Board, to be known as NHS England from 1 April 2013, would be well placed to oversee requests for funding on the basis of exceptionality on a national level.

In the proposed basket of care, there would be no necessity for cancer funding to be given special consideration, unless, of course, cancer emerged as a high national priority. The money allocated to the Cancer Drugs Fund could be pooled with the wider NHS budget.

11.4 The future

The NHS is in a state of flux. As PCTs transition to CCGs there is a risk that the reorganisation of IFR panels will result in a loss of the knowledge and experience that has been accumulated, with the consequence that decisions will be less robust and increasingly vulnerable to legal challenge. It is largely unclear how the IFR decision process will be managed by CCGs. Although GPs have had involvement with IFR decision making at PCTs, PCTs have been perceived as remote from patients. Any patient who makes an individual funding request to a CCG will be a patient of one of its member practices, with GPs appearing to be directly responsible for decision making. The potential conflict of interests which may arise if GPs are more closely involved with commissioning decisions has been highlighted.

Value-based drug pricing is planned for 2014. This was originally advocated by a report of the Office of Fair Trading, which argued for a major reform of the 50-year-old Price

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54 AC v Berkshire West Primary Care Trust op. cit. note 43, para 64.
56 Sheehan M. It’s unethical for general practitioners to be commissioners. BMJ;2011;342:d1430.
57 Iacobucci G. More than a third of GPs on commissioning groups have conflicts of interest, BMJ investigation shows. BMJ 2013;346:4-6.
Regulation Scheme in 2009.\(^58\) The aim of the scheme would be to ensure that prices better reflect the therapeutic value of a drug. It is hoped that this would avoid the NHS paying high prices for drugs with moderate benefits, and incentivise drug companies to focus development in areas of unmet need.\(^59\) Despite a government consultation on the concept of value-based drug pricing, details of how the proposed scheme will operate have yet to be announced.\(^60\) Whether the broader social value of drugs will be included in the evaluation remains unclear.\(^61\) It seems likely that NICE will continue to have significant involvement in the evaluation of drugs, and the scheme will only apply to new drugs reaching the market after December 2013. Inevitably, a major overhaul of the drug pricing scheme will involve significant set-up costs. The scheme may alter which drugs are prioritised for funding, but the bottom line is that Pharma will still want to see profit margins at least equivalent to current levels. The fundamental problem of affordability will persist.

The Cancer Drugs Fund is due to cease with the introduction of value-based pricing. From April 2013 the regional Cancer Drugs Funds will be amalgamated into one single fund, under the auspices of the National Commissioning Board.\(^62\) This is a significant change of course for the Cancer Drugs Fund, which was originally established to allow clinicians to make local level decisions about the drugs their patients needed.\(^63\) The very existence of the Cancer Drugs Fund continues to undermine NICE. However, if the Cancer Drugs Fund is to continue, a nationally administered fund is likely to result in less local variation in access to the resources of the Fund.\(^64\) Having recognised the value of centralising the Cancer Drugs Fund, and IFR decision making for cancer drugs, the same


\(^59\) It could be argued that the patent system already rewards innovation though, so value-based drug pricing would potentially result in drug companies being rewarded twice for novel treatments.


\(^61\) For example, the reduced burden on carers which might result from a more effective drug.


reasoning should be applied to IFR decision making for all other treatments and interventions, and the opportunity seized to centralise the IFR system more broadly.

In an effort to reduce ‘postcode prescribing’, Sir David Nicholson, NHS Chief Executive, has recently demanded that PCTs, and CCGs soon to replace them, must publish details of which NICE recommended drugs are included in their formularies by April 2013. Mike Rawlins, until recently Chair of NICE, has advocated legal proceedings against NHS bodies which refuse to fund NICE approved treatments, saying he would:

‘love one of the patient groups to take a trust to judicial review.’

Whilst Rawlins’ determination to ensure universal access to NICE approved medicines is admirable, his incitement of legal action, detraacting already stretched resources from clinical care, does not serve well in achieving his aim. The root cause of why PCTs are not including these recommended drugs in their formularies needs to be addressed. The provision of a nationally negotiated, and funded, basket of care would overcome this, ensuring adequate resources to provide the care agreed.

11.5 Concluding remarks

There are a number of issues that this thesis has not directly addressed. It has not examined the possibility of increasing the share of the national budget allocated to healthcare. This would appear to be a near impossibility in the current financial climate, but even if it could be achieved, the budget would still be limited. History has taught us that demand for healthcare will exceed the resources available to pay for it. In addition, this thesis has not investigated in any detail the option of more stringent control on drug prices. Pharma would no doubt argue that increasingly personalised medicines using pharmacogenetics requires more investment than older medicines, and already results in diminishing returns because of the smaller subset of patients for whom they are indicated. However, much basic science research takes place within publicly funded institutions, often backed by charitable donations. Furthermore, patients receive no financial reward for participating in the trials which yield evidence of the effectiveness of new treatments. In light of these factors, it could be argued that the balance between pricing and profits is set too far in favour of Pharma and the issue of drug pricing is worthy of further exploration.

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65 Torjesen I. Nicholson acts to ensure that trusts and CCGs do not blacklist drugs approved by NICE. BMJ 2012;345:e5465.

66 Dyer C. Trusts will not be able to exclude drugs approved by NICE from formularies, says Lansley. BMJ;344:e366.
I have examined the concept of exceptionality from ethical, legal and empirical perspectives and demonstrated that the concept of exceptionality is being expected to achieve work that was never anticipated for it when it first entered the medico-legal lexicon. The concept of exceptionality exists simply to permit the exercise of discretion in unforeseen circumstances. Use of the term should be restored to the rare and discretionary use originally intended. Further, it should be assessed on a supra-regional if not a national level, as has been accepted with respect to IFRs for cancer drugs, to ensure greater consistency of decision making. After a national debate, to achieve, as far as is realistically possible, consensus on an NHS basket of care, the services which could be expected from the NHS would be better defined, for both patients and clinicians. One would expect that, as a result, expectations would be modified and the number of IFRs would fall. Whilst I have offered a critical review of allocating resources on the basis of exceptionality, I have not fully developed the alternative I propose. To do so would require another thesis.

Undoubtedly further research is also needed to develop ethical frameworks which are of practical use in deciding which health services should go into the basket of care. If the DoH is serious about improving the moral legitimacy and legal robustness of resource allocation within the NHS, it should commission and fund this research.

Finally, there is no doubt that cancer is a dreadful disease. However, there are other equally awful diseases, many as life-threatening as cancer. In the absence of any convincing evidence that cancer deserves special status, the exceptional management of cancer funding must come to an end. In identifying that healthcare priority setting is a political rather than a judicial question, we should ensure that the funding of cancer treatment is not hi-jacked by politicians to achieve their own ends, distorting a potentially more equitable distribution of healthcare resources in the process.

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APPENDIX:

PUBLISHED PAPER

The Concept of Exceptionality; A Legal Farce? Medical Law Review; 2012; 20(3): 304-36
THE CONCEPT OF
EXCEPTIONALITY: A LEGAL FARCE?

AMY FORD*

Centre for Social Ethics and Policy, Institute for Science, Ethics and Innovation,
University of Manchester, School of Law, Manchester, UK
amy.ford@manchester.ac.uk

ABSTRACT

How do we decide which treatments should be offered by the National Health Service (NHS) when we cannot afford to fund them all? In the absence of a positive appraisal by the National Institute for Health and Clinical Excellence (NICE), which mandates the provision of a treatment by the NHS, Primary Care Trusts (PCTs) are free to decide whether to provide a particular drug to some, or all, of their population. However, as public bodies, it is a well-established principle of Administrative Law that PCTs are not at liberty to fetter the exercise of their own discretion. They must recognise the possibility that some patients will have exceptional circumstances, and as a consequence, any general policy prohibiting the funding of a drug cannot be absolute. In the absence of statutory guidance on what might constitute exceptional, clinicians are left guessing as to whether their patients might be eligible for funding on the grounds of exceptionality. Using the context of expensive cancer drugs, I will examine the concept of exceptionality from clinical, moral, and legal perspectives, focussing particularly on the role of social factors in determining exceptionality. I will review the cases where PCTs’ decisions not to fund cancer drugs were subject to legal action and argue that the courts have provided little guidance on interpreting the term exceptional, and that the concept has a

* National Institute for Health Research (NIHR) Doctoral Fellow, Centre for Social Ethics and Policy, Institute for Science, Ethics and Innovation, School of Law, University of Manchester, and Specialist Registrar in Medical Oncology, Clatterbridge Centre for Oncology, Merseyside. I would like to thank Professor Margaret Brazier, Professor Penney Lewis, and the two anonymous reviewers for their helpful comments on earlier drafts of this paper. I am indebted to the Brocher Foundation <www.brocher.ch> for their hospitality during the writing of this paper and gratefully acknowledge the financial support of the NIHR. This article presents independent research commissioned by the NIHR. The views expressed in this publication are those of the author and not necessarily those of the NHS, the NIHR, or the Department of Health.
limited role to play in the allocation of scarce health resources at a local level.

Keywords: Allocation of resources for health care, Cancer drugs, Exceptional circumstances, Primary Care Trusts, Judicial review, Health and Social Care Bill 2010

I. INTRODUCTION

How should we decide which treatments are offered by the National Health Service (NHS), when we cannot afford to provide them all? Drugs that may extend the life of cancer patients have attracted much media attention. When requested by patients in the absence of a positive appraisal by the National Institute for Health and Clinical Excellence (NICE), refusal of their provision has resulted in legal action against Primary Care Trusts (PCTs) who, at the time of writing, are the NHS authorities to whom difficult choices about such treatments fall. Looking forward, if the proposals outlined in the recent White Papers and the Health and Social Care Bill are enshrined in law, the NHS will undergo the most radical reform instituted since its inception in 1948. PCTs may cease to exist and GP led Clinical Commissioning Groups will have to decide who receives treatments not affordable to all. However, it is important to look back and review the lessons we can learn from the past. Wherever the responsibility for commissioning health care services ultimately lands, the need to prioritise resources will remain.

Increasing the availability of cancer drugs is perceived as being politically popular. However, as the NHS operates within the constraints of a limited budget, such choices are inevitably accompanied by opportunity costs

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1 NICE has recommended provision by the NHS of 71% of the cancer drugs it has appraised. See National Institute for Health and Clinical Excellence, ‘Nice and Cancer Drugs—the facts’ <http://www.nice.org.uk/newsroom/nicestatistics/niceandcancerdrugsthefacts.jsp> accessed 17 January 2011.


3 Health and Social Care HC Bill 2010–11 [132].

4 As an example, David Cameron, during his 2010 election campaign, unexpectedly pledged that all end of life cancer treatments would be provided without regard to cost. See N Hawkes, ‘The Political Power of Cancer’ (2010) 340 BMJ 946–7.
elsewhere in the system.\(^5\) The establishment of NICE, in 1999, was seen as an attempt to depoliticise these decisions and put an end to unequal access to treatments in different localities. NICE has undertaken technology appraisals of new drugs and treatments, to establish clinical and cost effectiveness. Generally, drugs costing below a nominal threshold of £30,000 per quality adjusted life year (QALY) have been considered by NICE to be cost effective, although this threshold was raised in 2009 for treatments likely to extend the life of patients with less than two years to live, by more than three months.\(^6\) PCTs are under a legal obligation to make available all NICE approved treatments within three months.\(^7\) NICE has been subject to extensive criticism,\(^8\) but despite its weaknesses it is an improvement on the system it replaced, when well-educated and empowered patients had disproportionately greater access to many treatments, at the expense of the rest of the population.\(^9\) For the first time, it seemed, we had a health system which, true to its name, was providing a national health service. Every ticket in the postcode lottery was a winner. In light of this, it must have come as a surprise to Ann Marie Rogers, following her diagnosis of breast cancer, to learn that whilst Barbara Clark, living in Somerset, was able to receive trastuzumab (Herceptin) on the NHS, she, residing in nearby Wiltshire, could not.\(^10\) Ultimately, Ann Marie Rogers sought recourse to the courts to access this new monoclonal antibody, reported to halve the risk of recurrence of breast cancer.\(^11\)

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\(^5\) In order to provide trastuzumab, one PCT had to cut their budget for learning disability services by £1 million/year. See AC v Berkshire West Primary Care Trust [2010] EWHC 1162 (Admin) 26 and A Barrett and others, ‘How Much Will Herceptin Really Cost?’ (2006) 333 BMJ 1118–20.


\(^11\) R (Ann Marie Rogers) v Swindon NHS Primary Care Trust [2006] EWHC 171 (Admin) and R (Ann Marie Rogers) v Swindon Primary Care Trust and the Secretary of State [2006] EWCA Civ 392.
How did this situation arise? At the time Ann Marie Rogers requested treatment with trastuzumab, it had not been appraised by NICE. Roche, its manufacturer, had not even applied for a product licence. PCTs can legitimately refuse to fund treatments not approved by NICE, save in exceptional circumstances. Barbara Clark’s PCT deemed her circumstances exceptional, whereas Ann Marie Rogers’ PCT did not, resulting in her seeking judicial review of the PCT’s decision. I will review the legal origins of the concept of ‘exceptionality’ and examine how it has been interpreted by the courts, in particular whether it is a term that should be applied solely to a patient’s clinical condition, or whether social circumstances should also be considered. I will demonstrate that based on judicial review cases to date, it is not possible to establish criteria against which to determine if a patient is exceptional.

Individual funding requests for cancer drugs constitute the largest number of funding requests to PCTs on the basis of patients’ exceptional circumstances. Cancer drugs were frequently the subject of such claims in part due to their relatively low cost effectiveness, resulting in them being less likely to gain NICE approval, and their high absolute cost, which makes them prohibitively expensive for PCTs to fund voluntarily, even for small cohorts. For many patients, they also represent the ‘last chance’ of active treatment at the end of life, making access a highly emotive issue. There is anecdotal evidence that funding patients on the basis of their exceptional circumstances is resulting in different survival outcomes from cancer within different PCTs. From an Oncologist’s perspective, the concept of exceptionality appears to be a legal farce. Cancer patients should not be treated because they are exceptional, but because they are sick and have symptoms that need alleviating, for which an effective treatment is available. The concept of exceptionality therefore has limited application clinically, morally, and legally.

Acknowledging that every public authority must be careful not to fetter the exercise of its own discretion, I shall argue that exceptionality has been far too broadly and loosely defined. It is feasible that some drugs and treatments may have such low response rates, minimal benefits, and significant side effects that it would not be unreasonable to deny their provision without anticipating exceptional circumstances in which they might be funded.

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12 R v North West Lancashire Health Authority, ex p A, D & G [2001] 1 WLR 977, 991. PCTs can, of course, choose to commission drugs for their local population which are not approved by NICE.


II. WHERE DID THE LEGAL CONCEPT OF EXCEPTIONALITY ARISE FROM?

It is a well-established principle of administrative law that a public body is not entitled to fetter the exercise of its discretion.\(^{15}\) In the context of health care, this principle was made explicit in \(R v\) \(North\ West\ Lancashire\ Health\ Authority,\ ex\ p\ A,\ D\ &\ G,\)\(^{16}\) a case where three transsexuals were refused funding for gender reassignment treatment. Auld LJ acknowledged that within limited health budgets, health authorities have to establish priorities for funding. He went on to say

> The precise allocation and weighting of priorities is clearly a matter of judgment for each authority, keeping well in mind its statutory obligations to meet the reasonable requirements of all those within its area for which it is responsible. It makes sense to have a policy for the purpose—indeed it may well be irrational not to have one.... It is proper for an authority to adopt a general policy for the exercise of such an administrative discretion, to allow for exceptions from it in ‘exceptional circumstances’ and to leave those circumstances undefined...\(^{17}\)

Auld LJ emphasised that such a policy must recognise the possibility of there being exceptional circumstances, such as overriding clinical need.\(^{18}\) This was interpreted in \(Rogers\ v\ Swindon\ PCT\ and\ the\ Secretary\ of\ State\) as meaning that

> ... withholding assistance save in exceptional circumstances ... will be rational in the legal sense provided that it is possible to envisage, and the decision maker does envisage, what such exceptional circumstances might be.\(^{19}\)

This interpretation by Clarke MR appears to raise the bar for allowing exceptions, from one where they could remain undefined, to one where it should be possible to envisage what such exceptional circumstances might be. This has resulted in a lack of clarity in the law. Exceptional cases often, by their very nature, cannot be identified in advance.\(^{20}\) Although frequently cited in subsequent cases, in practice,

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\(^{15}\) See \(R v\ Port of London Authority, ex p Kynoch Ltd\) [1919] 1 KB 176 and \(R v\ Secretary of State for Home Department, ex p Venables\) [1998] AC 407.

\(^{16}\) \(R v\ North West Lancashire Health Authority, ex p A, D & G\) (n 12) 989 and 994.

\(^{17}\) \(R v North West Lancashire Health Authority, ex p A, D & G\) (n 12) 991.

\(^{18}\) Ibid.

\(^{19}\) \(R (Ann Marie Rogers) v Swindon Primary Care Trust and the Secretary of State\) (n 11) para 62.

\(^{20}\) This issue was highlighted by the defendant in \(AC v Berkshire West Primary Care Trust\) (n 5) para 31.
Clarke MR’s comments have been taken to mean that it should be possible to envisage exceptional circumstances in general rather than specific terms. The courts have made it clear that it is not sufficient for PCTs to have a policy that theoretically allows for exceptions, when in reality a blanket ban is being enforced. In order to accommodate this requirement of allowing for exceptions to any general policy, PCTs have established Exceptional Case Panels to consider individual funding requests for treatments which are not funded for the general population.

Historically, there have been regional differences in the volume and outcome of individual requests for funding on the basis of exceptional circumstances, associated with a wide variation in the processes used to assess applications. There were also marked variations in the time taken to process requests. The NHS Constitution, implemented in 2010, was a missed opportunity to standardise the individual funding request process. With respect to local decision making, it did little more than clearly communicate the already well-established legal right that such decisions should be made rationally after consideration of the evidence. It was a survey of PCT processes by the National

21 R (Jean Marie Murphy) v Salford Primary Care Trust [2008] EWHC 1908 (Admin), para 6; R (Colin Ross) v West Sussex Primary Care Trust [2008] EWHC 2252 (Admin) para 35 and AC v Berkshire West Primary Care Trust (n 5) paras 32–33.


23 In different PCTs, these are known by a variety of names, including Individual Funding Request Panels, Clinical Priorities Committees, Commissioning Advisory Groups, and Effective Use of Resources Groups.

24 For example, not all PCTs had written protocols for assessing funding requests, and where panels were used to consider requests, membership of the panel was not always made public. See Department of Health, ‘Improving access to medicine for NHS patients’. A report for the Secretary of State for Health by Professor Mike Richards CBE (November 2008). I am currently undertaking an empirical study of the individual funding request decision making process, focussing on how PCTs interpret the term ‘exceptional’ and assess claims of exceptional circumstances. I intend to publish my results in due course.

25 The Handbook to the NHS Constitution reads ‘You have the right to expect local decisions on funding of other drugs and treatments to be rationally following a proper consideration of the evidence. If the local NHS decides not to fund a drug or treatment you and your doctor feel would be right for you, they will explain that decision to you’. Department of Health, ‘The NHS Constitution’ (March 2010) p 6 <http://www.nhs.uk/choiceintheNHS/Rightsandpledges/NHSConstitution/Documents/nhs-constitution-interactive-version-march-2010.pdf> accessed 12 October 2010. The right of patients to receive an explanation of the outcome of decisions created a new obligation on PCTs. See n 37.
Prescribing Centre\textsuperscript{26} which triggered guidance from the Department of Health, with the aim of standardising the assessment of these applications.\textsuperscript{27} This guidance also emphasises the need to distinguish between a request for funding on the basis of exceptional circumstances and multiple requests from a heterogeneous population for a new drug, the latter being more appropriately managed through the submission of a business case for a service development by the treatment provider. No specific guidance is provided on the number of patients who could plausibly be regarded exceptional before a new policy should be formally considered. However, the NHS Confederation suggests that for highly unusual conditions, if more than one case per year is expected, a policy approach should be adopted.\textsuperscript{28}

\section*{III. A MATTER OF CLINICAL EXCEPTIONS OR RAISING EXPECTATIONS?}

Many patients with cancer are exceptional, for a wide variety of reasons. Some are exceptional because of personal factors, such as the fortitude they demonstrate during treatment or the feats they accomplish during their illnesses.\textsuperscript{29} Others are exceptional on clinical grounds, perhaps because of the rarity of their cancer, or the age at which they presented with a particular tumour type.\textsuperscript{30} However, exceptionality is never a condition of treatment. In clinic, patients are not expected to show that their

\textsuperscript{26} National Prescribing Committee (n 13) Slide 28.
\textsuperscript{27} Department of Health, ‘Defining Guiding Principles for Processes supporting Local Decision Making about Medicines’ (January 2009) and National Prescribing Centre, ‘Supporting rational local decision-making about medicines (and treatments) - A Handbook of Good Practice’ (February 2009).
\textsuperscript{29} Few would deny, for example, that Jane Tomlinson, CBE, whose achievements after being diagnosed with incurable cancer included completing a marathon, a full ironman race, a 4200 mile bike ride across America and raising nearly £2 million, was an exceptional patient.
\textsuperscript{30} One possible criterion for defining an exceptional disease course for cancer is presented in M Frenkel and others, ‘Activism Among Exceptional Patients with Cancer’ (2011) 19 (8) Supportive Care in Cancer 1125–32. For examples of such patients reported in the academic literature, see GB Challis and HJ Stam, ‘The Spontaneous Regression of Cancer: A Review of Cases from 1900 to 1987’ (1990) 29 Acta Oncologica 545–50; M Glasser, MZ Rosenberg and R Gaito, ‘Widespread Adenocarcinoma of the Colon With Survival of 28 Years’ (1979) 241 JAMA 2542–3 and W Snyder, RM Clark and JR Rubini, ‘Long-term Survival of Mother and Son with Widespread Metastatic Adenocarcinoma of Colon’ (1968) 21 Cancer 129–33.
need is greater than the next patient’s, or justify their request for treatment on the basis of their domestic responsibilities, or social standing. Clinicians treat patients because they are ill, with the aim of returning them to full health, or improving their quality of life if this is not achievable.

The one respect in which a patient’s exceptional features might be a consideration for the treating physician is if these features are *clinical* in nature, such as being particularly fit relative to others with the same stage of cancer, or having had a response of unusual magnitude, or duration, to a previous treatment. These might lead one to offer non-standard anti-cancer treatment, in the belief that they might gain more benefit from this than would normally be expected. Another small subset of patients whose exceptional features might result in them being offered non-standard treatment are those who suffer intolerable side effects from conventional treatment. Additionally, patients who are ineligible for clinical trials, or who are exceptional by virtue of having a rare cancer might, in the absence of an established treatment, be offered a drug not widely available on the NHS, were there strong hypothetical reasons to believe that this treatment might be of value.

In its current form, the exceptional funding route is used to access cancer drugs which are awaiting appraisal by NICE, or have been deemed not to be cost effective, when the treating Oncologist believes that the drug offers a realistic chance of benefitting the patient, usually when there are no alternative treatments available on the NHS. The trigger for requesting funding is therefore the patient’s clinical need, rather than anything about their personal or social circumstances. It is an avenue of funding which clinicians are encouraged to explore by Department of Health guidance, before applying to the recently established Cancer Drug Fund or suggesting that

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the only option is private funding, through ‘top up’ fees, or otherwise.33 It is therefore perhaps not surprising that some PCTs have been overwhelmed by exceptional funding requests, receiving up to 1,000/year.34 Combined with a rejection rate of greater than 25%, the end result, on a national level, is a large number of disappointed patients. Anger is a common reaction when patients feel they are being denied treatment.36 Usually, the responsibility for communicating a PCT’s rejection of funding is passed to the Oncologist providing care,37 many of whom have consequently been reluctant to discuss unfunded drugs with patients.38 Clinicians are being placed in the unenviable position of raising patient’s hopes, only to shatter them. As I will demonstrate in a later section of this paper, the legal concept of exceptionality in the context of health is so elusive that Oncologists cannot use this as a basis on which to advise a patient as to whether or not it is likely to be worthwhile making an individual application for funding. A patient’s ‘exceptionality’, as far as it is applicable to clinical management at all, is very limited. Clinical factors influence the choice of treatment offered, but the wide-ranging interpretation of the concept of exceptionality which has been applied by the courts bears little relevance to this.

IV. EXCEPTIONALITY: A JUST INEQUITY OR JUST INEQUITABLE?

The idea that PCT funding of cancer drugs, in some instances, hinges on whether or not a patient is exceptional does not sit comfortably with the

34 National Prescribing Committee (n 13) Slide 5. Not all of these applications are for cancer drugs, but the survey revealed that the majority of requests for funding based on exceptional circumstances are for oncological treatments. Since the introduction of the Cancer Drugs Fund, the number of applications for cancer drugs is likely to have fallen significantly.
37 National Prescribing Committee (n 13) Slide 72.
axiom that doctors should treat all patients with equal concern and respect. GMC guidance advises doctors that the:

\[\ldots\text{treatment you provide or arrange must be based on the assessment you and the patient make of their needs and priorities, and on your clinical judgement about the likely effectiveness of the treatment options.} \ldots\]

That one individual with the same cancer should be treated differently from another, as occurred with Ann Rogers and Barbara Clark, when their respective PCTs passed differing judgments on whether their circumstances amounted to being exceptional, would appear to be a distinction not embraced by this code of conduct. Both women had breast cancer. Barbara Clark was considered exceptional by her PCT and received funding for trastuzumab, whereas Ann Rogers was not and had to seek judicial review of her PCT’s decision in order to obtain funding for identical treatment.\(^{40}\) If discriminating on the basis of age, colour, culture, ethnic or national origin, gender, lifestyle, marital or parental status, race, religion, beliefs, sexual orientation or social or economic status is not permitted, are there any non-clinical ‘exceptional circumstances’ that can morally be used to distinguish between patients when choosing who should have treatment funded? It is hard to think of any factors which would not fall under the umbrella of one of the GMC’s categories. Non-urgent NHS treatment can legally be withheld from patients who are violent towards NHS staff, if their behaviour is not a product of their medical condition and they are deemed competent to take responsibility for their actions. In this instance, non-clinical factors are used to limit to access to treatment, but this is driven by the need to ensure the safety of NHS staff, rather than the need to determine who should be prioritised for treatment when resources are limited.

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\(^{39}\) This includes personal views about a patient’s age, colour, culture, disability, ethnic or national origin, gender, lifestyle, marital or parental status, race, religion or beliefs, sex, sexual orientation, or social or economic status. General Medical Council, ‘Good Medical Practice- Guidance for Doctors’ (March 2009) para 7. <http://www.gmc-uk.org/guidance/good_medical_practice/good_clinical_care_decisions_about_access.asp> accessed 15 July 2010.

\(^{40}\) R (Ann Marie Rogers) v Swindon NHS Primary Care Trust (n 11); R (Ann Marie Rogers) v Swindon Primary Care Trust and the Secretary of State (n 11); BBC News, ‘Nurse wins breast cancer row’ (n 10).
In clinical practice, social circumstances are certainly a consideration in the management of medical conditions, and most clinicians aspire to providing holistic care, which inevitably encompasses social factors. In managing renal failure, for example, social considerations such as a patient’s occupation may determine the type of dialysis offered. Someone with a manual job, in an unsanitary environment, might be offered haemodialysis over peritoneal dialysis. This decision would be based on the clinical risk of infection if peritoneal dialysis were undertaken in an unclean environment. NICE guidance for the management of pregnant women explicitly considers social factors such as homelessness, domestic abuse, and refugee status, but again this is because of the impact of these factors on clinical outcomes for this group. However, there are also examples where social factors are considered, where there is no direct clinical relevance. Religious beliefs can influence end of life care, particularly in intensive care units. Where this influences a decision to maintain active treatment, the cost implications can be significant. An example of where occupation influences the urgency with which treatment is provided, again not based on clinical considerations, is the Department of Health mandate that armed forces veterans should be scheduled for treatment faster than others of similar clinical priority. The practice is defended on the grounds that the armed forces put their lives and health at increased risk in the interests of others, although the same claim could be advanced for members of the fire service and other public sector employees. In the past, at least, social criteria were openly used to limit access to IVF, with provision on the NHS in some areas only being available to those who were married, or in a heterosexual relationship. Here, it appears that resources were being

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43 For an example in the Canadian context, see Golubchuk v The Salvation Army Grace General Hospital 2008 MBQB 49, the case of an 85-year Orthodox Jew whose family’s religious beliefs led them to take legal action to prevent his life support machine being turned off. Three physicians, who maintained the man had no chance of meaningful recovery, resigned over the case. The man remained on life support for over eight months and eventually died despite this.
45 Ms Harriot was refused IVF on the grounds that she had a criminal record for prostitution offences, and had been rejected as a prospective adoptive or foster parent by social services. She challenged the decision, which was deemed lawful at judicial review. R v Ethical Committee of St Mary’s
allocated according to what kind of families it was deemed desirable for public money to help create.\textsuperscript{46}

Beauchamp and Childress argue that social utility should be a criterion in priority setting, but only in emergency situations, such as pandemic flu. In this context, they advance that giving priority to health professionals and other essential workers is justified on the basis that it will increase the survival of the population as a whole. They advocate limiting judgments of social value to the specific attributes which will contribute to the protection of the community, rather than assessing general social worth.\textsuperscript{47} Rescher goes further, claiming that where a social investment allows scarce medical technologies to be made available, the interests of wider society should help determine who should benefit. For this reason, he advocates assessing both a patient’s past and likely future contribution to society.\textsuperscript{48} Using social utility as a consideration in the allocation of health resources creates challenges of its own relating to the ways in which social utility is ranked, deciding whose idea of social value should be adopted, and whether those who could have conceivably contributed to their illness, through life style choices such as smoking and alcohol consumption, should be denied treatment, or given lower priority?\textsuperscript{49} Discrimination could easily arise. If carers were favoured over non-carers, it is likely more women would receive preferential treatment. And if treatment necessary to enable someone to function at work was given priority, the employed would be favoured over the unemployed.

Prioritising treatment on the basis of a person’s social function amounts to regarding them as a means to an end, rather than an end in themselves, contravening Kant’s widely accepted categorical imperative.\textsuperscript{50} Any such policy risks increasing inequity of access to


\textsuperscript{46} The ethics of this are beyond the scope of this paper. A detailed discussion can be found in MM Peterson, ‘Assisted reproductive technologies and equity of access issues’ (2005) 31 Journal of Medical Ethics 280–5.


\textsuperscript{49} For a full discussion of the use of personal responsibility in the allocation of health resources see AM Buyx, ‘Personal Responsibility for Health as a Rationing Criterion: Why We Don’t Like It and Why Maybe We Should’ (2008) 34 Journal of Medical Ethics 871–4. Draper and Sorrell also argue that patients have an ethical responsibility to promote their own health in H Draper and T Sorell, ‘Patients’ Responsibilities in Medical Ethics’ (2002) 16 Bioethics 335–52.

\textsuperscript{50} I Kant, \textit{Foundations in the Metaphysics of Morals}, trans. Lewis Beck (Bobbs Merrill Company, Indianapolis 1959) at 47 [429].
healthcare and holds the potential to give rise to claims of discrimination based on human rights. Newdick argues that unless a person’s circumstances are ‘wholly exceptional’, the practice should be avoided.\textsuperscript{51} On grounds of justice, it is time to move away from the idea that some patients are exceptional, whilst others are not, on the basis of their social circumstances. Irrespective of which theory of justice one subscribes to, fundamental to all is the principle of formal justice, attributed to Aristotle, that ‘Equals should be treated equally, and unequals treated unequally.’\textsuperscript{52} This principle has been widely interpreted as meaning that with regard to the respects which are considered relevant to the issue in question, persons equal in those respects should be treated equally. It follows that despite the many differences between patients, no person should be treated unequally, unless the difference between them and others is relevant to the treatment in question. Social differences between patients are not morally relevant to the allocation of expensive cancer drugs and should not, therefore, be used in the determination of exceptionality.

Furthermore, the current policy of funding patients at a local level, on the basis of their ‘exceptional circumstances’, results in the unjust consequence that similar patients may be treated differently depending on the PCT area within which they reside. The case for giving PCTs greater control of the health budget was to enable the purchasing of health care to be more responsive to local needs.\textsuperscript{53} The value of localism is in achieving more equal outcomes across heterogeneous regions. This is a valid goal where a community has a specific health problem relating to a particular population, or a local environment, but it makes a mockery of the concept of a ‘national’ health service when the management of some common cancers is determined on a local level. Postcode lotteries exist in other public services too, but given the extent to which health status impacts on life opportunities, inequality in health care provision is especially unjust. The current system also results in substantial inefficiencies if separate PCTs around the country have to review the evidence and cost effectiveness of new cancer drugs on an ad-hoc basis, as and when individual patients request funding.\textsuperscript{54} Given the social

\textsuperscript{53} C White, ‘Primary Care Trusts Need Local Flexibility to Deliver on Public Health’ (2002) 324 BMJ 996.
\textsuperscript{54} Some PCTs are now collaborating on a regional level to develop priority setting policies. The Priorities Support Unit, based in Oxford is an example of such an arrangement. <http://www.sph.nhs.uk/priorities> accessed 10 January 2011. It was acknowledged in \textit{AC v Berkshire West Primary
insurance nature of the NHS, patients have a legitimate expectation that even if the NHS cannot provide them with every available treatment, they will at least be treated in the same way as others using the service with the same need.55

V. THE LEGAL CONCEPT OF EXCEPTIONALITY

A. What Does It Mean to be Exceptional?

The discretionary powers PCTs have with respect to determining exceptionality allow them significant flexibility and the ability to be responsive to the needs of individual patients. However, given how fundamental this concept of exceptional circumstances is in assessing individual funding requests, to leave these circumstances undefined presents a considerable challenge for PCT policy makers and results in their decisions being vulnerable to legal dispute.56 Furthermore,

55 The NHS Constitution goes someway to addressing this. See n 25. Harris argues that individuals’ rights go beyond this, claiming that within a public health system, everyone should be entitled to an equal opportunity to benefit, irrespective of the chance of benefitting and irrespective of the quality and duration of that potential benefit. J Harris, ‘Justice and Equal Opportunities in Health Care’ (1999) 13 Bioethics 392–404.

56 Unfortunately, space constraints prohibit a full examination of what the right and proper role of the courts in the context of health care priority setting should be. Daniels and Sabin have argued against the involvement of the judiciary in this setting, where the focus is on the individual patient, with little consideration given to the institutional context and interests of the wider community. They highlight the lack of technical expertise of legally trained judges, who may lack knowledge of health economics and clinical medicine. (See N Daniels and J Sabin, Setting Limits Fairly - Learning to Share Resources for Health (2nd edn, OUP, Oxford 2008) 59). This is in keeping with Lord Bingham’s sentiment that the allocation of resources in health care was an issue ‘not fitted’ to the courts in R v Cambridge Health Authority ex parte B [1995] 1 WLR 898 at para 907. Contrary to this view, Stewart has advanced that administrative law has the potential to improve the process of decision making in resource allocation, increasing transparency and the public’s awareness of why such decisions are needed. See C Stewart, ‘Tragic Choices and the Role of Administrative Law’ (2000) 321 BMJ 105–7. Similarly, Sheldrick argues that judicial review can do more than challenge decisions with which individuals disagree, ‘leveraging access’ to policy makers and ‘opening up the system to a broader range of interests and voices’. See BM Sheldrick, ‘Judicial Review and the Allocation of Health Care Resources in Canada and the United Kingdom’ (2003) 5 Journal of Comparative Policy Analysis 149–66. James and Longley also believe that the courts have a role in explaining and justifying policy choices. R James and D Longley, ‘Judicial Review and Tragic Choices: ex parte B’ (1995) Public Law 367–73. Syrett reflects this sentiment, proposing that the courts have a role to play in enabling priority setting in healthcare to become a more deliberative process. K Syrett, ‘Priority Setting and Public Law: Potential Realised or Unfulfilled?’ (2006) 7 Med L Int 265–79.
Clinicians and patients are left uncertain as to patients’ eligibility for this funding. In an attempt at clarity, and perhaps also to try and establish consistency in their decision making, some PCTs have formulated their own definitions of exceptionality. West Sussex PCT, for example, had advanced that exceptional means ‘a person or thing or case to which the general rule is not applicable’. Barking and Dagenham PCT had suggested that exceptional was ‘not just “not the norm”’. Both of these definitions were scrutinised during judicial review. As a consequence of the lack of an agreed legal definition of what constitutes exceptional, the interpretation of this term is often pivotal when decisions regarding funding in exceptional circumstances reach the courts. However, there are strict limits on the extent to which the court can intervene in such decisions. The process of judicial review limits the courts to considering whether a PCT is guilty of procedural impropriety, has acted irrationally, or beyond its powers. The court cannot substitute its judgement for that of the PCT, but is limited to quashing the decision or remitting it back for further consideration.

B. Do Previous Judicial Reviews Serve to Elucidate the Concept of Exceptionality?

1. An ordinary reading?

Given that the concept of exceptionality is such a source of contention, one might hope that when decisions relating to the funding of drugs in such circumstances are subject to judicial review some enlightenment as to how the term should be applied might be provided. Grenfell J, in Ross v West Sussex PCT, a case in which a man with multiple myeloma sought funding for lenalidomide, has been most explicit in this regard. Here, he advised that ‘an ordinary reading’ of the term exceptional should be upheld. Yet what constitutes an ‘ordinary’ reading? Did...

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57 R (Colin Ross) v West Sussex Primary Care Trust (n 21) para 28.
59 R (Victoria June Otley) v Barking and Dagenham NHS Primary Care Trust (n 58) paras 23–25.
60 An irrational decision is one which is considered so demonstrably unreasonable, that no reasonable body could have reached it. This concept is commonly referred to as ‘Wednesbury reasonableness’, after the case from which it arose Associated Provincial Picture Houses Ltd v Wednesbury Corp [1948] 1 KB 223. Where breaches of the Human Rights Act 1998 are involved, the standard of proportionality, whereby any restriction on rights must be proportionate to the legitimate aim persuaded, can instead be applied. See R (on the application of Daly) v Secretary of State for the Home Department [2001] UKHL 26.
61 R (Colin Ross) v West Sussex Primary Care Trust (n 21) para 82.
Grenfell J mean for PCTs to open their Oxford dictionaries and apply the definition of exceptional as ‘unusual, not typical’ found within? If so, in what regard? With respect to clinical features, psychological status, family circumstances, socio or economic status? Many patients are unusual in one respect or another, so in itself, this definition is not discriminating enough. Rather than giving rise to a blanket ban, applying this definition could easily result in universal approval of individual funding requests, with all patients being considered exceptional and PCT coffers being quickly drained. PCTs would be as well to do without an exceptional funding policy and concede immediately to all patient requests for funding.

2. Consideration of social factors in determining exceptionality

Further examination of Grenfell J’s comments reveals that making decisions based purely on social circumstances should be avoided where possible. Remarks to this effect had also been made in Otley v Barking and Dagenham PCT, the case of a fifty-seven-year-old woman with metastatic colon cancer, who having tolerated five cycles of privately funded bevacizumab, sought funding for further treatment from her PCT. This must be married with Clarke MR’s assertion in Rogers v Swindon PCT and the Secretary of State that a PCT facing financial limitations could, reasonably, chose to fund cancer treatment for a woman caring for a disabled child, whilst not funding it for another with different personal circumstances. This comment strongly suggests that in some instances, social circumstances can be a determining factor of exceptionality. However, Clarke MR also makes clear his view in this case that where limited resources are not a consideration, the PCT should concern themselves only with the clinical needs of the patient, and where these needs are equal, discrimination between patients on the basis of personal characteristics is not warranted.

In Murphy v Salford PCT, one of the non-clinical factors contributing to her exceptionality submitted by Jean Murphy, who sought funding for sunitinib to treat her renal cancer, was that she was the main carer for her husband. In keeping with the example cited by Clarke MR, this was not dismissed by the judge as immaterial, but as a factor which should be considered in combination with all the other factors.

63 R (Colin Ross) v West Sussex Primary Care Trust (n 21) para 93.
64 R (Victoria June Otley) v Barking and Dagenham NHS Primary Care Trust (n 58) para 9.
65 R (Ann Marie Rogers) v Swindon Primary Care Trust and the Secretary of State (n 11) para 77.
66 R (Ann Marie Rogers) v Swindon Primary Care Trust and the Secretary of State (n 11) para 79.
67 R (Jean Marie Murphy) v Salford Primary Care Trust (n 21) para 17.
advanced. Clarke MR suggests that a carer of a disabled child could be deemed exceptional, but provides no clue as to where the line should be drawn in considering social factors in the determination of exceptionality, or how different social factors should be weighed against each other.

It is the very recent case of Condliff v North Staffs PCT, a case concerning bariatric surgery, which has finally brought clarity to this issue. Condliff was not obese enough to meet his PCT’s criteria for funding of a gastric bypass. His doctor therefore applied for funding on the basis that he was exceptional. Various reasons to support this were advanced, including that he was housebound, could no longer attend church, or play the guitar. When his application was declined, Condliff applied for judicial review. One of the grounds for judicial review was that North Staffs PCT had an established policy of excluding social factors from the assessment of exceptionality. Condliff claimed that this contravened his human rights under Article 8 of the European Convention on Human Rights. Judge Waksman deemed that social factors and Article 8 private factors are not synonymous, highlighting that whilst some private life factors may have clinical relevance, in which case they should be considered, not all social factors equate to private life matters. However, he accepted that because the PCT’s policy of excluding social factors was capable of prohibiting considerations which might fall within the wide definition of private life under Article 8, it was imperative that he did review the lawfulness of the policy.

Judge Waksman subsequently dismissed Condliff’s claim. He concluded that it would be difficult for PCTs to investigate the credibility of patients’ social exceptionality claims, let alone objectively assess them, and that taking into account social factors would be unfair to others in the cohort against which the individual claiming exceptionality was compared, whose social circumstances were unknown. In addition, he highlighted that unfair discrimination could arise if social factors were considered and reasoned that it was consistent for PCTs to follow the same broad approach as taken by the NHS in not considering social factors in treatment decisions, when they considered claims for funding on the basis of exceptionality. However, it is noteworthy that during his judgement, Judge Waksman acknowledged that some

68 Ibid, para 36.
70 Ibid, para 3.
71 Ibid, para 14.
72 Ibid, para 26.
73 Ibid, para 30.
74 Ibid, para 65.
75 Ibid.
social factors might have direct clinical implications, and he distin-
guished these from ‘non-clinical’ social factors. Condliff subsequently took his case to the Court of Appeal. Again, it was concluded that the PCT’s policy of excluding social factors did not bring Article 8 into play, and furthermore, it was deemed that even if it were applicable, the PCT’s policy was within the margin of appreciation open to it, because it had reached a fair balance between meeting the needs of individual seeking treatment and the medical needs of the wider community. The judge commented that Article 8 would not require the PCT to undertake a further balancing exercise for every individual funding request application.

3. Consideration of social factors awaits a European judgement

Condliff has now lodged an application at the European Court of Human Rights (ECTHR), challenging North Staffordshire PCT’s refusal to approve the operation. Like the UK Courts, the European Court has consistently held that Article 8 has a limited role in decisions allocating health resources. The cases cited in Condliff v North Staffs PCT illustrate this. In Sentges v Netherlands, which concerned a person with muscular dystrophy who sought a robotic arm, Article 8 was interpreted to protect the individual, creating negative obligations on public bodies and only exceptionally, positive obligations. In the latter instance, it was advised that a fair balance must be struck between individual and community interests, with a wide margin of appreciation in cases involving the allocation of resources. It was acknowledged that national authorities are in a better position to undertake this balancing act than the ECTHR. In Pentiacova v Moldova, where it was claimed that the state failed to provide adequate resources for dialysis, it was acknowledged that the boundaries between a State’s positive and negative obligations do not lend themselves to precise definition. The need for a fair balance between competing individual and group interests, and the margin of appreciation enjoyed by the State were re-iterated. The ECTHR has sent a strong message that in the context of allocating healthcare resources, complying with Article 8 requires the balancing of conflicting interests, best undertaken by the State, and involves a margin of appreciation.

76 Ibid, para 23. No examples were provided, but factors might include homelessness, domestic abuse, and refugee status. These factors are recognised by NICE as impacting on the clinical outcomes of pregnant women, see n 41.
77 R (Alexander Condliff) v. North Staffordshire Primary Care Trust and the Secretary of State [2011] EWCA Civ 910.
78 Ibid, para 52.
79 Ibid, paras 31 and 54.
80 Sentges v Netherlands, no 27677/02, 8 July 2003.
81 Pentiacova v Moldova, no 14462/03, 4 January 2005.
Other relevant cases include *Tysiac v Poland*\(^8^2\) and *X and Y v Netherlands*.\(^8^3\) *Tysiac v Poland* concerned limited access to abortion, where the rights of eligible women were more apparent than real.\(^8^4\) A positive obligation on States was found, to ensure that rights provided for, and within the remit of Article 8, could be properly adjudicated upon. *X and Y v Netherlands* did not concern access to medical care, but is relevant, because it identified a positive obligation on States to provide a framework for the enforcement of Article 8 rights.\(^8^5\) These two cases were considered by the courts in *Condliff v North Staffs PCT*. In the first instance, the judge felt that it was nonsensical to consider a framework to either adjudicate or enforce Article 8 rights in this context, given that Article 8 rights are not generally engaged in resource allocation decisions in healthcare, and individual funding requests represent part of this process.\(^8^6\) In the Court of Appeal, Toulson LJ said

> In my judgment the Strasbourg jurisprudence not only does not support, but runs counter to, the proposition that it was unlawful for the PCT to adopt a policy that IFRs [individual funding requests] should be considered and determined exclusively by reference to clinical factors.\(^8^7\)

Condliff’s hopes of success in the ECtHR look slim. However, a definitive answer from the European Court on the role of social factors in determining exceptionality maybe a long time coming. Before the judicial review of his case by the Appeal Court had been concluded, Mr Condliff re-submitted his individual funding request application with additional information, and his PCT have agreed that the new clinical information provided means he now meets the criteria for exceptionally. As a result, his case is unlikely to be expedited for consideration by the ECtHR. In the meanwhile, the English judiciary is clear; in the absence of direct clinical implications, social factors do not have to be considered in the assessment of exceptional circumstances.

4. Consideration of clinical factors in determining exceptionality
Consideration of clinical factors emerges from judicial reviews to date as less controversial, although there is little guidance as to how these

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\(^8^2\) *Tysiac v Poland* (2007) 22 BHRC 155.
\(^8^3\) *X and Y v Netherlands* (1986) 8 EHHR 235.
\(^8^4\) *Tysiac v Poland* (n 82).
\(^8^5\) *X and Y v Netherlands* (n 83).
\(^8^6\) *R (Alexander Condliff) v North Staffordshire Primary Care Trust* (n 69) para 62.
\(^8^7\) *R (Alexander Condliff) v North Staffordshire Primary Care Trust and the Secretary of State* (n 77) para 51.
should be prioritised. Reference is made to clinical need of an ‘overriding nature’,88 but what constitutes an overriding clinical need? Auld LJ, in *NW Lancs v ex p A, D & G* elaborates on this, suggesting that authorities might give priority to life threatening and other ‘grave’ diseases.89 He provides the examples of cancer, heart disease, and kidney failure as illnesses that one might expect to receive prioritisation over the treatment of transexualism.90 That this intervention may reasonably be considered as low priority was re-iterated in the recent case of a male to female transsexual seeking breast augmentation on grounds of her exceptional circumstances, which it was advanced were physical in nature, due to poor breast growth in response to hormone treatment. Her claim for judicial review was dismissed, despite an appeal.91 However, there remains a dearth of guidance from the courts on how to prioritise between other illnesses, such as the examples of cancer, heart disease, and kidney failure provided by Auld LJ.

Despite Auld LJ’s suggestion in *NW Lancs v ex p A, D & G* that life-threatening illnesses should be ordered a high priority for resource allocation, there has been no consensus over prognosis in subsequent judicial reviews. In *Rogers v Swindon PCT*,92 it was acknowledged that the PCT’s Exceptional Circumstances Urgent Review panel had considered whether prognosis might be a factor in determining exceptionality and concluded that it could not. This was not disputed in the course of the appeal.93 Duration of survival was also discussed in *Gordon v Bromley PCT*. Linda Gordon was a non-smoker, who developed lung cancer. She initially raised private funds to finance the drug erlotinib before applying, unsuccessfully, to her local PCT for continued funding. Although duration of survival was not considered to be applicable to the claimant, Ouseley J acknowledged that there may be instances where the need for short-term survival constitutes exceptional circumstances. The example, advanced by counsel for the defence, was when someone had to make arrangements for the care of children.94 The issue of prognosis also arose in *Otley v Barking and Dagenham PCT*. Mitting J highlighted the possibility that treatment with bevacizumab, the drug at the centre of the judicial review, might shrink Victoria

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88 R *v North West Lancashire Health Authority, ex p A, D & G* (n 12) 990–991 and *R (Ann Marie Rogers) v Swindon Primary Care Trust and the Secretary of State* (n 11) para 62.
89 R *v North West Lancashire Health Authority, ex p A, D & G* (n 12) 991.
90 R *v North West Lancashire Health Authority, ex p A, D & G* (n 12) 990.
91 R *v Berkshire West Primary Care Trust* [2011] EWCA Civ 247.
92 *R (Ann Marie Rogers) v Swindon NHS Primary Care Trust* (n 11).
93 *R (Ann Marie Rogers) v Swindon Primary Care Trust and the Secretary of State* (n 11) para 46.
94 *R (Linda Gordon) v Bromley NHS Primary Care Trust* [2006] EWHC 2462 (Admin) para 41.
Otley’s liver metastases sufficiently to enable a potentially curative resection.\(^{95}\) He did not explicitly suggest that this factor should be determinative of exceptionality, but his repeated reference to the PCT’s failure to evaluate the possibility that the treatment might have an impact on long-term survival suggests he thought that prognosis was relevant to the assessment of exceptionality.\(^{96}\)

5. Exceptional in comparison to whom?
A more detailed analysis of judicial review of PCT decision making in exceptional circumstances elicits several further principles with respect to determining exceptionality. One of the earliest to emerge was that the index case should be compared against the cohort of people eligible for treatment when assessing exceptionality.\(^{97}\) This appeared to provide a clear benchmark against which comparisons of ‘unusual’ features could be determined, until the subsequent judgement in *Ross v West Sussex PCT*. The latter judicial review suggested that the index case cannot be deemed *un*exceptional simply because he is representative of a group of patients.\(^{98}\) The standard of uniqueness Grenfell J perceived West Sussex PCT to have set was considered unreasonable.\(^{99}\) Combining these two outcomes leads one to conclude that whilst the comparator is the cohort eligible for treatment, the index case does not have to be uniquely different to other members of that class to be exceptional. As a clinician, this leaves one perplexed. Exactly how different from his peers does a patient need to be for it to be worthwhile pursuing funding on the basis of exceptionality?

6. Does an increased likelihood of benefit from treatment make one exceptional?
Demonstrating features which suggest the index case is more likely to benefit from treatment than others does not invariably make the index case exceptional in the eyes of the judiciary.\(^{100}\) This is a relevant clinical consideration when prescribing some cancer drugs, as several of the new monoclonal antibodies have been shown to be more effective in specific subgroups. Erlotinib, when used for non-small cell lung cancer, for example, has been shown in clinical trials to be more effective in those of Asian origin, lifelong non-smokers, and those with

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\(^{95}\) *R (Victoria June Otley) v Barking and Dagenham NHS Primary Care Trust* (n 58) paras 11–12.

\(^{96}\) *R (Victoria June Otley) v Barking and Dagenham NHS Primary Care Trust* (n 58) paras 13, 16, 18, and 26.

\(^{97}\) *R (Ann Marie Rogers) v Swindon Primary Care Trust and the Secretary of State* (n 11) para 67.

\(^{98}\) *R (Colin Ross) v West Sussex Primary Care Trust* (n 21) para 78.

\(^{99}\) Ibid, para 79.

\(^{100}\) *R (Linda Gordon) v Bromley NHS Primary Care Trust* (n 94) para 39.
adenocarcinoma on histological examination. 101 Linda Gordon possessed two out of three of these characteristics, associated with a statistically significant increase in the chance of a response, but Ouseley J was clear that possessing features which increased the likelihood of benefit did not inevitably make her exceptional. 102 However, in Otley v Barking and Dagenham PCT, a case where the PCT was deemed not to have properly applied its own exceptionality criteria, the court gave significant weight to the fact that Victoria Otley was young and fit compared to other patients in her cohort, had suffered negative reactions to alternative treatment, and had appeared to benefit from the new drug without common side effects. 103 In her case, the increased likelihood of benefiting from the drug in question was considered a relevant factor. The inconsistency in the way this aspect was considered in these two cases is particularly incoherent from a medical perspective, as gaining more benefit from a treatment than might normally be expected is one of the few clinical justifications for treating a patient as an exceptional case.

7. Considering exceptionality in the round
One of the few very clear principles to emerge from judicial review of decision making by PCTs in exceptional circumstances is that all features that might contribute to the determination of exceptionality should be considered in their totality, rather than individually. 104 In Murphy v Salford PCT, Jean Murphy advanced seven reasons for her exceptionality, of both a clinical and social nature. These included that she had metastatic renal cancer, that she had a history of breast cancer, which made her ineligible for entry into a clinical trial through which she may have been able to obtain the treatment she sought, and a history of mental health problems which were exacerbated by the treatment initially used to treat her renal cancer. In addition, she suffered from other side effects which prevented administration of the full dose and was the main carer for her husband who suffered with multiple health problems. 105 The judicial review pivoted on the fact that the PCT had considered each of the factors individually and had found none of them on their own to be of enough significance for Ms Murphy’s case to be classed as exceptional, but had not reviewed all

102 R (Linda Gordon) v Bromley NHS Primary Care Trust, n, 94, para 39.
103 R (Victoria June Otley) v Barking and Dagenham NHS Primary Care Trust (n 58) paras 20 and 26.
104 R (Jean Marie Murphy) v Salford Primary Care Trust (n 21) para 31.
105 R (Jean Marie Murphy) v Salford Primary Care Trust (n 21) para 33.
the factors ‘in the round’. Burnett J was not satisfied that had all the issues been considered together, the decision would inevitably have been the same and he therefore ordered that the decision be retaken. When the PCT re-evaluated Jean Murphy’s case in light of the judicial review, their decision that she was unexceptional remained unchanged. There was no further legal challenge.

C. Is It Possible to Establish a Model of Exceptionality to Help to Advise Patients If They are Likely to be Considered Exceptional?

The criteria for determining exceptionality, to emerge from judicial review cases to date, can be summarised as follows:

(i) An ordinary reading of the term ‘exceptional’ should be applied.

(ii) Features of exceptionality should be reviewed ‘in the round’, rather than individually.

(iii) The index case should be compared against the cohort of people eligible for treatment, but he cannot be deemed unexceptional because he is representative of a group of patients. He does not have to meet a standard of uniqueness.

(iv) In the absence of direct clinical implications, social factors do not have to be considered in the assessment of exceptional circumstances.

(v) Demonstrating an overriding clinical need for treatment presents a strong case for being considered exceptional.

(vi) Demonstrating features which suggest the index case is more likely to benefit from treatment than others can, but does not necessarily, make the index case exceptional.

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106 Ibid.
107 R (Jean Marie Murphy) v Salford Primary Care Trust (n 21) para 36.
109 R (Colin Ross) v West Sussex Primary Care Trust (n 21) para 82.
110 R (Jean Marie Murphy) v Salford Primary Care Trust (n 21) para 33.
111 R (Victoria June Otley) v Barking and Dagenham NHS Primary Care Trust (n 58) para 78.
112 R (Colin Ross) v West Sussex Primary Care Trust (n 21) para 79.
113 R (Alexander Condliff) v. North Staffordshire Primary Care Trust and the Secretary of State (n 77).
114 R v North West Lancashire Health Authority, ex p A, D & G (n 12) 990 and R (Ann Marie Rogers) v Swindon Primary Care Trust and the Secretary of State (n 11) para 62.
115 R (Linda Gordon) v Bromley NHS Primary Care Trust (n 94) para 39; R (Victoria June Otley) v Barking and Dagenham NHS Primary Care Trust (n 58) paras 20 and 26.
The patient’s prognosis need not be a consideration, but survival for a short period of time can make one exceptional, and the example provided is where care arrangements need to be made for a young child.

However, these emerging principles are of limited value to PCTs, either in formulating policy for decision making in exceptional circumstances, or for determining whether an individual should be considered exceptional. If we take the five cancer patients who sought judicial review of the funding decisions made by their respective PCTs, Ann Rogers, Linda Gordon, Victoria Otley, Jean Murphy, and Colin Ross, and apply the criteria outlined above to them, using the information available to us in the court reports about their circumstances, the manifest lack of objectivity in the concepts that emerges, aside from the suggestion that social circumstances can be disregarded, means that each individual could be determined to be both exceptional and unexceptional, depending on how the criteria are interpreted. It is no wonder that PCTs find themselves in a conundrum when attempting to establish the existence, or otherwise, of exceptional circumstances and reach decisions that will withstand the scrutiny of the courts. All five of the cancer patients who resorted to judicial review were successful in getting their PCTs’ decisions quashed. On a national level, around

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116 R (Ann Marie Rogers) v Swindon Primary Care Trust and the Secretary of State (n 11) para 46.
117 R (Linda Gordon) v Bromley NHS Primary Care Trust (n 94) para 41.
118 Although operating against a background of different cultural values, Health Maintenance Organisations (HMOs) in Israel find themselves in a parallel situation. In Israel, the state covers the cost of a minimum package of health care, referred to as the basket of services. Patients wishing to access treatments not included in the basket can claim that their exceptional circumstances warrant the provision of additional services. If these claims are rejected by the HMOs, patients may seek judicial review. Similar challenges in defining exceptionality as described in the English context have been encountered. Attempts at creating criteria against which to consider exceptionality have been made and assessment is limited to objective medical criteria. However, disagreement between judges still exists and there is regional variation in the outcomes of similar cases. Gilbar and Bar-Mor argue that the use of the concept of exceptionality is appropriate despite its difficulties, but that more just outcomes could be achieved by including all life prolonging treatments in the basket of care, taking into consideration social and personal circumstances in the assessment of exceptionality, and limiting the discretion of HMOs. See R Gilbar and H Bar-Mor, ‘Justice, Equality and Solidarity: The Limits of the Right to Health Care in Israel’ (2008) 16 Med L Rev 225–60.
119 Subsequently, all received approval for funding of the requested drug by their PCT. Jean Murphy initially received two months funding for sunitinib from a private benefactor. She then reapplied to Salford PCT for funding, on the basis that she had responded unusually well to the drug. On this occasion, her IFR was approved. BBC News, ‘Cancer patient wins drug battle’
half of patients who appeal their PCT’s decision on exceptional funding are successful in reversing a negative outcome.\textsuperscript{120} It is possible that PCTs concede to avoid costly court proceedings, which they are unlikely to win.\textsuperscript{121} The actual processes of applying for exceptional funding, appealing decisions, and seeking judicial review have become mechanisms of limiting access to drugs in themselves, with only the most empowered patients being able to pursue these avenues. Patients are often dependent on the Internet to obtain information about new drugs\textsuperscript{122} and many are not aware of the existence of the judicial review process, or the availability of pro bono legal assistance for those not eligible for legal aid.

1. An attempt at uniformity

The NHS Confederation suggests the following definition of exceptionality to aid PCTs in understanding the meaning of exceptionality within the individual funding request process:

The patient is significantly different to the general population of patients with the condition in question and the patient is likely to gain significantly more benefit from the intervention than might normally be expected for patients with that condition.\textsuperscript{123}

The first part of the definition is in keeping with Rogers \textit{v} Swindon PCT\textsuperscript{124} and Ross \textit{v} West Sussex PCT,\textsuperscript{125} in that the patient needs to be different from the cohort of patients with the condition, but not uniquely so. However, its usefulness is limited by the absence of guidance as to how the patient should be ‘significantly different’. The latter half of the definition is consistent with Otley \textit{v} Barking and Dagenham PCT,\textsuperscript{126} which suggested that increased likelihood of benefitting from a drug was a relevant factor. This case was subsequent to

\begin{itemize}
  \item[\textsuperscript{120}] National Prescribing Committee (n 13) Slide 61.
  \item[\textsuperscript{122}] This is illustrated by \textit{R (Ann Marie Rogers) v Swindon Primary Care Trust and the Secretary of State} (n 11) para 4 and \textit{R (Victoria June Otley) v Barking and Dagenham NHS Primary Care Trust} (n 58) para 2. Both Rogers and Otley gained their knowledge about the new treatments they sought from the Internet.
  \item[\textsuperscript{124}] \textit{R (Ann Marie Rogers) v Swindon NHS Primary Care Trust} (n 11) para 67.
  \item[\textsuperscript{125}] \textit{R (Colin Ross) v West Sussex Primary Care Trust} (n 21) para 79.
  \item[\textsuperscript{126}] \textit{R (Victoria June Otley) v Barking and Dagenham NHS Primary Care Trust} (n 58) paras 20 and 26.
\end{itemize}
Gordon v Bromley PCT when Ouseley J passed comment that possessing features which increased the likelihood of benefit did not inevitably make her exceptional.\textsuperscript{127} Whether this definition can withstand legal scrutiny will not become apparent until a PCT which has adopted it is subject to judicial review.\textsuperscript{128}

VI. CAN THERE BE MORE THAN ONE LAWFUL ANSWER TO A POLICY QUESTION?

As judicial review is essentially an assessment of procedural, rather than substantive correctness, \textit{prima facie} it appears that there could be more than one lawful answer to a policy question. This suggestion was advanced by Bean J in Rogers v Swindon PCT.\textsuperscript{129} He was making reference to the fact that some PCTs had chosen to fund trastuzumab for the entire eligible group, whilst others had not. Although his ultimate judgement in this case was subsequently overturned by Clarke MR,\textsuperscript{130} Bean J raises an interesting possibility. If there can be more than one lawful answer to a policy question, how would this apply to the funding of cancer drugs in exceptional circumstances? It would follow that a patient could legitimately be considered exceptional within one PCT, but not within another, as effectively happens at the moment with the so-called ‘postcode lottery’. Why should the same person potentially be treated differently in two PCTs? One possibility is that X might appear exceptional in PCT A when compared with the cohort of patients with the same disease living in that region, but not when compared with the cohort of patients in PCT B. Thus, that X could be treated differently is based on the evidence that there are significant differences between two groups with the same disease but who live in different PCT regions. The existence of such factors is not implausible, and may relate, for example, to the genetics of the local population. These factors would seem most credible when the number of patients in each cohort is small; i.e. the disease in question is relatively rare. However, if the number of patients in each cohort is large, for example those with breast cancer, then it would seem unlikely that there would significant differences between the populations with the

\textsuperscript{127} R (Linda Gordon) v Bromley NHS Primary Care Trust (n 94) para 39.
\textsuperscript{128} It is noteworthy that in R (Alexander Condliff) v. North Staffordshire Primary Care Trust and the Secretary of State (n 77) paras 19–25, the judge quoted extensively from the NHS Confederation document containing this definition. Although reference was not made to the definition itself, the document was clearly regarded as an authoritative source.
\textsuperscript{129} R (Ann Marie Rogers) v Swindon NHS Primary Care Trust (n 11) para 68.
\textsuperscript{130} R (Ann Marie Rogers) v Swindon Primary Care Trust and the Secretary of State (n 11).
disease in PCT A and B. Under these circumstances, if Patient X is considered exceptional against the comparator pool in PCT A, she should, logically, also be considered exceptional against the comparator pool in PCT B, which will consist of like patients to the comparator pool in PCT A. So, if Bean J is right, and the cohort against which exceptionality should be measured is those patients with the same condition, it follows that, at least with respect to determining exceptionality for the funding of cancer drugs, there should only be one policy answer to the policy question; a patient who is considered exceptional within one PCT should be considered exceptional within every PCT. This deduction presents a strong case for the determination of exceptionality on a national level, if the concept is to be used as the basis on which to allocate funding.

VII. MUST AN EXCEPTION BE ENVISAGED FOR EVERY INDIVIDUAL DRUG?

As discussed earlier in Section II, the principle that it must be possible to envisage circumstances in which a drug might be funded when declining applications on the basis of exceptional circumstances was established in R v North West Lancashire Health Authority and re-affirmed in Rogers v Swindon PCT. The first suggestion that this principle might be deviated from appeared in Gordon v Bromley PCT. In response to the question of whether Bromley PCT had imposed a blanket ban on the provision of erlotinib, Ouseley J suggested that:

The claimant might well go too far in saying that an exception must be capable of being envisaged for every drug in order for refusal in an individual case to be lawful.

He proceeded to give the example of a drug that ‘...may simply not have sufficient proven routine clinical benefit...’ However, in Murphy v Salford PCT, which was decided subsequent to Gordon v Bromley PCT, it was strongly re-affirmed that this original principle not only still held, but was not controversial. It was also considered in Ross v West Sussex PCT and AC v Berkshire West PCT.

Ouseley J’s remark that it might not be imperative to envisage an exception for every drug is worthy of exploration. Are there some drugs

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131 R v North West Lancashire Health Authority, ex p A, D & G (n 12) 991.
132 R (Ann Marie Rogers) v Swindon NHS Primary Care Trust (n 11) para 62.
133 R (Linda Gordon) v Bromley NHS Primary Care Trust (n 94) para 39.
134 Ibid, para 39.
135 R (Jean Marie Murphy) v Salford Primary Care Trust (n 21) para 6.
136 R (Colin Ross) v West Sussex Primary Care Trust (n 21) para 35.
137 AC v Berkshire West Primary Care Trust (n 5) paras 32–33.
and therapies for which there is so little evidence of benefit that it would be preposterous for a PCT to be expected to envisage exceptional circumstances when they might be funded?\(^{138}\) If a PCT denied funding of Chinese herbal medicine, or Gerson Therapy,\(^{139}\) would they be expected to envisage circumstances in which they would be provided? It may be that in the future, there will be licensed cancer drugs which are so expensive, and with such low response rates, which even when they do work provide very limited extension of life, accompanied by such significant side effects, that it would be reasonable to deny provision without being able to envisage exceptions where they would be funded. This is not to refute that the cancer patients whom they are designed to treat do not have an ‘overriding clinical need’, but unfortunately in many cases it is a need for which no effective magic bullet

\(^{138}\) Assessing the clinical effectiveness of new treatments is a common challenge for exceptional case panels, as the treatments requested are often in early clinical use, or for rare conditions where little evidence exists. The traditional hierarchy of evidence places well conducted meta-analyses of randomised controlled trials (RCTs) at the top, followed by individual RCTs, observational studies (such as cohort and case control studies) and finally case studies and expert opinion. See T Greenhalgh, *How to Read a Paper—The Basis of Evidence Based Medicine* (4th edn, Blackwell Publishing, Oxford 2006) 16. In the absence of RCTs, PCTs must rely on forms of evidence lower down the hierarchy. Even when RCTs and meta-analyses exist, results may be conflicting. It is usual for Exceptional Case Panels to have at least one or two people specifically responsible for researching and presenting the evidence for requested treatments, often with a Public Health background. It is much less common for panels to include a hospital consultant, although supporting evidence is usually sought from the requesting physician. See National Prescribing Committee (n 13) Slide 11. In *R (Colin Ross) v West Sussex Primary Care Trust* (n 21) para 91 confusion over the outcome of some of the relevant trials was apparent. The limited information available in law reports may not reveal the true extent of this problem. Although there is no formal role for a medical expert ‘witness’ in the judicial review process, both parties can submit written evidence from a medical expert to support their position. Given the relatively low position of personal opinion in the evidence hierarchy, the weight which has been given to individual expert’s views during judicial review is surprising. This is particularly apparent in *R (Victoria June Otley) v Barking and Dagenham NHS Primary Care Trust* (n 58) para 20 and *R (Colin Ross) v West Sussex Primary Care Trust* (n 21) paras 57, 71, and 72. In the latter case, the defendant challenged the claimant’s medical specialist of straying into territory beyond his expertise, by commenting on the PCT’s application of their exceptionality policy, but this objection was dismissed by the judge. It would appear that the limits of medical opinion in cases concerning exceptionality have yet to be defined.

\(^{139}\) A controversial cancer treatment involving the consumption of fruit and vegetable juices, coffee enemas, and weekly injections of vitamin B12 and liver extract. The latter alone are reported to cost £20,000/year. ‘Now Charles backs coffee cure for cancer’ *The Observer* (27 June 2004) <http://www.guardian.co.uk/society/2004/jun/27/themonarchy.medicineandhealth> accessed 1 March 2010.
exists. If resource constraints were not an issue, it could be argued that little would be lost by trying drugs even with low effectiveness. However, in a social insurance health system, every treatment carries an opportunity cost. Providing an expensive cancer treatment with low effectiveness means that another patient, and possibly many other patients, will be deprived of treatments with better effectiveness. It is neither a rational or ethical use of limited resources to spend money on very high cost, low benefit, treatments. Whilst it would be an appropriate and logical action for a self-interested patient approaching the end of life, when funding is provided by a social insurance system, it makes no sense from a societal perspective. That patients who apply for funding on the basis of their exceptional circumstances are identifiable makes these decisions harder, especially when individual’s stories are sensationalised in the media, but statistical patients treated are of no less value than identified patients. A preference for identified lives is irrational and the heart wrenching tales in the court must be subject to dispassionate analysis, so that unknown patients without a voice do not suffer.

VIII. AN END TO LOCAL EXCEPTIONALISM?

Lord Darzi proposed to end the postcode lottery three years ago and Andrew Dillon, Chief Executive of NICE, has also called for consistency in PCT decision making. In the absence of clear legal criteria on the determination of exceptionality, reaching decisions which are robust enough to withstand judicial review is challenging and PCTs are exposed to the risk of costly legal action. Furthermore, the money and time spent by PCTs on defensive legal action cannot be invested in improving clinical care. Clinicians are left bewildered as to why some seemingly very similar patients are deemed exceptional, when others are not. The process of applying for funding on the basis of exceptional circumstances creates unrealistic expectations for patients, fuelled by

141 Ibid.
142 Department of Health, ‘High Quality Care For All NHS Next Stage Review Final Report’ (June 2008) p 44.
144 This point was acknowledged by the judiciary in R v Secretary of State for Social Services, ex p Walker (1987) 3 BMLR 32, one of the early judicial review cases involving the allocation of resources for infant cardiac surgery.
media hype145 and indirect marketing by pharmaceutical companies.146 In addition, seeking recourse in the courts is not an option easily accessible to all, further increasing inequities between patients.147 If there are inadequate resources to fund all effective cancer treatments, we should not hide behind the concept of exceptionality, but should have an open and honest debate as to how we reach a consensus on which drugs to fund, and how we are prepared to pay for those

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146 Pharmaceutical companies are governed by strict guidelines with respect to direct marketing to patients, but human interest stories of individuals ‘fighting’ to obtain cancer drugs help raise public awareness and stimulate demand. Of 361 national news stories reviewed between 1998 and 2006 focusing on trastuzumab, 65% named breast cancer patients. See P Wilson and others (n 145). There is suggestion that the drug industry actively seeks out suitable patients to support through public relations companies. For example, after writing about her diagnosis of breast cancer, Professor Lisa Jardine was contacted by a public relations company working for Roche, and offered help in obtaining trastuzumab prior to its approval by NICE. See S Berg, ‘Herceptin: Was patient power the key?’ BBC News (9 June 2006) <http://news.bbc.co.uk/1/hi/health/5063352.stm> accessed 7 February 2010. Pharmaceutical companies also have a close relationship with patient advocacy groups, providing significant financial sponsorship. Given their common interest in increasing access to cancer drugs they are not uneasy bedfellows, but there is a risk that the association may result in a lack of objectivity on the part of patient groups. For a more detailed discussion, see K Jones, ‘In Whose Interest? Relationships between Health Consumer Groups and the Pharmaceutical Industry in the UK’ (2008) 30 Sociology of Health and Illness 929–43 and RE Ferner and SE McDowell, ‘How NICE may be Outflanked’ (2006) 332 BMJ 1268–71. The House of Commons Health Select Committee has recommended that steps should be taken to restrict the influence of drug companies on patient support groups, see Health of Commons Select Committee, ‘The influence of the pharmaceutical industry: Fourth report of session’ HC (2004–05).

147 As Sheldrick highlights, multiple factors influence patients’ access to the courts, including the existence, or not, of legal aid and the organisational capacity of interest groups. BM Sheldrick, ‘Judicial Review and the Allocation of Health Care Resources in Canada and the United Kingdom’ (2003) 5 Journal of Comparative Policy Analysis 149–66. For example, in her attempt to access trastuzumab from Bristol North NHS PCT, Elisabeth Cooke, a psychiatric nurse, was supported by the trade union Unison. ‘Thompsons and trade union campaign for Herceptin’ (12 June 2006) <www.thompsons.law.co.uk/ntext/thompsons-trade-union-campaign-herceptin.htm> accessed 7 January 2011.
treatments it is agreed should be provided. The Cancer Drugs Fund has widely increased access to oncological treatments, although evidence of regional variations in access is already beginning to emerge,148 and there has been no evaluation of the opportunity cost to other health services of financing the Fund. With the introduction of value-based drug pricing, planned for January 2014,149 and Clinical Commissioning Groups, there is a risk that access to cancer drugs could become an even bigger postcode lottery. Unlike PCTs, Clinical Commissioning Groups will not operate at arm’s length from patients, and GPs may be more vulnerable not only to pressure from patients and their families, but also to the external influences which arise in funding requests on the basis of exceptionality, including those from the media, patient support groups, and the pharmaceutical industry.150 The decision for the outcome of NICE technology appraisals to remain mandatory will help reduce this.151 When a drug is not nationally approved, there


150 In a survey of PCT decision making in ‘exceptional circumstances’, ten PCTs admitted that local publicity and media influenced their decision making. ‘Cancer patients facing exceptional difficulties to get funding for cancer drugs’ Macmillan Press release (29 October 2008) <www.macmillan.org.uk/Aboutus/News/Latest_News/Cancer_patients_facing_exceptional-difficulties_to_get_funding_for_drugs.aspx> accessed 22 March 2011. This decision to change the status of outcomes of NICE technology appraisals from mandatory to advisory was reversed during the Government’s ‘listening exercise’ on the Health and Social Care Bill, when many GPs said they were not happy to effectively have the power to ration treatments. Removing NICE’s mandatory powers would have moved the NHS from a position where local funding of the relatively few cancer drugs not approved by NICE was at the discretion of PCTs, to a position where the funding of all cancer drugs was at the discretion of Clinical Commissioning Groups. See A Gulland, ‘NICE Confirms Its Role in New NHS after Government
will, on occasion be reason to treat one cancer patient differently from others with the same condition, on clinical grounds. For example, if there is reason to believe, they may benefit more from a treatment than usually expected, or if they suffer intolerable side effects from standard treatment. From a medical perspective, these patients could be considered exceptional. The restructuring of the NHS presents a perfect opportunity to start assessing these patients on a national, or at least supra-regional basis, to enable standardisation of the concept of exceptionality and consistency in the determination of exceptionality.\(^{152}\) This would be more just, ensuring that like patients are treated in the same manner, irrespective of their place of residence. A nationally ring fenced pot of money to fund those patients deemed to be exceptional would also prevent destabilisation of the budgets of the proposed new Clinical Commissioning Groups from the need to find funds to finance expensive treatments at short notice.

The misconception that all new cancer treatments emerging onto the market are wonder drugs must be challenged. This myth serves only to provide false hope and defer conversations about the end of life, a topic which both the healthcare profession and wider society need to learn to address more comfortably. This is not to say that the pharmaceutical industry should not be rewarded fairly for innovation. Drug research and development is expensive, but pharmaceutical companies spend twice as much on marketing as research.\(^{153}\) Patient access schemes\(^{154}\) and regulation of drug pricing may go some way towards making new cancer drugs affordable, but with the pace of development of medical

\(^{152}\) Consistency of decisions could be improved, if, for example, the individual funding decision process were to be run by clusters of Clinical Commissioning Groups, covering larger populations. In Wales, it has already been suggested that the appeals process for exceptional funding requests should move to a single national system. M Aylward, ‘Health Commission Wales: A Review’ (June 2008) <http://www.wales.nhs.uk/sites3/Documents/568/Health%20Commission%20Wales%20A%20Review%20%28Eng%20Report%29.pdf> accessed 10 January 2011.


\(^{154}\) Patient access schemes involve either the supply of a limited amount of free drugs, or drug rebates. Whilst having the potential to save the NHS money, such schemes have been criticised because of their high administration costs and the failure of the NHS to reclaim all monies due. For sunitinib alone, a drug used to treat kidney cancer, it is alleged the NHS has failed to reclaim nearly £4 million. For more detail see S Williamson and T Thomson, ‘A Report Into the Uptake of Patient Access Schemes in the NHS’ (2010) 2 Clinical Pharmacist 268–70.
technologies it is inconceivable that we will ever be able to afford every available treatment. Even if the health budget were to be increased, we would still need a fair and just way of deciding which treatments should be financed. Funding patients on the basis of exceptionality, determined locally, is not the answer.