

Priority setting: managing individual funding requests



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Introduction

In undertaking priority setting, one of the key challenges for primary care trusts (PCTs) is how to strike the right balance between providing services that meet the needs of the majority and accommodating the differing needs of individual patients.

Commissioning by its very nature focuses on the larger scale. As a result, it cannot be undertaken in a way that meets all needs of all patients in any one clinical group or address the specific needs of patients with less-common conditions. Therefore, PCTs will always need an individual funding request (IFR) process to consider making additional NHS funds available for the atypical or uncommon patient.

Decision making is compounded by the fact that legitimate demands for healthcare will always exceed PCT budgets. There have always been individuals whose need for healthcare has not been met by the NHS and this will inevitably continue in the future. Indeed, unmet need is an unfortunate feature of all healthcare systems. So, how should a PCT decide which individual patients should have their requests for special consideration funded? These are some of the most difficult decisions a PCT will have to face.

This report explores this area of decision making and provides some good-practice points in relation to managing individual funding requests and dealing with clinicians and patients.

What is an individual funding request (IFR)?

An IFR is a request to a PCT to fund healthcare for an individual who falls outside the range of services and treatments that the PCT has agreed to commission.

There are several reasons why a PCT may not be commissioning the healthcare intervention for which funding is sought. These are shown below.

- It might not have been aware of the need for this service and so has not incorporated it into the service specification (this can be true for common and uncommon conditions).
- It may have decided to fund the intervention for a limited group of patients that excludes the person making the request.
- It may have decided not to fund the treatment because it does not provide sufficient clinical benefit and/or does not provide value for money.
- It may have accepted the value of the intervention but decided it cannot be afforded in the current year.

IFRs should not be confused with:

- decisions that are related to care packages for patients with complex healthcare needs
- prior approvals, which are used to manage contracts with providers.¹

What approach should PCTs take to individual funding requests?

PCTs need to have clear policies. It is important to understand that there is a direct link between IFR decisions and other aspects of PCT priority setting, so any approach a PCT takes should be in harmony with its wider policy.

It may be helpful to consider that IFRs generally come in one of three circumstances:

- the patient has a rare condition and makes the request for funding for the usual way of treating the condition
- the patient has a more common condition but claims that the usual care pathway does not work for him or her
- the patient wants to take advantage of a medical treatment that is novel, developing or unproven, and which is not part of the PCT's commissioned treatment plans.

Commonly, the first type of application is dealt with on its individual merits, while the latter two are only funded in exceptional circumstances.

The law shapes this area of decision making quite considerably. Please note, therefore, another NHS Confederation publication in this series, *Priority setting: legal considerations*.

Exceptionality

Patients' healthcare needs that are not currently met are still legitimate. They are judged to be of differing priority. A PCT cannot agree to support every claim but neither can it decide in advance to refuse to consider funding someone whose needs do not fit the established range of commissioned services. How does the PCT identify those cases that it should fund? In making these decisions,

PCTs have to be mindful that they always have opportunity costs, and a decision to fund an IFR has the potential to result in direct displacement of another service.

In the majority of cases, PCTs will need to consider whether or not the exceptionality rule applies (those instances where this does not apply will be covered later).

Exceptionality is essentially an equity issue that is best expressed by the question: *'On what grounds can the PCT justify funding this patient when others from the same patient group are not being funded?'*

PCTs must be able to explain coherently their decisions to clinicians, patients, the public and the courts. There is a debate over whether exceptionality can, or indeed should, be defined in a PCT policy. At the very least, there should be a framework to guide decision making but it is difficult to give a comprehensive list of cases that are exceptional because, by definition, it is not possible to anticipate all instances of the unusual or the unexpected.

There are four stages to considering exceptionality, three of which are done well in advance of the IFR itself (see page 4). The first two provide the foundation of the PCT's approach to exceptionality, while the third forms part of generating a treatment-specific commissioning policy, and the fourth is consideration of the individual case itself.

'PCTs must be able to explain coherently their decisions to clinicians, patients, the public and the courts.'

Figure 1. An example of a PCT's policy on exceptionality

The PCT does not offer treatment to a named individual that would not be offered to all patients with equal clinical need.

In making a case for special consideration, it needs to be demonstrated that:

- *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 be normally expected for patients with that condition.*

The fact that a treatment is likely to be efficacious for a patient is not, in itself, a basis for exceptionality.

Courtesy of Dr Henrietta Ewart (adapted)

Stage 1. Understanding the meaning of exceptionality within the IFR process

PCTs need to clarify what their organisation means by exceptionality by either defining or describing it. The approach that is gaining most popularity is one that Dr Henrietta Ewart developed, as shown in Figure 1. The text in italics can be considered to be the definition.

Once the meaning of exceptionality is clearly understood, decision making becomes easier.

Stage 2. Agreeing the factors that can be taken into account in deciding if a patient is exceptional

The second consideration is the list of factors that the decision maker can take into account when judging whether or not a patient is different to other patients.

PCTs are increasingly adopting policies that only allow clinical considerations. Using the definition in Figure 1 as an illustration, the PCT would first

consider whether there were any clinical features that made the patient unique or unusual compared to others in the same group. If so, then it would also consider whether there were sufficient grounds for believing that this unusual clinical factor meant the patient would gain significantly more benefit than that would be expected for the group.

It is necessary to differentiate here between exceptional benefit for an individual and the identification of a patient subgroup for which outcomes are better. The latter issue should have been dealt with by the PCT when assessing the treatment (see 'Service developments', page 9). It must be recognised, however, that occasionally an IFR alerts the PCT to the existence of such a subgroup. In these instances, the PCT might have to go back and review its policy.

Serious mental health issues should be viewed as clinical considerations and not put under the catch-all phrase of 'psychosocial factors'.

Are social and demographic factors exceptional?

There are several other factors frequently cited as grounds for being treated differently. Each PCT will need to come to its own view about which are acceptable. Caution is advised, however, as many feel 'intuitively right' although closer examination may throw up some difficult issues. Here, employment can be used as an illustration.

Many IFRs are made and funded in order to keep an individual in employment. From a public health point of view, there is no doubt that this has wider health and social benefits. It can also be argued that the treatment is more cost effective when these wider benefits are taken into account. It therefore feels right to fund on this basis – and on one level it is.

However, what would this say about access to healthcare for the unemployed? The PCT has inadvertently made a decision to dedicate more resources to maintain the health of the employed compared to the unemployed in identical clinical circumstances. Whatever the benefits of keeping patients in employment, it is suggested that there is a higher principle that overrides this consideration. This is that the NHS should treat people equally if they have equal need. There may yet come a time when society decides that the NHS should give preference to the employed, but NHS organisations are not mandated to make this value judgement at present.

However, even if a PCT were inclined to fund such a treatment, in what way could the need to stay in employment be considered exceptional? Being in work is normal, unless the employment circumstances are themselves exceptional. Thus if the PCT were to fund one individual on this basis, it

may have set a precedent that inadvertently leads to a policy that employed patients should be favoured in some situations.

The nature of employment also has the potential to be discriminatory. Should a concert pianist who might benefit from a treatment to improve hand function be given preference when others such as plumbers and hairdressers, whose livelihoods also depend on hand function, are not awarded funding?

Employment is not always irrelevant, however. For example, there are two ways of providing peritoneal dialysis for end-stage renal failure. The first method is a simple system that involves the patient draining fluid in and out of their abdomen. The second method, which is more expensive, has a machine do this while the patient is asleep. Some patients have to dialyse at work but strict hygienic conditions must be maintained. An individual who works in a dirty environment might be considered exceptional because the nature of the employment significantly increases the clinical risk. A decision to fund may be justified because it is based on clinical, not social, considerations.

Many of the above arguments are relevant to other commonly cited factors such as having educational potential, being a parent and being young.

Funding on the grounds of compassion may also be sought for terminally ill patients in order that key life events can be experienced, such as a patient wanting to live to see the marriage of a son or daughter. These events are laden with emotion and meaning for the patient and their family. It can be heart wrenching to have to consider these tragic circumstances, but can it be a reason to regard such a patient as exceptional, given that a favourable decision may affect others?

The factors covered on page 5 illustrate how important it is that those making decisions be aware of their own prejudices and also those of society in relation to deservedness, as these are not always compatible with the principles underpinning healthcare provision in the NHS.

No document on IFRs can ignore the issue of *rule of rescue*. AR Johnsen² coined the term in 1986 to describe the imperative people feel to rescue identifiable individuals facing avoidable death. This is a complex subject and there is no consensus about its place in resource allocation. In common commissioning parlance, the term has come to mean the proclivity of people to rescue an identifiable individual who has a life-threatening condition, regardless of cost and the chances of success. Put more crudely, it is often viewed as the last heroic attempt to save a life against the odds. Its main significance for the practitioner is that it draws attention to the emotion of the decision maker. The need and urge to do something for the patient is very strong. Most of us share this impulse. PCTs, however, do not owe a direct duty of care to

individuals and are not rescuers in any real sense. To give in to the impulse to “do something” can result in inconsistent and unfair decision making because agreed principles and policies are set aside *in order to meet the needs of the decision maker* (i.e. to feel good, avoid feeling bad, avoid unpleasantness or reduce risk).

Stage 3. The likelihood of exceptional cases

Normally, when assessing a specific treatment, it is advisable for a PCT to consider the nature of potential exceptions, as different diseases and treatments have differing potential to generate exceptional circumstance. It is possible to anticipate some exceptions in advance and these can be individually addressed in a treatment-specific commissioning policy.

Stage 4. Considering the individual funding request itself

Having set the context, the PCT can take the IFR decision itself. This involves examination of the specifics of the case in relation to the above three considerations.

What does the law have to say in relation to what is considered material to IFR decisions?

The law relating to priority setting is not at all clear about the factors that PCTs should use and what they can rule out. There are a number of cases which have gone before the courts that suggest social factors may be taken into account, even though there may be good rational and ethical arguments against their consideration. Greater certainty can only be achieved through further litigation that addresses these issues.

The courts can only consider the arguments that are put before them. Poorly argued cases may set uncomfortable precedents.

PCTs need to balance a concern not to use social and demographic considerations in a way that is discriminatory against the risk that a court may be inclined to set aside a decision that failed to take such factors into account.

The IFR decision-making process

As with all priority setting, the aim is to have *protocol* and *policy-based* decision making that is *robust*. Different PCTs have different approaches and there is no one 'right' IFR process. However, the following points are representative of good practice.

- The adoption of a policy document that sets out the framework and the process.
- A logging and tracking system to ensure that IFRs are dealt with consistently and in a timely way.
- A screening system. This should be delegated to senior officers and enables the PCT to screen out IFRs:
 - that represent service developments
 - for which there clearly is no clinical case
 - that raise a major policy issue and need more detailed work
 - that can be funded because they meet pre-agreed exceptions (some of which are set through precedent)
 - that can be dealt with under another existing contract
 - for which an alternative satisfactory solution can be found.

The above step should be documented.
- Standard letters for screened cases.
- Adoption of a standard pro-forma that clearly indicates the information that the IFR panel needs. Many IFR forms fail to do this and look more like business cases pro-formas.
- Two leaflets that explain the IFR process and exceptionality – one for clinicians and one for patients.
- The PCT ensures that all individuals involved in decision making, at whatever level, are familiar with legal and ethical issues, as well as the PCT's own approach to priority setting.
- A support team that can gather necessary supplementary information. Such a process should not be labour intensive or duplicate effort.
- A system that allows for the possibility of gathering more clinical information or receiving information from the patient.
- A clear policy statement that the IFR panel must never make policy decisions for the PCT. Policy questions should always be referred for consideration to the board, or another appropriate policy-making committee, before the IFR can be considered.
- An appeals process. Most PCTs consider it good practice to establish an appeals panel. The remit of this panel should be set out and understood by its members so that it does not undermine the PCT's priority-setting processes. One model for appeals panels that is gaining favour is for them conduct a quality-control check on decisions, as the High Court does in a judicial review case. The National Institute for Health and Clinical Excellence appeals process follows this format.³ In this model, the appeals panel is limited to inquiries about whether the IFR panel:
 - followed the PCT's own procedures and policies
 - considered all relevant factors and did not take into account immaterial factors
 - made a decision that was not so unreasonable that it could be considered irrational or perverse in the light of the evidence.

If the appeals panel identifies a problem, the issue is referred back to the IFR panel for reconsideration. The patient or their clinicians should not normally be permitted to introduce additional evidence at the appeal stage. If there is new evidence to support a case, this does not mean that the original decision – made on the evidence then available – was wrong. Thus the policy should say that the case should be referred back to the IFR committee to decide whether the information is significant enough to merit reconsideration.

- There is good documentation of the process of decision making as well as the outcome.
- The reasoning, as well as the outcome, is communicated to the requesting clinician, and (and this should be the norm unless inappropriate) to the patient directly.
- There is a mechanism for dealing with emergencies. Urgent decisions will normally be delegated to senior public health staff.
- Decisions are regularly audited and the process reviewed if necessary.

Should the process allow patients to present their case at IFR or appeal panels in person? There is no single answer to this. One judicial review case has said that this is not necessary, provided the patient knows of all the arguments that have to be addressed, can submit written documents to the panel (with the doctor's support if necessary) and is guaranteed an impartial hearing. The case noted the disadvantages of "judicialising" these procedures. This is a matter for PCTs. Some are not comfortable with patients presenting to panels, while others see it as a way to make their decisions more open and accountable.

'If there is new evidence to support a case, that does not mean that the original decision – made on the evidence then available – was wrong.'

Working with patients and their families

The following points can help PCTs communicate effectively with patients and families.

- Set standards for making decisions in a timely way.
- Keep parties informed of progress if delays occur.
- Have protocols for dealing directly with patients.
- Never engage in email dialogue with patients as this risks saying something ill-considered. If needed, send a letter by email.
- Be frank, open and sincere in all dealings with patients.
- When communicating decisions not to fund treatments, consider adopting some of the practices used for breaking bad news.
- Consider training staff to deal with angry patients and carers.

Service developments

Service developments have largely been dealt with in the NHS Confederation publication in this series, *Priority setting: managing new treatments*. However, a discussion is needed here because clinicians often use the IFR route as a means to gain early access to a new treatment.

The NHS Contract for 2008/09 makes it clear that the hospital provider is expected to seek funding for new treatments through submission of a business case to the commissioner (Schedule 6, point 8.3). There is, therefore, an expectation that new treatments will be properly assessed and prioritised. It is not rational for a PCT to manage a new treatment by considering one patient at a time. Nor would this be fair, because it breaches a principle commonly adopted by PCTs, namely that:

The PCT does not offer treatment to a named individual that would not be offered to all patients with equal clinical need. (See Figure 1, page 4).

The use of the IFR system as a means to fund some patients ahead of others could be viewed as an abuse of the system. This is not the purpose of IFR processes but it has not stopped the reported rise in the number of requests in this category.

This situation needs active management. There are several options open to PCTs, such as using the NHS contract to full effect and having an ongoing dialogue with provider executives and clinicians. A PCT can also use interim commissioning policies.

Interim commissioning policies

Between the time when clinicians and patients want access to a treatment and the time when the PCT makes its definitive decision, there is the potential

for a policy vacuum. This makes managing service developments and IFRs extremely difficult. For drugs, this interim period can start well before the date of licensing. It is recommended that PCTs adopt an interim commissioning policy for use during this period. Logic suggests that a PCT should not fund treatment for some patients ahead of others and that time should be allowed for the assessment and prioritisation decisions to be made.

Once a PCT has assessed a treatment, its conclusion may be one of the following:

- that the treatment provides good health gain, is value for money, has met the exceptionality criteria for in-year service development and will be funded
- that the treatment provides good health gain, is value for money and will be referred to the annual commissioning round for prioritisation
- that the treatment provides good health gain, is value for money for a sub-group of patients and a service development for this group alone will be referred to the annual commissioning round for prioritisation
- that the treatment will not be funded because there is insufficient evidence of clinical effectiveness, it represents poor health gain or is not cost effective.

PCTs come under understandable pressure to fund treatments as soon as the claimed effects appear in the national media. It is recommended that, until such time as a treatment is *actually* funded, the policy should clearly say that the PCT will refuse to use the IFR process to fund service developments.

That is not to say that exceptional cases cannot arise in this interim period. However, the reader is again referred to Figure 1.

Difficulties in identifying some service developments

There is currently a deficiency in PCT planning for some new interventions for uncommon conditions that represent a significant service development for PCTs sharing a tertiary centre. Some of these will fall under the commissioning arrangements for specialised services but many will not. There is a temptation in these instances for a PCT to manage such developments through the IFR route, rather than making policy decisions about the treatment or working with other PCTs to manage them. This is poor practice for many reasons. In the absence of an alternative, it will be difficult for providers to fulfil the requirements of Schedule 6 of the standard NHS Contract. As a result, the IFR route will be the only route open to providers to obtain approval for treatment.

Equally problematic is the fact that the IFR panel in such instances considers only whether the patient will benefit – not whether they are exceptional.

Using the IFR route in such cases may be appropriate for highly unusual conditions, but if the PCT expects to see more than one case a year, a policy approach will deliver greater certainty and consume fewer PCT resources to manage.

'The IFR panel in such instances considers only whether the patient will benefit, not whether they are exceptional.'

Working with clinicians and trusts

The following points can help PCTs communicate effectively with clinicians and trusts.

- Ensure that trusts and clinicians understand:
 - what constitutes a service development, a prior approval and an IFR
 - what is expected of them
 - what they can expect from the PCT.
- Use the NHS Contract to full effect to manage new treatments.
- Be consistent in your responses – do what you said you would do.
- Develop a range of standard letters for common circumstances.
- Be frank and open in all dealings with clinicians and providers.
- If there is a consistent failure by a clinician or department to comply with procedures that have been set down by the PCT, take it up with the chief executive of the provider trust and ensure it is resolved.

Other difficult areas

Co-payment

Co-payment is the situation in which a patient pays for some aspect of treatment while being treated in the public sector. The NHS Act does not allow the recovery of charges for healthcare.⁴ In addition, the *Code of conduct for private practice: guidance for NHS medical staff*⁵ indicates that if a patient wishes to become a private patient, he/she cannot be treated as a private patient and an NHS patient during a single visit to an NHS organisation. The *Code of conduct* also states that: "Any patient changing their status after having been provided with private services shall not receive an unfair advantage over other patients." This document is, however, only guidance and trusts have discretion to depart from it if they make a policy decision to do so. Equally, PCTs could, as a policy, decide that the trusts with whom they contract are required to work within the guidance.

A typical IFR of this type is a request to pay for the service costs to help a patient access a treatment that the PCT itself does not fund. The Government's current position is to rule out co-payment and it is recommended that PCTs' policies follow this guidance. This is because it would provide access to a treatment that the PCT was not making available to others.

There is currently a case going before the courts that might clarify the issue.

Trial pick-up

There are several situations in which an external organisation will take a decision to start treatment, either hoping or assuming that the NHS will pick

up funding. IFRs asking the PCT to pick up the funding for patients leaving clinical trials are illustrative of this problem.

What should happen to patients at the end of trials in which they have participated is indicated in the Declaration of Helsinki (2004)⁶:

At the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study.

With a clarification note

The World Medical Association hereby reaffirms its position that it is necessary during the study planning process to identify post-trial access by study participants to prophylactic, diagnostic and therapeutic procedures identified as beneficial in the study or access to other appropriate care. Post-trial access arrangements or other care must be described in the study protocol so the ethical review committee may consider such arrangements during its review.

The Medicines for Human Use (Clinical Trials) Regulation 2004 also makes reference to patients leaving trials:⁷

Schedule 3: *Particulars and documents that must accompany an application for an ethics committee opinion.*

Part 1: *An application document including the following information or, in each case, an explanation of why that information is not being provided...*

(m) *Details of –*

(iii) *the plan for treatment or care of subjects once their participation in the trial has ended.*

These documents suggest that:

- there should be a plan that describes the arrangements for treating patients leaving trials
- the plan should be considered during the ethical approval process
- the exit strategy should enable the patient to have ongoing access to any healthcare that has been shown to be beneficial in the study.

Neither of these documents states who should be responsible for ongoing access to treatment. PCTs are entitled to agree to pick up trial funding but they are not required to do so unless they commissioned the trial or agreed to fund at an earlier stage. In all other instances, liability cannot rest on the PCT unless it has given prior commitment. It is recommended that PCTs adopt an approach that makes it clear that they cannot be held responsible for decisions to which they were not party.

Many PCTs adopt a policy of not generally funding patients coming off trials and only funding trial patients when the service development has been funded and the treatment is made available to all.

For trial patients, in particular, it is difficult to anticipate what might constitute exceptional circumstances. Being in a trial is not, of itself, unique; nor is benefiting from the treatment being studied. Trials are also frequently designed to recruit a uniform patient group.

'There is often a real problem in instances where there is no prospect of evidence ever being gathered, such as in treatments for children.'

Patients who have part-funded themselves in the private sector for treatments

Another category of IFR that is on the increase comes from patients who have sought private care to access a treatment that their PCT is not currently funding, but who have not been able to afford the full course. Having run out of their own funds, they seek funding from the PCT to complete the course. To pick up funding routinely in these instances would place PCTs in an untenable position. However, if a PCT is faced with such an application, it is obliged to consider the application on the basis of all the evidence in the case.

This situation raises two other issues. The first relates to questionable governance within the private sector for failure to ensure that a patient is able to fund a complete course and, if not, failure to agree an exit strategy for patients in much the same way as clinical studies are required to do. NHS pick-up of funding cannot be assumed. The other issue relates to the behaviour of clinicians. Clinicians are at liberty to treat patients privately. Having done so, however, it is unacceptable for a clinician to transfer moral responsibility for creating differential access to treatment onto a PCT. While the PCT cannot influence these behaviours, it is always worth raising such issues with clinicians and private providers.

Experimental treatments

A cornerstone of the NHS today is that it provides treatments of proven cost effectiveness. When a treatment has not been subject to adequate study and where it would be possible to undertake a study (even if the research community is not currently prioritising it) the treatment should be classified as experimental and not generally funded. There is, however, often a real problem in instances where there is no prospect of evidence ever being gathered. These include many treatments for children. In these instances, the PCT might need to make a different assessment, as discussed in the section on 'one-off decisions' (see page 14).

In certain circumstances, it may be worth considering funding a patient to enter an existing trial or even working collaboratively with other PCTs and organisations to establish a trial. There is no legal barrier to this. There is also the potential to fund what are known as 'n of 1' trials. These are formal trials where the patient acts as his or her own control. These cannot be used in all situations and their role in evaluating treatments has yet to be fully ascertained. Currently, there is no 'n of 1' trial unit operating in the UK, although there is at least one initiative to seek to establish one.

The above list of potentially difficult areas is not exhaustive but illustrative.

IFRs related to treatment-specific policies

The IFR process was largely designed to deal with two other patient groups and these will be briefly discussed in the next two sections.

As part of its commissioning policies, a PCT may chose either to not fund a treatment at all or to fund it only in particular sub-groups of patients. In either instance, the PCT should produce a commissioning policy that explains its approach.

Those patients falling into the non-funded group will not all be the same – the degree of difference will depend on the heterogeneity of the condition, and to some extent the nature of treatment. It is

highly likely, therefore, that there will be patients who do not fit the typical patient profile and who might be expected to do better on treatment.

In these situations, the principle of exceptionality is the key consideration for assessing IFRs.

One-off decisions

Off-licensed use for unusual clinical conditions or complications, children with uncommon conditions and adults with rare diseases

As was discussed earlier, in some situations the *principle of exceptionality* cannot readily be applied. For some IFRs there is simply no reference point: the patient does not come from a sizeable group of patients (often they may be unique) nor is there much evidence about the treatment in question and there may never be. In these instances, the IFR panel has to assess only whether the patient is likely to benefit from the treatment and the priority to be given to the patient. Namely, it is treated as a 'service development for 1'. Under these circumstances, in addition to questions about priority and value for money, the following need to be asked:

- What is the nature of the condition?
- What is the nature of the treatment?
- What is the evidence that this treatment might work in this situation? Is there biological plausibility that this treatment might work?

The majority of these can be dealt with through the IFR process alone. However, occasionally the financial commitment is so large the decision needs to be referred to the PCT board. A decision to fund a treatment that costs £300,000 per patient per annum is probably not one the IFR panel alone can make.

How to support the decision makers

- Give recognition to the demanding nature of the area of work.
- Provide a clear priority-setting framework – it is always easier for individuals to operate within clear policies and protocols.
- Provide training.
- Develop organisational cohesion. Having established a priority-setting framework, the PCT's board must support its officers when they operate within that framework.
- Decision making should largely be undertaken by groups rather individuals.
- Delegated functions should operate within clear protocols.
- Identify those situations that are best dealt with by those within the PCT who are clinically trained.
- Develop professional networks so that when the going gets tough there is a source of support.

Conclusion

The IFR process is demanding but improvements can be made to make the system more efficient, robust and fair. Although this is a high-risk area for a PCT, funding individual treatments should contribute relatively little to the PCT's priority setting. However, if done poorly, it has the potential to drive the PCT's priorities, resulting in resources being committed to low-priority areas. This may adversely affect other patients.

Exceptionality is difficult in ethics, medicine and law. It is impossible to be definitive as to its meaning at this stage. PCTs and clinicians should collaborate with one another to share best practice and learn from experience.

Key action points

Step 1: Agree key principles to underpin priority setting

- Describe exceptionality and the factors that the PCT panels can take into account in their decisions.

Step 2: Develop and establish priority-setting structures and processes

- Agree and document the process for managing IFRs, paying attention to the role of the appeals panel.
- Ensure that there is good documentation of the panel's decisions, including the reasons.
- Ensure that there is a schedule of delegation.
- Ensure that the board and members of panels are versed in the relevant law and understand the policies adopted by the PCT.
- Offer training in breaking bad news and dealing with difficult patients.

Step 3: Consider how to approach key relationships

- Ensure consistency of action in all dealings with providers and clinicians.
- Set standards and policies for dealing with patients and their families, and ensure that they are adhered to.

Step 4: Produce key policy documents

- The overarching policy document on resource allocation should include the PCT's management of IFRs and commonly faced issues (although these can be in supplemental documents).
- Ensure that generic policies are developed for difficult areas of policy.
- There should be documented commissioning policies whenever the PCT has made a decision about a treatment.

See *Priority setting: an overview* for a description of the steps.

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The author alone is responsible for the opinions expressed. Responsibility for errors and omissions are the author's alone.

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Glossary

Service developments – a catch-all phrase referring to anything that needs investment. It refers to all new developments, including: new services; new treatments, including drugs; changes to treatment thresholds; and quality improvements, such as reduced waiting times. It also refers to other types of investments that existing services might need, such as pump-priming to establish new models of care, training to meet anticipated manpower shortages and implementing legal reforms.

Overarching policy document on resource allocation – the document that sets out a PCT's approach to resource allocation, which may be supplemented by more detailed policy documents and protocols. This document and any associated documents should comprehensively set out key principles, policies, protocols and any scheme of delegation for decision making.

Priority setting: managing individual funding requests

This report is the third in a series of publications that aims to help organisations review their current priority-setting processes and, if needed, provide a reference document for PCTs who still have to develop a comprehensive priority-setting framework.

It is hoped that this series will also promote understanding and debate amongst a wider audience, particularly providers of healthcare who have always undertaken prioritisation at patient and service level, albeit less explicitly.

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