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Exceptionality in the context of individual funding requests

James Hart
Sapfo Lignou
Mark Sheehan
Ethox Centre, University of Oxford
Correspondence email: james.hart@ethox.ox.ac.uk.

ABSTRACT

The National Health Service operates under significant resource constraints, both financially and in terms of staffing, leading to challenges in providing comprehensive healthcare for all. This poses a problem for commissioners: how do we prioritise treatment allocation? Chris Newdick's influential work in ethics and law has shaped discourse in this area for over three decades. However, we critique a specific aspect of Newdick's work concerning individual funding requests (IFRs) within the healthcare resource allocation system.

The allocation problem involves balancing population-wide healthcare needs with the ethical imperative to treat individuals. Decision-making frameworks like the 'Accountability for Reasonableness' (A4R) framework aim to address this by fostering fair processes. In the United Kingdom, local priority forums, guided by ethical frameworks, play a crucial role in resource allocation decisions. While these processes strive to be fair, they are not flawless. These processes cannot consider every potential patient perspective, circumstance or reason for needing treatment. To address this, A4R frameworks include mechanisms for revision and appeals. IFRs form an important part of this picture by providing a recourse for patients whose cases may not have been adequately considered because they are in some sense unusual or 'exceptional'.

However, current processes often rely on a problematic interpretation of 'exceptionality' which fails to align with A4R principles. This interpretation sometimes excludes those who ought to be included, and includes those who ought to be excluded. We argue for a revised understanding of exceptionality to ensure fairness and effectiveness in resource allocation processes informed by Newdick's work.

Keywords: individual funding requests; IFR; exceptionality; significant clinical benefit; resource allocation; accountability for reasonableness.

INTRODUCTION – THE PROBLEM OF ALLOCATION

The NHS has persistently been operating in circumstances of limited resources, both financially and with regards to staffing. Unfortunately, this means the National Health Service (NHS) cannot treat everyone for every condition. This poses a big problem for commissioners: who should receive treatment and for which conditions? Chris Newdick's work both in academic and in policy contexts over the past 30 years has had a profound effect on how the NHS, policymakers and academics have thought about and dealt with this question. His book, *Who Should We Treat?*, tackled this question head on and has set the standard for academic work in ethics and law in this area since it was first published in 1995.[1] In what follows below, we take issue with one small part of the Newdick corpus of work, which deals with individual funding requests (IFRs) within the healthcare resource allocation system.

The problem of allocation is a nasty one. The NHS does not just face the challenge of providing comprehensive healthcare for the whole population within budgetary constraints, but it must also take seriously the particular needs of individual patients. Ethics and justice require that the NHS must be open to treating individuals, and it should sometimes actually treat them, even when this means a less effective distribution of resources at the population level.[2]

Of course, the NHS needs to weigh these various obligations to solve how it will allocate healthcare resources in any given timeframe. But inevitably it is impossible to find agreement on any solution to how we ought to allocate these resources and which obligations the NHS ought to meet. More fundamentally, we cannot even find agreement on the strength of various obligations and needs, nor on which principles govern how we ought to weigh such obligations. This disagreement occurs even among those who recognise that there is reasonable disagreement and are disposed to find a just and fair solution. How then do we solve problems where there is reasonable disagreement but where decisions need to be made?

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[1] Chris Newdick, *Who Should We Treat?* (Clarendon Press 1995).

[2] See Chris Newdick, 'Judicial review: low-priority treatment and exceptional case review' (2007) Medical Law Review 236–244, and Chris Newdick, 'Rebalancing the rationing debate: tackling the tensions between individual and community rights' in Eckhard Nagel and Michael Lauerer (eds), P*rioritization in Medicine: An International Discussion* (Springer 2016) 123–140.

In the context of reasonable disagreement, United Kingdom health law follows an 'Accountability for Reasonableness' (A4R) framework.[3] As Newdick has carefully articulated, the central insight of this approach is that, where we cannot agree on any solution or particular distribution of resources, the only way to make progress is to construct a process that treats the disagreement respectfully so that all those affected by the outcome can sign up to the decisions that the process generates.[4] That is, we should adopt a decision-making process that treats reasonable claims fairly and gives all patients a fair opportunity for the best healthcare that can be provided.

In the NHS, local and regional priorities forums/committees are an instantiation of this process. They make recommendations to commissioners about allocations and the recommendations typically become policy for that region. These forums have 'ethical frameworks' which include sets of relevant considerations that guide (but, importantly, do not determine) the decision-making process. Forums receive evidence appraisals, expert advice and, crucially, patient perspectives and consider the information provided in accordance with the ethical framework.[5] In the South Central region, the *Ethical Framework* was initially drafted by Newdick in 2004 and represents the gold standard, adopted and adapted across the NHS.

This process thus treats all those with claims to healthcare with respect. It listens to the concerns of patients, their carers and clinicians. It allows reasonable disagreement to be aired, promotes discussion of the various ethical considerations and gives space for different values to be expressed and accounted for. The ensuing policy, whilst not to the satisfaction of everybody, ought to be acceptable to all as the conclusion of a fair procedure.

Nonetheless, these processes are not flawless. Relevant considerations which ought to have been taken into account can be missed, and reasonable perspectives accidentally ignored. In such cases, the persons whose circumstances or perspectives have been left out of the process have not been treated fairly and have grounds for not assenting to the policy decision that affects them.

For this reason, A4R frameworks include versions of the following Revision and Appeals Condition:

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[3] See Norman Daniels and James E Sabin, *Setting Limits Fairly: Can We Learn to Share Medical Resources?* (Oxford University Press 2002) and Norman Daniels, Mary B Saltonstall and James E Sabin, 'Accountability for reasonableness: an update' (2008) British Medical Journal 337.

[4] Chris Newdick, 'Can judges ration with compassion? A priority-setting rights matrix' (2018) Health and Human Rights Journal 107–120.

[5] Thames Valley Priorities Committee, *Terms of Reference* (2021).

> **Revision and Appeals Condition:** There must be mechanisms for challenge and dispute resolution regarding limit-setting decisions, and, more broadly, opportunities for revision and improvement of policies in the light of new evidence or arguments.[6]

This condition achieves two goals. First, it allows decision processes to improve and to correct prior errors in light of new evidence. Secondly, it gives voice to those whose circumstances or perspectives were excluded from the initial decision process and who thus have not been treated fairly by the otherwise fair process.

In practice, this condition is partly captured in the local priorities committee's ethical framework via exceptionality conditions. For instance, the Thames Valley Priorities Committee (TVPC) used to include the following:

> There will be no blanket bans on treatments since there may be cases in which a patient has special circumstances which present an exceptional need for treatment. Individual cases are considered by each respective CCG [clinical commissioning group]. Each case will be considered on its own merits in light of the clinical evidence. CCGs have procedures in place to consider such exceptional cases through their Individual Funding Request Process.[7]

Individuals thus have access to recourse against the CCG (and the priorities committee) if they have not been given the proper consideration that they are owed. To do so patients, alongside their clinicians, submit an IFR, outlining why their case is exceptional.[8] This IFR is then screened to ensure it meets the relevant initial exceptionality criteria and has a reasonable chance of success. If it passes the screening, it will then be sent to an IFR panel to decide whether the funding request is successful. The IFR process thus provides fair consideration for the individuals who were originally excluded from the decision-making process.

For instance, the NHS does not routinely fund breast reduction surgery.[9] Such surgery is considered cosmetic and thus is not routinely commissioned: it is one of a whole set of procedures that are understood, broadly, to be not medically necessary (or 'medically indicated') and so are low priority. However, there are clearly cases where patients might claim exceptionality. For example, when a patient develops severe and chronic back pain as a result of excessive breast size. Such patients can currently apply via the IFR process for surgery on this basis.

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[6] Daniels and Sabin (2002) 45 (n 3 above)

[7] Thames Valley Priorities Committee, *Ethical Framework* (2017) 5.

[8] NHS England, *Commissioning Policy: Individual Funding Requests* (2023).

[9] Thames Valley Priorities Committee, *Commissioning Policy Statement No TVPC 16: Aesthetic Treatments for Adults and Children* (2015).

The IFR process is only intended to decide in a particular individual's case and does not change the policy itself. However, during the screening process (or at the request of the IFR panel), if the individual's circumstances indicate that there is a wider group of patients for whom these considerations of exceptionality apply, then changes to the policy might be necessary and these would need to be considered either via reconsideration by the priorities forum or through the alternative Service Development process.[10] The Service Development process develops new (or makes amendments to) routine commissioning policies by looking at the clinical evidence for new services or clinical pathways, their financial and organisational impact, and their value for money.

Importantly, the IFR and Service Development processes together capture the Revision and Appeals Condition of A4R. Both processes allow individuals with reasonable claims to appeal decisions, and they ensure that those who might have been excluded from the fair process have a means to be included. The Service Development process also means that, where necessary, policies can be revised and improved.

Of course, the entire process turns on how we understand exceptionality and, specifically, how we determine when an individual's case is exceptional. In our view, this issue has not been given sufficient attention and has led to, what we take to be, a weakness in local priorities forums' ethical frameworks and the current IFR processes they oversee.[11]

On the face of it, we can separate out two different interpretations of exceptionality in this context:

1. *Particular patients themselves are taken to be exceptional cases.* On this interpretation, patients are compared with other patients in order to determine their status: the key reference point is the population of patients (with this condition/requiring this

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[10] NHS England (n 8 above) 10.

[11] There has been some consideration of these issues in the academic literature: see Amy Ford, 'The concept of exceptionality: a legal farce?' (2012) Medical Law Review 1–33 and 'Accountability for reasonableness: the relevance, or not, of exceptionality in resource allocation' (2015) Medicine, Healthcare and Philosophy 217–227. Ford's criticisms largely focus on the lack of conceptual, ethical and legal clarity around the concept of exceptionality, and she, largely, argues against funding on the basis of exceptionality. Whilst we agree with many of her criticisms, we believe exceptionality still plays an important role in just allocation. In our opinion, many of her criticisms are predicated on the first of the two interpretations of exceptionality that we outline and argue against in this article. We hope our article also provides some more needed conceptual and ethical clarity on how the concept should be used, though there will be legal and practical issues that will still need addressing.

treatment). The patient will be taken to be exceptional if, on some measure, they stand out markedly from all other patients. The most obvious scale of comparison here will be the benefit that they stand to gain from the treatment.

2. *Particular patients represent, or present as, exceptions to the rule or policy.* On this second interpretation, the key reference point is the rule or policy. What matters here are the considerations that lie behind the policy. The patient's circumstances are compared to the circumstances considered when setting the policy. In particular, this may involve considering the kind of benefit to the patient or the patient's reasons for needing or valuing the benefit.

In the following we consider both of these interpretations. We will argue in favour of the second interpretation and against the first. We will show that the first interpretation is problematic because it includes in the process those who ought to be excluded and excludes some of those who ought to be included. It also does not match the A4R reasoning and justification that Newdick has helped develop and implement.

Importantly, Newdick has been instrumental in developing the current IFR process. In particular, he was central in the writing of both the Welsh individual patient funding request (IPFR) policy and the TVPC *Ethical Framework*.[12] Unfortunately, both of these policies are based on the first interpretation of exceptionality. As such, we suggest that current, Newdick-informed processes are not fair and not fit for purpose. In the final section, we will outline how the ethical frameworks and IFR processes could be amended to capture exceptionality in line with the second interpretation.

EXCEPTIONAL PATIENTS AND SIGNIFICANT CLINICAL BENEFIT

Let us start then with the first interpretation. On this interpretation patients are exceptional if they can sufficiently distinguish themselves from the reference population, namely others with the same or similar conditions. In practice, this has been further limited only to differences in clinical benefit, where a patient is deemed exceptional only if they can gain significantly more clinical benefit from a given treatment than others in similar positions. For instance, a patient whose breast size is causing chronic pain issues that have not been resolved with other treatments, can demonstrate that she will gain significantly more clinical benefit than other patients requesting breast reduction surgery.

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[12] NHS Wales, *NHS Wales Policy: Making Decisions on Individual Patient Funding Requests (IPFR)* (2017); Thames Valley Priorities Committee, *Ethical Framework* (2021).

She would thus count as exceptional. We can see this approach in IFR policy. The Welsh IPFR's exceptionality condition reads as:

> It is important to note that the NHS in Wales does not operate a blanket ban for any element of NHS healthcare. We will consider each IPFR on its individual merits and in accordance with the arrangements set out in this policy. We will determine if the patient should receive funding based on the *significant clinical benefit* expected from the treatment and whether the cost of the treatment is in balance with the expected clinical benefits.[13]

Clinicians thus need to submit an IPFR application describing:

> i. why the patient is likely to gain a significant clinical benefit from the proposed intervention; and
>
> ii. demonstrating that the value for money of the intervention for that particular patient is likely to be reasonable[14]

Similarly, the TVPC has the following exceptionality condition:

> There will be no blanket bans on treatments since there may be cases in which the clinician providing the care can demonstrate why an individual patient is likely to obtain *significant clinical benefit* at reasonable cost from an intervention which is not normally funded.[15]

Plus these two clauses for determining if an intervention meets the exceptionality condition:

> (a) the clinician can demonstrate persuasive evidence why the patient's clinical circumstances are significantly different to those of the population of patients for whom the recommendation has been made not to use the intervention, **and**
>
> (b) the clinician can demonstrate why the patient is likely to gain significantly more clinical benefit from the intervention than would normally be expected from patients for whom the recommendation is not to fund it[16]

In practice this means that those who can demonstrate that they have more capacity to benefit from the treatment are eligible for funding whilst those who do not have such capacity (or cannot show that they have such capacity) are ineligible.

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[13] Ibid 5 (our italics).

[14] Ibid.

[15] TVPC (n 12 above) 5 (our italics).

[16] Ibid.

Criticism 1 – the scope is too wide

Firstly, this approach includes patients in the process who ought not to be included. Allowing individual cases to be evaluated via the IFR process will sometimes allow the re-litigation of issues that have already been considered in the development of the policy. Of course, re-litigating issues is an inefficient use of an IFR panel's time, but more importantly, it is unfair.

If the policy has been developed with the knowledge that some patients might receive significantly more clinical benefit relative to others (or stand out markedly from all other patients for some other reason), and it has nevertheless been decided that the treatment will not be funded for those patients, then they have already been included in the process. This means that these individuals have already had their circumstances considered, and their perspectives listened to, in the policy-setting decision. Whilst there might still be reasonable disagreement about whether the decision was the right one, the individuals' circumstances have been included in the process and thus not treated unfairly.

For instance, consider again our breast reduction surgery case. Suppose that the initial policy-setting process considered breast reduction surgery not just for aesthetic reasons, but also for chronic pain-related reasons. Suppose it, nevertheless, came to the same conclusion that surgery should not be routinely funded, and made no exception for pain-related reasons. In this case, on the significant clinical benefit account, the small number of patients with chronic pain would still be eligible for consideration by IFR. This is because they stand out significantly from the majority of the population for whom the recommendation is not to fund, and they are capable of gaining significantly more benefit than that population. But given that the initial policy discussion included their circumstances, this would simply be re-litigating these cases.

To re-litigate these individual cases then, is to give the individuals a second opportunity to settle the reasonable disagreement in their favour. But this is clearly unfair. The whole point of an A4R framework is that a fair procedure is agreed at the outset such that all claims are considered, and the resulting decision can be agreed to in advance and assented to by all involved. To use a crude analogy, it is like permitting a rematch for a team already knocked out of a competition, or moving from best of three to best of five after someone has already lost. If we allow certain individuals a second opportunity, whilst denying that opportunity to others, we undermine the credibility of the entire process. Those who do not get a second opportunity are treated unfairly. Of course, we are not suggesting that those who unfairly benefit from these processes are purposefully cheating the system, or are acting unfairly themselves. They are individuals, often in desperate circumstances, trying to navigate a complex healthcare system, and deserve compassion. But such compassion does not justify unfair treatment, when there are others just as deserving of compassion who will miss out.

As is so often the case, this unfairness does also look likely to intersect with, and be magnified by, socio-economic disparities: those from disadvantaged groups are much less likely to receive a second opportunity to advance their case. There is some, admittedly anecdotal suggestion, that access to the IFR process is not distributed equally across regions and demographic contexts: those patients and clinicians who are better educated and better placed to access more specialised healthcare are similarly better placed and more likely to access the IFR process. Whilst disparities are neither unique to IFR nor to this particular definition of exceptionality, this definition of exceptionality does have the potential to worsen their effects. Disparities affecting people's ability to access and navigate a fair process will apply to all approaches (though they should, of course, be mitigated where possible), but this approach to exceptionality also introduces disparities where some can disproportionately benefit from an *unfair* second opportunity to have their case considered.

Criticism 2 – the scope is too narrow

Perhaps more problematically, this approach also excludes many whom it ought to include. Firstly, the current conditions require clinicians to demonstrate the potential for significant clinical benefit. This seems reasonable, until we recognise that this includes only those who can provide evidence of the potential to benefit. Naturally, this means many for whom gathering evidence is difficult, or for whom there is a lack of evidence, are excluded from the process.

Of course, those who are most exceptional are likely to be those who are least able to provide evidence in support of their claims. For instance, patients with rare diseases, unusual presentations or complex comorbidities present some of the most exceptional cases and are least likely to have been considered in the policy-setting process. However, the nature of these cases means there is less research and evidence available on the effects of any particular intervention on those individuals. If evidence was relatively available, then it ought to be (and is likely to have been) accounted for in the initial policy decision. Perversely then, on the 'significant benefit' criteria, those who are most exceptional are those most likely to be excluded by the exceptionality condition! Moreover, this is likely to adversely affect those from minority and disadvantaged groups disproportionately more than those from majority groups because they are under-represented in medical research.[17]

Furthermore, in the way this has been developed in practice, it also puts the burden of proof on the wrong people. It should not be up to the clinician, or the patient, to demonstrate that there is potential for significant benefit. This role ought to be performed by the experts assigned to collect and review the evidence (in the TVPC's case this is a specialised Commissioning Support Unit) that is then presented to the IFR panel. Clinicians are not well placed to gather and assess this evidence, and we might think it is an inefficient use of their time. It also introduces too much arbitrary luck into the process. Certain clinicians will be much better at demonstrating a patient's need or ability to benefit than others, and this will lead to disparities in access.

Secondly, this approach limits the kinds of considerations that can make an individual's circumstances exceptional to the clinical realm. Doing so excludes many potentially relevant considerations from the process before deliberation even occurs. It is important to remember that the scope of reasonable disagreement that the priorities forums intend to address is supposed to allow space for disagreement about fundamental values, to give voice to patient perspectives and consider a wide variety of ethical considerations. By limiting the initial scope to clinical benefit, we ignore these vital elements of the process.

For instance, a drug may not normally be funded because there is a cheaper and more effective alternative. However, suppose the alternative uses compounds derived from blood. A Jehovah's Witness could not demonstrate significantly greater clinical benefit than others with her same condition, and so she would be excluded from the IFR process. However, it seems as if she has a good claim to being an exceptional case. The process has ignored her important core beliefs and fundamental values, and so she has a strong claim to having been treated unfairly and not having had a chance to express her disagreement. By defining exceptionality as significant clinical benefit, we have missed the inherent value laden-ness of these decisions.

Furthermore, there are cases where a patient may gain significant benefit from treatment by allowing them to perform 'activities of daily living', though these might not register as clinical benefits.[18] In one case a grandmother of a particular ethnicity who lived in a close-knit ethnic community was unable to leave her house due to

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[17] Andrew Smart and Eric Harrison, 'The under-representation of minority ethnic groups in UK medical research' (2017) Ethnicity and Health 65-82.

[18] Thames Valley Priorities Committee, *Commissioning Policy Statement Policy No TVPC 101: Application of the Use of 'Activities of Daily Living' to Individual Funding Requests* (2020).

the stigma caused by her hirsutism. This also prevented her from looking after her grandchildren, picking them up from school and such, and performing other basic activities. Whilst depilatories are not particularly expensive, the TVPC (and its constituent CCGs) did not routinely fund cosmetic surgery. Thus, her case might also have been excluded from consideration as the way in which she would benefit is not clinical.

These cases are good examples of how the narrow scope can get things wrong. But it is important to note here that these are not just unfair consequences caused by an ineffective process. The process itself is unfair if it excludes these considerations. When the initial policy decision was made, it would have been made in light of these wider relevant features, not just the clinical benefits.[19] Patient perspectives, a variety of values and the wider ways patients could benefit would all have been considered in the development of the policy. Thus, there was scope for reasonable disagreement on these features. If those whose cases were initially excluded from that deliberation do not have their cases judged on the same range of features, then they have not been treated equally to those who were.

More broadly, this entire approach of treating certain individuals as exceptional seems to go against the fundamental A4R justification. It treats some people as exceptional, as if the rules do not apply to them. If we have a fair process that we use to settle disagreement, but then we allow some people to have their cases determined outside of that process, this undermines the whole justification and process for settling the reasonable disagreement. How are patients supposed to sign up to the conclusion of such a process in such circumstances? They would have good claims to withholding their assent.

Understanding exceptionality in this way then is clearly flawed. No patient should themselves be considered exceptional. The rules and policies ought to apply to everyone equally, and no one should be considered above or outside those rules. This is the only way that we can treat everyone equally and ensure all reasonable individuals can sign up to the ultimate decision that commissioners have to make.

However, if this is the case, how ought we to understand exceptionality, and how can the Revision and Appeals condition of A4R be met?

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[19] Of course, if these features were not taken into consideration, then the policy-making process was itself deficient.

EXCEPTIONAL CIRCUMSTANCES

We need to develop an understanding of exceptionality then that does not violate the fair procedure with which we make decisions. Such a definition ought to exclude those who ought to be excluded and include those who ought to be included. We suggest that exceptionality should thus be understood not relative to other patients, but relative to the considerations that determined the rule. Recall the second interpretation of exceptionality:

2. *Particular patients represent, or present as, exceptions to the rule or policy.* On this second interpretation, the key reference point is the rule or policy. What matters here are the considerations that lie behind the policy. The patient's circumstances are compared to the circumstances considered when setting the policy. In particular, this may involve considering the kind of benefit to the patient or the patient's reasons for needing or valuing the benefit.

For instance, in the breast reduction surgery case, a patient who has very severe pain issues would count as having exceptional circumstances if the policy was only developed with aesthetic considerations in mind. The kind of benefit she would receive, and her reasons for needing the surgery, differ from the circumstances that were considered when determining the policy. The policy was determined in light of aesthetic considerations, but this patient's reasons for needing care are pain-related. Her circumstance thus represents an exception to the rule.[20]

Fundamentally, this approach better matches the A4R framework and allows us to settle reasonable disagreement in a way that is procedurally fair to all participants. The conclusion of the process can thus receive broad assent. Instead of treating some people as deserving to be treated outside of the process, we treat all people as deserving to be included in the process. In this way it does not undercut the ethical legitimacy of the initial commissioning decisions but reinforces it.

We thus suggest amending (in italics and underlined) the Welsh IPFR policy to something like the following, to better capture this second approach to understanding exceptionality:

> It is important to note that the NHS in Wales does not operate a blanket ban for any element of NHS healthcare. We will consider each IPFR on its individual merits and in accordance with the arrangements set out in this policy. We will determine if the patient should receive funding based on *(a) whether the patient has special circumstances which were not considered when the policy not to fund treatment was decided, (b) the patient's reason for needing treatment, and (c)* whether the cost of the treatment is in balance with the expected clinical benefits.

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[20] If there is a sufficiently large cohort of individuals whom this affects, as there is for breast-reduction surgery, then there should also be an update in the policy.

And simplifying the evidence clinicians need to submit as part of an IPFR application to:

i. *why a patient's reasons for needing the intervention differ significantly from the reasons considered when setting the policy*; and

ii. demonstrating that the value for money of the intervention for that particular patient *has the potential to be* reasonable.

In the TVPC context, we suggest reverting to the older definition of exceptionality with a few tweaks and updates:

> There will be no blanket bans on treatments since there may be cases in which a patient has special circumstances which *were not considered when the policy not to fund treatment was decided*. Individual cases are considered by each respective ICB [integrated care board]. Each case will be considered on its own merits in light of *the patient's reason for treatment and* the clinical evidence. ICBs have procedures in place to consider such ~~exceptional cases~~ through their Individual Funding Request Process.

And that the clauses for determining whether a patient's circumstances count as exceptional should be updated in the following way:

(a) the clinician can demonstrate ~~persuasive evidence~~ why the patient's clinical circumstances are significantly different to the general population of patients for whom the recommendation is not to use the intervention, **and**

(b) the clinician can demonstrate why the *patient's reasons for needing the intervention differ significantly from the reasons for needing the intervention given by* patients for whom the recommendation is not to fund it[21]

Of course, these amendments to both the Welsh and TVPC policies are only sufficient for determining whether a case is eligible for review. The panel will have to adjudicate on whether the individual's case is strong enough, and the cost reasonable enough, to be worth funding. Nevertheless, these eligibility criteria may reduce the burden on clinicians (in doing so they may also reduce disparities in applications) and mean the IFR experts are the ones who will gather evidence on effectiveness. Most importantly, these changes would mean that the process is more consistent with A4R and so fairer: those who were excluded from the process can now have their claims included with fewer barriers to entry.

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[21] It might be necessary to include guidance about what kinds of circumstances, considerations and reasons might count as exceptional. This may look like a list of potential sources of reasons and could include example cases to help guide clinicians and relevant support staff.

Correct scope

This approach to exceptionality gets the scope right in all the cases that the prior definition got wrong. First, it excludes all those who ought to be excluded: those whose circumstances have already been considered in setting the policy do not have a second opportunity to have their circumstances considered.

Now, it is important to say here that this does not mean there is no process for appealing the decision not to fund treatment. The appeals and revision condition in A4R requires that all policy decisions can be appealed and updated if necessary. There need to be options for holding decision-makers to account for their decisions, and there needs to be a mechanism for adjusting policy in light of new evidence, or changes in finance, opportunity cost, and even social values, as well as to correct for errors made in prior decisions.

What is importantly different, however, is that exceptionality and the IFR process would not be the way that individuals can challenge or appeal such decisions (if their circumstances were considered in the original policy-setting decision). Such individuals would only have access to the same appeals process as others who might benefit from a treatment that is not funded, but who could not demonstrate significantly greater clinical benefit than average. Any successful appeal would then change the routine commissioning policies. In this way, there is no two-tier system of appeals, and, if an appeal is successful because the policy is lacking in some way, then the update will apply to everyone, not just that individual.[22]

Our interpretation of exceptionality also includes everyone who ought to be included and was excluded by the significant clinical benefit approach. Firstly, it includes individuals whose cases are perhaps so unusual that there is a lack of accessible evidence to demonstrate their exact potential to benefit. Of course, this is not to say that decisions ought to be made without regard to clinical evidence or without good reason to think that the patient might benefit. Only that such factors should not initially exclude such cases from consideration. Relevant experts via the IFR screening process ought to be responsible for

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[22] There are, of course, further questions that fall outside of the scope of this article about what these appeals processes look like, and how they should relate to IFR. Both successful and unsuccessful IFR appeals may tell us about how policies should be improved, and more attention should also be paid to service development processes and reviewing current policies. It will be particularly important that there is a level of consistency between these different processes and that individuals do not fall through the gaps between different processes or are left in policy development limbo. See Warwick Heale and Keith Syrett, 'Challenging NHS England's individual funding request policy' (2018) British Journal of Healthcare Management 218–221.

identifying evidence and deciding whether the case has a reasonable chance of success, rather than leaving it to clinicians to provide such evidence. Such cases would thus still be included in the process, even if they were ultimately unsuccessful.

Secondly, it includes all those whose circumstances (or reasons for needing treating) were not considered in the initial policy-setting process. This includes those whose clinical circumstances are different, but importantly also those whose fundamental values and beliefs were not included in the initial process (ie the Jehovah's Witness case) and those whose social circumstances mean they stand to benefit by allowing them to perform more basic activities of daily living (ie the hirsutism case). Again, even if there are good reasons not to fund the treatment in these cases, simply including them in the process respects the individuals by giving them a fair chance.

Nevertheless, we might still worry that our approach sometimes excludes some people from consideration when they ought to be included. There may be cases where an individual has the potential for significant clinical benefit, and their case is so unusual that it would be inappropriate for the Service Development process. In which case it seems appropriate for this individual to go through the IFR process. We might think that by stepping away from the significant clinical benefit approach, this person's case would not be eligible for review.

However, whilst we have presented our approach as an alternative to significant clinical benefit, that is not to say significant clinical benefit could not count (in some limited circumstances and in conjunction with other features) as exceptional circumstances. A patient's potential for significant clinical benefit can count as exceptional when that larger amount of clinical benefit was not (or indeed could not have been) considered in the original policy-setting decision. In that case, the individual was initially excluded from the process. They thus need to have their case included. But note here that the justifying reason to include their case is because they were initially excluded, not because they could gain significant clinical benefit. The significant clinical benefit is simply the contingent property which generates that justifying reason.

For instance, suppose there is a drug that helps tackle anxiety and depression. The drug is expensive, and its effects are only very minor, so the drug is not funded. Now suppose that there is strong evidence that the effects on one individual will be very strong. It is not known why the effects on this individual are so much stronger than for others, and there seem to be no other exceptional circumstances to explain it.[23] In this case, whilst we cannot identify any other exceptional reasons, the individual's greater capacity to benefit will itself count as exceptional circumstances. The policy decision did not consider individuals who would gain such large benefits and so such individuals were excluded from the process and are eligible for IFR review.

In this way, the significantly greater scale of benefit to the patient becomes a difference in the kind of benefit to the patient. It is now a kind of benefit that was not previously considered in the decision-making. Of course, in most such cases there will also be some other reason as to why the individual would gain significantly more clinical benefit than others, and that reason is also likely to be exceptional to the cases the commissioning team will have considered. Either way, individuals in such cases would not be excluded from consideration, and thus the exceptional circumstances approach correctly includes everyone it ought to.

Exceptional circumstances in practice

Where exceptionality is determined as an exception to the rule, it becomes necessary for clinicians and others involved in the IFR process to understand the reasoning behind the rule. If they do not, then they will not be able to assess correctly whether an individual is an example of an exception to the rule. This does seem to pose a practical problem and might require much more understanding of the commissioning decisions than clinicians currently have.

There are a few ways to tackle this practical wrinkle. Firstly, it should be noted that, whilst this approach asks more of clinicians in understanding the reasons behind the commissioning decision, it asks less of them overall as they do not need to find persuasive evidence of significant clinical benefit. Secondly, steps can be taken when commissioning decisions are made to clearly express the types of cases considered and the reasons for denying funding. Not only will this simplify the process for clinicians, but it will also provide greater transparency in decision-making.

Third, broad guidance should be released to help clinicians identify the types of cases and considerations which typically fall outside the scope of the policy. Of course, there will still be a large scope of

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[23] Of course, without having a reason to explain why the effects would be particularly strong, it is unlikely that there would be evidence of the significant clinical benefit. But for the purpose of argument, we can set such considerations aside. Let us suppose that the individual has previously been on the drug (perhaps abroad or on a drug trial or for some other condition that it is approved for) such that there is evidence of its effect on the individual without identifiable reasons for why they receive much greater clinical benefit.

discretion for the committee to make decisions about whether a particular consideration or reason is sufficiently different from prior considerations or reasons to require evaluation. Just as there may be reasonable disagreement about whether a particular treatment ought to be funded, there is likely to be reasonable disagreement about whether someone's circumstances represent an exception to the rule.

This consequence, however, should not be seen as a downside. The significant clinical benefit approach does not allow this reasonable disagreement to be settled as part of the process, but instead predetermines under what conditions someone counts as exceptional: once again excluding certain features from fair consideration. Conversely, acknowledging and accommodating reasonable disagreement about what counts as exceptional allows our approach to be more responsive to the relevant features and perspectives that will come up when dealing with exceptional and unusual cases and to be fairer in doing so.

Lastly, there has been some concern that the language of exceptionality is confusing, for patients as well as providers.[24] Our own discussion further highlights that ambiguity. Patients whose applications are unsuccessful may wonder why they are not considered 'exceptional', and not unreasonably understand the judgement to mean that they are not as deserving of the intervention as others. It is partly for this reason that Newdick attempted to clarify the exceptionality concept as significant clinical benefit in the first place. In order not to return to such confusion, in practice it may be best to replace talk of exceptionality with talk of omission. A patient's circumstances are eligible for IFR review if those circumstances were omitted from the initial policy-setting procedure. This language captures the exceptional circumstances approach, whilst more clearly focusing on the rule, and the considerations behind the rule, such that it avoids the distress and confusion of exceptionality.

SUMMARY

To conclude, IFRs play a vital role in justifying allocations of healthcare resources. Not only do they allow the NHS to be sensitive to individual needs, but they also ensure all patients – no matter their circumstance, perspectives and values – are included in the resource allocation process. Such inclusion is crucial if the allocation process is to be fair and the outcome of the process to be acceptable to all.

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[24] Andrew Blakeman et al, 'Independent Review of the Individual Patient Funding Request (IPFR) Process in Wales' (2017) Welsh Government 14–15.

However, whilst the purpose of IFRs is to play a role in a fair process, they are currently undermined by their focus on clinical outcomes rather than fair process. In some respects, they have become a second-chance saloon and a way to pass the buck on the difficult decisions made in policy-setting discussions. As we have shown, not only does this undermine the IFR process, but it undermines the justifiability of the initial policy-setting decision too.

Thus, the NHS ought to abandon IFRs understood in terms of significant clinical benefit and clinical outcomes. Instead, it ought to adopt an understanding of individual exceptions to the rule and/or omissions from fair process: exceptionality should not give us resources for treating people outside the normal process but should equip us to include those exceptions who have not been included in the process.