Primary Care Trust Network

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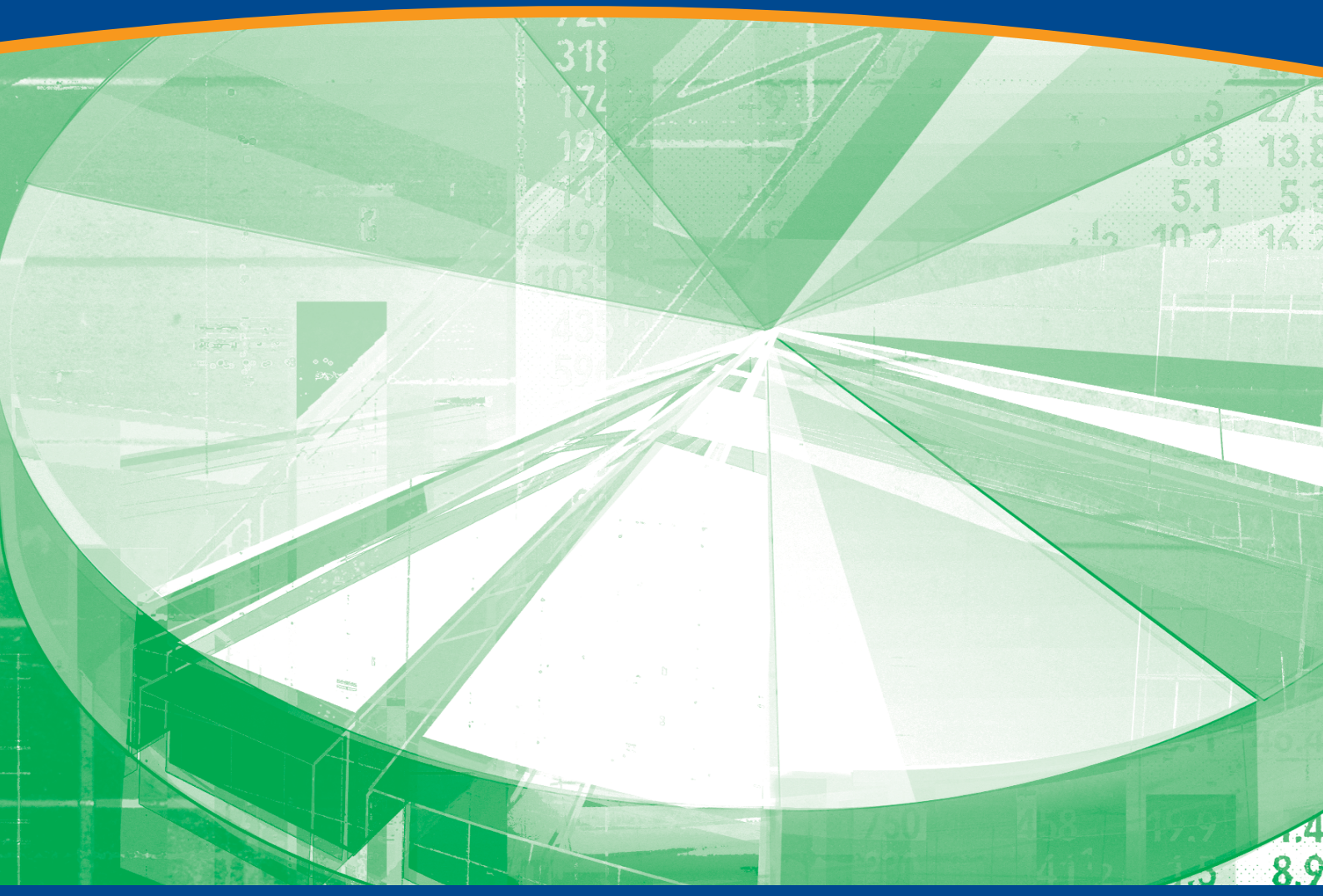
Priority setting: managing new treatments



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Contents

Introduction

Managing the constant demand for new treatments can be difficult for primary care trusts (PCTs). They are under pressure to invest in them, while ensuring cost effectiveness. Drugs, technologies and treatments appear throughout the financial year but PCTs rarely have large contingency funds.

This report sets out some of the key considerations for developing priority setting in relation to new treatments, with a useful list of action points.

Managing the introduction of new treatments can be interpreted in different ways. This report looks at those differences in understanding, specifically:

- the nature of funding decisions for new treatments
- what constitutes a service development
- the role of licensing
- the duties of PCTs to provide treatments that are effective and cost effective.

In-year service developments

PCTs should build up a set of criteria for making in-year funding decisions, as part of an overarching policy on resource allocation.

Managing requests for new treatments during the financial year

- Assess rapidly to screen for exceptionality
- If the treatment does not meet the criteria, assess it through the normal processes in time for the next annual commissioning round
- Prioritise in annual commissioning round.

Key action points for PCTs

- Agree key principles to underpin priority setting
- Develop and establish priority-setting processes
- Consider how to approach key relationships
- Produce key policy documents.

Information needed to assess and prioritise a treatment

Assessment processes need to be flexible. Figure 3 on page 9 sets out the information commonly used. It includes information about the treatment, the evidence and the costs.

Cost effectiveness

PCTs do not generally measure cost effectiveness using health economics techniques. However, it is helpful to have a cost-effectiveness measure, particularly when considering disinvestment in a potentially controversial area or to identify a group of patients in whom an otherwise cost-ineffective treatment is highly cost effective.

Commissioning policies

Policies should state explicitly what PCTs will and will not fund. They should facilitate consistent decision making, and consider:

- what, if anything, is to be provided
- controls
- what information the PCT wants
- compliance checks and monitoring spending
- exceptionality criteria
- who can make which decisions.

Why is managing new treatments so important?

Managing new treatments is different to managing other service developments. The pressure exerted on PCTs to invest in new treatments makes it a high-risk area. This report sets out some of the key considerations for developing priority setting in relation to new treatments.

The term *'managing the introduction of new treatments'* is commonly used in relation to the NHS but it means different things to different people. Many perceive that successful management results in patients having smooth and timely access to new technologies and drugs, where 'timely' means when a treatment is licensed. However, commissioners frequently have a different interpretation. Their aim in 'managing' new treatments is to ensure that a treatment only becomes available when funding has been agreed through a formal prioritisation process and that access is in line with the PCT's commissioning policy.

Underlying these potentially opposing perspectives are differences in understanding that can cause tension between stakeholders. Four common sources of that tension are shown below.

1. **Differences in understanding about the nature of funding decisions for new treatments**
   In *Priority setting: an overview*[1], the concept of singular decision making as opposed to prioritisation was discussed. Singular decision making focuses on the clinical and cost effectiveness of an individual treatment without reference to opportunity costs or affordability. Prioritisation, which is how PCTs aim to make their decisions, is a much more complicated process. This takes a comprehensive view of a treatment and sets its priority against existing services and other potential service developments. Problems arise when clinicians, patients and other lobby groups believe that decisions should be based purely on whether a treatment works or not.

2. **Differences in understanding about what constitutes a service development**
   A long-standing feature of the NHS is that service developments are prioritised in the annual commissioning round. There is, however, no definition of what constitutes a development. Many clinicians and provider organisations tend to think of them only in terms of service infrastructure. But a service development is *anything* that has resource implications, including new treatments, changes to more expensive treatment protocols and expanded access to a treatment. Under this definition, a new treatment for an uncommon condition that costs £30,000 per patient would be considered a service development even if the PCT expected only one patient in its population to be eligible each year. The £30,000 would still have to be found recurrently. The treatment must therefore be subject to prioritisation.

   Although there is ready acceptance from clinicians and providers that investments in infrastructure have to be prioritised as part of the annual commissioning round, this is often not the case for new treatments. As a result, a different set of behaviours can be observed from clinicians in relation to new treatments as opposed to requests for other service developments.

'A service development is anything that has resource implications for the PCT.'

3. Differences in understanding about the role of licensing

Licensing processes are designed to give confidence to the public that products are safe. In the UK, drugs and medical devices are made available under a strict regulatory framework. In addition, the National Institute for Health and Clinical Excellence (NICE) carries out a licensing function with its interventional procedures programme (which is to be distinguished from its technology appraisal programme.) Although it is not a regulatory body, NICE looks at the safety and efficacy of new interventional procedures and gives guidance to the NHS on whether procedures, such as new surgical operations, can be safely adopted into routine practice. Taken together, these organisations provide scrutiny over the safety of many new clinical interventions.

Patients and healthcare professionals often view an approval from these organisations as a mandate for the intervention to be made available in the NHS. This is not the case. These processes make no judgement on the clinical effectiveness, cost effectiveness or relative priority of treatments.

4. Differences in understanding about the duties of PCTs to provide treatments that are effective and cost effective

It goes without saying that in a system that operates with fixed budgets and significant unmet healthcare need, there can be no guarantee of funding for any service development, even those that are cost effective. Cost effectiveness, at least as presently defined, should generally be seen as a minimum requirement for a service development being referred to the annual commissioning round for prioritisation. Clinicians often see the provision any new effective treatments as an absolute duty for the NHS, which, legally speaking, is not correct. It is also impossible in a cash-limited system.

The above four points illustrate the need for PCTs to work much more actively to raise awareness and understanding about how they go about priority setting.

Figure 1. Organisations carrying out licensing-type functions

Responsible organisation	Type of treatment
Those working within a strict regulatory framework	
European Agency for the Evaluation of Medicinal Products	Drugs
Medicines and Healthcare Products Regulatory Agency	Drugs and medical devices
Working within a clinical governance framework	
National Institute for Health and Clinical Excellence	Interventional procedures

In-year service developments

Currently, PCTs undertake one major priority-setting exercise towards the end of every financial year.

It is during the annual commissioning round that decisions are made about investments for the coming year. Those developments that are supported are not all necessarily made available on the first day of the new financial year. The largest group in this category are those assessed under NICE's technology appraisal programme, which are released throughout the year. Some new treatments will therefore be made available during the financial year – but these are all *planned* developments, for which funds are set aside.

New drugs, technologies and procedures regularly come on line throughout the financial year. Under what circumstances might a PCT fund an *unplanned* development during the financial year?

One of the risks of unplanned developments is that they bypass prioritisation processes. It is in these situations that PCTs are most likely to slip into singular decision making, which is ethically questionable for all the reasons set out in *Priority setting: an overview*. Furthermore, because PCTs rarely operate large contingency funds, when new commitments are made during a financial year something else has to give way – either through disinvestment or by delaying other planned developments. Unplanned investment decisions, therefore, should only be made in exceptional circumstances.

PCTs are familiar with the concept of *exceptionality* in relation to individual funding requests but the concept applies to other areas of priority setting. One of these is in-year service developments.

PCTs need to build up a set of criteria for making in-year funding decisions. These should form part of the overarching policy document on resource allocation that sets out how the PCT will carry out priority setting in key areas of activity: strategic planning; the annual commissioning round; the management of in-year service developments; and individual funding requests.

The following are examples of exceptional circumstances that might require unplanned funding:

- a major incident that requires additional funds to manage a serious health risk, such as an outbreak of an infectious disease, or a major environmental accident, such as the spillage of a toxic chemical
- an urgent service problem, such as a major failure in clinical practice that requires a look-back exercise to identify at-risk individuals to whom additional screening and treatment might be offered
- a new intervention that is of such important strategic importance that it should be introduced immediately, for example a vaccine against HIV infection. (In reality it is improbable that such a development would not be known about in advance)
- a new treatment that provides such significant health benefits that the PCT wishes to introduce it immediately
- a new directive issued from the Secretary of State or a new legal ruling requiring immediate implementation.

The fourth bullet point above presents some difficulty because 'significant health benefit' has to be defined. This is difficult to quantify but, by definition, it has to be exceptional. In the author's view, there has only been one drug in this category

in 17 years and that example might be illustrative of exceptionality. On the evidence available at the time of licensing, there was *very good reason* to consider this treatment to be *life saving*, providing *health gain that could be measured in years* rather than weeks or months. The drug also appeared to provide this benefit to almost *100 per cent of patients* who received it. This is an extremely rare occurrence. Even those treatments that are generally considered to be good fall well short of this.

It is therefore reasonable to make an assumption that most unplanned investment will be reserved for the management of serious events or new legal requirements.

It is self-evident that any new service or treatment that is considered important can be funded at any time *if* matched disinvestment of a *lower-priority* intervention or service can be found.

How might a request to make a new treatment available in-year be handled?

Let us take the example of a new cancer drug that has entered the market, having been granted a licence in July. A local provider seeks funding to enable it to add this to its hospital formulary. Consider the following sequence of steps.

1. The first step is to make a rapid assessment to screen for exceptionality. An experienced individual can readily gather the required information in a few hours.
2. Using this information, the treatment is checked against the PCT's own criteria for exceptionality. The process and outcome is documented. If it is considered to be a potential exception, an urgent, thorough assessment is initiated. If, following this, the drug meets the criteria then the PCT's board will have to agree how it will be funded. A commissioning policy is produced.
3. If the treatment does not meet the criteria then time can be taken to assess it through the PCT's normal processes in readiness for the annual commissioning round. A PCT is likely to have a number of routes for this. A cancer drug, for example, might be referred to the cancer network's drug and therapeutics committee. Thereafter, the network would be asked to prioritise the drug against all other interventions related to cancer services (primary prevention, screening, treatment and palliation) and its recommendations would be considered as part of the priority setting of the annual commissioning round. An interim commissioning policy is produced to state that the treatment will not be available until it has been fully assessed and prioritised.
4. The treatment is then prioritised as part of the annual commissioning round. If it is given high priority and can be afforded, it can be made available to the local population. A commissioning policy is produced defining the access criteria. If it is low priority, a commissioning policy is produced saying the treatment will not be made available. If a treatment is desirable but cannot be afforded in the coming year, the PCT should ensure that there is a bring-forward system to enable it to be reconsidered in subsequent commissioning rounds.

'Most unplanned investment is reserved for serious events or new legal requirements.'

Treatments in the NICE technology appraisal programme

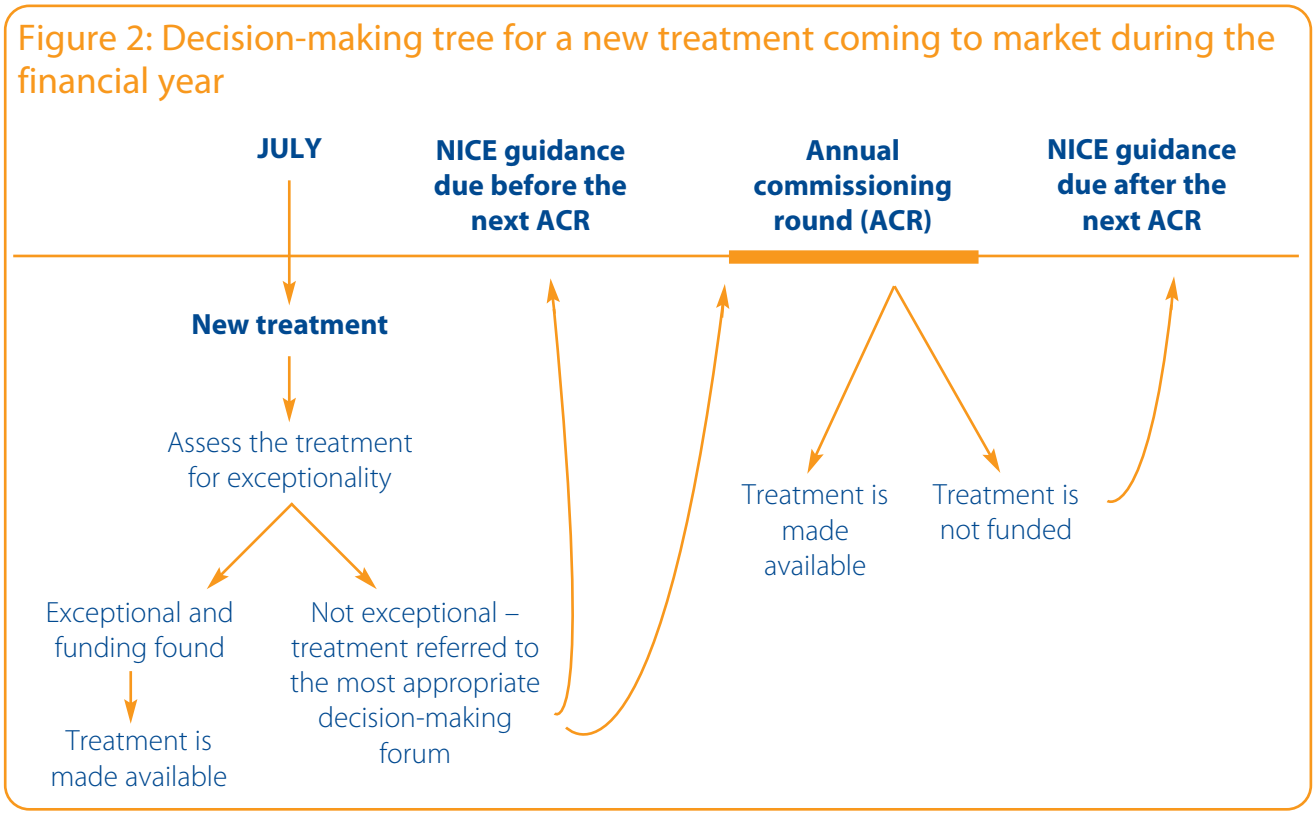
Much is made of whether a treatment is in NICE's technology appraisal programme or not. This is irrelevant. All new treatments should be approached in the same way – all should be screened and, if not exceptional, referred to the earliest decision-making point as shown in Figure 2. For some treatments, this point is when NICE issues its guidance. In others, it will be the PCT's own annual commissioning round.

Horizon scanning

Horizon scanning enables a PCT to put new treatments in the annual commissioning round before demand occurs. The point at which demand for a drug is most readily identified is its licensing date; this point is much less clear for medical devices and operations, which cannot always be identified in advance. In addition, early assessment of a forthcoming treatment is not always possible because the information needed may not be available. It is likely, therefore, that there will always be a mix of proactive and reactive management by a PCT.

Horizon scanning can also identify potentially controversial treatments. There may only be one or two per year but a PCT needs to plan fully for them, sometimes collaboratively with other PCTs. Horizon scanning, therefore, is about preparedness – not, as some might suggest, about avoiding controversy.

Figure 2: Decision-making tree for a new treatment coming to market during the financial year



What information is needed to assess and prioritise a treatment?

The level of scrutiny a PCT might wish to adopt for any given treatment will vary, so any assessment process needs to be flexible. In addition, PCTs can only use the best information they have available to them when they make their decision. Thereafter, they might be able to review their decision when more information comes to light. This review might lead to a change in policy in either direction – investment or disinvestment.

Figure 3 opposite gives the key pieces of information a PCT might use in assessing a treatment.

Experimental treatments

The NHS has not yet developed a comprehensive approach to experimental treatments and it is an area that needs more attention. PCTs should, however, aim to set out an approach to this group.

From the PCT's point of view, there are two key questions:

1. **What does the PCT define as an experimental treatment?**
   The simple answer to this is anything for which there is no robust evidence. The most likely types of interventions falling into this category are treatments for rare conditions, interventional procedures and medical devices. The way that the scope of existing treatments tends to expand is directly analogous to experimental treatments and PCTs may need to have systems in place to monitor this.

2. **How will the PCT manage experimental treatments and in what context might the PCT fund an experimental treatment?**
   Experimental treatments should generally not be funded. It is legitimate, however, for PCTs to choose to fund a treatment in the context of a clinical trial. They can do this by contributing to an existing trial or by choosing to work collaboratively with other PCTs to set up their own trial. The latter is a challenge but there is precedent. It is likely that a PCT will take this course of action only for strategically important treatments. Funding a trial generally demands new funds, so any such proposal should be subject to prioritisation.

A note of caution is raised against funding of what can be described as 'pseudo trials'. These are poorly constructed trials often carried out only at a local level. They are not methodologically robust and so will not generate any useful evidence. 'Local evaluation', for example, is something that needs to be scrutinised closely as it can be nothing other than case series observations.

'It is legitimate for PCTs to choose to fund a treatment in the context of a clinical trial.'

Figure 3. Information commonly used to assess a new treatment

Item of information	How does this help the decision maker?
The treatment Information about the disease, its course of development and its management.	This provides important background information and indicates the potential impact of the treatment.
Information about the new treatment and how it is thought to work.	This helps inform the validity and value of the outcome measures used in trials. This is particularly important when proxy measures, such as biological changes, have been used, as they may not translate into actual benefit for the patient.
The number of people in the local population who are likely to be treated now and in the future.	This is needed to estimate the benefit and cost impact.
Information about key aspects of delivering the new treatment.	This provides information related to prioritisation (for example, related service costs that have to be taken into account), feasibility of introducing the service (for example, manpower requirements and potential shortages), policy making (for example, the need to impose controls on a treatment's use) and planning implementation.
The evidence The health outcomes found in trials.	This indicates the health gain that might be associated with the treatment.
The quality and nature of the evidence.	This indicates the level of confidence with which the treatment will provide the outcomes stated.
Identification of subgroups of patients that might gain more or less benefit than other patients.	This provides some policy options.
The NNT (number needed to treat). For example, if the NNT is 20 then 20 patients will need to be treated before one patient will gain benefit.	When combined with other information, this gives an indication of value for money.
The costs The total cost of providing the new treatment.	This is needed to assess affordability and the size of the opportunity costs.
The cost of different policy options.	This provides the opportunity cost and affordability of policy options. This is particularly useful if it is not possible to provide access to all patients.
Other Identification of new ethical or policy principles.	This indicates whether the PCT needs to initiate a piece of work to address wider policy questions.
How does this treatment support the delivery of agreed priorities for the service area?	This, together with other information, helps shape the priority of the treatment within a programme area.

Cost effectiveness/value for money

Cost effectiveness is considered one of the key principles underpinning the provision of healthcare in the NHS. Cost effectiveness helps to answer questions such as *"Is this good value for money?" "Can I justify spending money on this?"* and *"Does society value this enough to pay this price?"*
In adopting this principle the NHS has, by implication, made a commitment to not funding treatments that are not cost effective.

In order to decide what is good or poor value for money, cost effectiveness has to be assessed or measured in some way.

For a number of reasons, PCTs do not generally employ health economics techniques: they are labour intensive and therefore expensive to generate; it is not feasible to generate cost-effectiveness analyses for all services; they do not provide sufficient information about health outcomes; and they do not incorporate all factors important to decision makers when setting priorities. There are nevertheless times when such a measure is invaluable. Examples are when considering disinvestment or identifying a sub-group of patients in whom an otherwise cost-ineffective treatment is highly cost effective.

The measure used by organisations such as NICE is cost per quality adjusted life year (QALY). The QALY takes into account both the quality and quantity of life. A treatment that provides one QALY for £5,000 is considered to be more cost effective than one that does so for £10,000. The current cost-effective threshold NICE uses is less than £20,000 per QALY. NICE will consider treatments in the range of £20,000 to £30,000 and also above £30,000 but with additional qualification. These thresholds are themselves controversial.

There has been a call to increase them on the grounds that treatments have become more expensive since NICE was established. There has also been a call to lower the thresholds from those who consider the current levels unsustainable.

For PCTs, a key problem with the QALY is that, although it is a measure of health gain, it does not distinguish qualitatively between one person getting a whole year and 365 people getting one day each (and all the states in between). Indeed, it is designed *not* to. The measure is therefore neutral about how a QALY is achieved. PCTs, on the other hand, place very different values on one person getting one extra year of life and 12 people each getting one month, even if the cost per QALY is the same in both instances. For PCTs, the nature of the health outcome is an independent factor that they take into account. PCTs tend to consider cost effectiveness using value-for-money assessments based on the health gain, the NNT and cost (see figure 3, page 9).

Whatever the threshold and however it is measured or estimated, services are going to fall either above or below a given line and PCTs have to take a view about what to do with each category. This is not as straightforward as it might seem.

Treatments that lie above the cost-effectiveness threshold

Treatments above the threshold should not normally be funded. However, not all treatments above the threshold are the same.

- Some are treatments that do not provide any valued health gain. These simply should not be funded and there is little point in attempting to seek ways to make them more affordable.

- Other treatments provide valued health gain but are too expensive. The PCT might consider providing such treatments if they were cheaper. One option for dealing with this group is to set a price for the treatment that the NHS is willing to pay. Currently, there is no legal mechanism for PCTs themselves to do this. Another option is to use a rebate scheme, whereby the NHS is reimbursed when a treatment has not been successful for a particular individual. So far there are only two rebates schemes in operation – one for drugs for multiple sclerosis and one for the cancer drug Velcade. These schemes are controversial and many PCTs feel that they have not been fully thought through.
- With or without the ability to change the price PCTs pay for a treatment, there will always be treatments that sit above the cost-effectiveness threshold. It is possible that there are occasions when a PCT might wish to fund a treatment in this category. Here again, the concept of exceptionality arises.

Applying the concept of exceptionality to treatments that are not cost effective

A policy framework is required to consider treatments that offer valued health benefits but are very expensive. Such decisions cannot be made on an ad-hoc basis. The framework that is adopted needs to be:

- coherent with overall decision making
- principled
- objective in the way it assesses treatments
- sustainable.

In Figure 4 overleaf, two scenarios for agreed exceptions above a threshold are shown. The aim in developing a framework is that it results in scenario 1 – namely, relatively few exceptions are agreed. Scenario 2, on the other hand, is a situation in which so many exceptions are agreed that the very notion of cost effectiveness is undermined. This can be viewed as unsustainable.

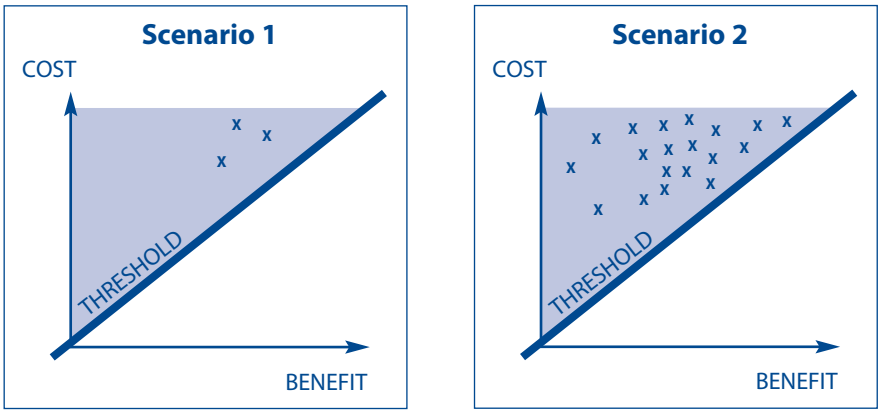
The major problem facing PCTs is that it has been impossible to come up with criteria that do not eventually create scenario 2. The author is not aware of any that have been successfully developed. There is a growing suspicion that such a set of principles might not exist. This leads to a rather stark (and perhaps currently unpalatable) conclusion that the cut-off might point just be that – a point above which nothing will be funded. The NHS urgently needs to find a resolution to this question or ad-hoc decision making will continue.

The only organisation that has made some attempt at documenting potentially relevant principles is NICE, in its *Guide to the methods of technology appraisal*[2]. It has published the following considerations for agreeing treatments above the £20,000 / QALY level:

- the degree of uncertainty surrounding the calculation of the QALY
- the innovative nature of the technology
- the particular features of the condition and the population receiving the technology
- instances where there are wider societal costs and benefits.

All of these, however, are ill defined and, as such, contestable. For example, what particular features of the condition is the decision maker looking for?

Figure 4: Two possible outcomes for agreeing to treatments above the cost-effectiveness threshold



Does rarity qualify as an exceptional circumstance?

Most of the treatments that are very expensive belong to the 'orphan drugs' group, although not all orphan drugs are very expensive. Orphan drugs are treatments that have been developed for rare disorders and which have been given special privileges related to licensing. The policy question these treatments raise is whether or not the NHS should pay a premium for rarity. There is no consensus on this issue. There are many who believe rarity should not be considered as a separate issue. Both the Scottish Medicines Consortium (SMC) and the All Wales Medicine Strategy Group (AWMSG) have taken the step of giving rarity some special consideration, although neither body provides an ethical framework or rationale for having done so. The SMC[3] allows additional considerations for orphan conditions (fewer than five affected individuals per 10,000 population) and the AWMSG[4] for ultra-orphan conditions (one affected individual per 50,000 population). In both cases, additional consideration is given to the following factors: the degree of severity of the untreated disease in terms of quality of life and survival; whether the drug can reverse rather than stabilise the condition; overall budget impact; whether the drug may bridge a gap to a 'definitive' therapy; and that such a definitive therapy is currently in development. The SMC also requires information on possible extensions to use.

An illustration of the some of the ethical dilemmas that treating rarity different might create can be found in Figure 5 opposite.

Another issue raised by high-cost drugs is whether or not there is a limit to the amount society is willing to pay to improve the health outcome for one individual. Ultra-orphan drugs, for example, can cost £350,000 per patient per year. Treating a

patient for ten years would cost £3.5 million and some patients are expected to be on treatment for life. There are now a number of treatments that require the NHS to commit millions of pounds for the healthcare of one individual. This is compared with the average spend on healthcare of £80,000 per person over the course of 75 years, with the majority of people using about £40,000 (based on 2002/03 prices)[5]. The question that has to be asked is not whether a person is worth this amount of money but can this level of expenditure be justified within a healthcare system subject to finite resources?

There is no emerging consensus view on these questions, so PCTs are going to have to come to a view themselves. Given the potential to set major precedent when making decisions in this area, caution is advised for agreeing funding treatments above the threshold.

Figure 5: Possible ethical dilemmas presented by consideration of rarity

Example 1:
Drug 1 improves the quality of life for patients with a common disorder.
Drug 2 does the same job but for patients with a rare disorder.
Drug 1 is cost effective but because of higher pricing drug 2 is not.
Is it fair to discriminate against patients treated by drug 2 just because they have a rare condition?

Example 2:
Drug 1 improves the quality of life for patients with a common disorder.
Drug 2 does the same job for patients with a rare disorder.
Both treatments fall above the cost-effectiveness threshold.
Are there any grounds for agreeing to fund drug 2 just because the treatment is for a rare condition?

Example 3: Increasingly, 'new' rare conditions are being identified. These are subgroups of patients with variants of more common conditions.
Drug 1 improves the quality of life for patients with a common disorder X.
Drug 2 does the same job but for only a small subgroup of patients who have a rare genetic variant of a common disorder.
Both treatments fall above the cost-effectiveness threshold.
Are there any grounds for agreeing to fund drug 2 just because the treatment is for a rare genetic variant of a common disorder?

Example 4:
Drug 1 is developed for a rare disorder.
Its price is set high, which puts it above the threshold.
Funding has been agreed because rarity has been granted special favour.
The treatment is then becomes licensed for a common condition.
Are there any grounds for denying treatment for patients with a common disorder (the price is rarely reset)? What impact does this have on other patients with common disorders whose treatments have not been funded because they are not cost effective?

Treatments that lie below the cost-effectiveness threshold

It is assumed that treatments that fall below the threshold should be automatically funded. This is not necessarily the case.

It is possible, because of how a QALY is measured, for a treatment to have a cost per QALY that is below the threshold without offering valued health benefit. Unfortunately, neither the NHS nor PCTs have defined the minimum health gain that is of interest within any health programme area. However, there are many treatments that are currently supported by NICE on cost-effectiveness grounds that PCTs would reject on grounds that they provide insufficient value health benefits. For example, a PCT would not wish to invest in a cancer drug that extends life by six weeks when local palliative care services still required investment.

Pricing issues are also relevant for treatments below the threshold. It is possible, because of the way in which drugs are priced, to have a group of drugs all of which do roughly the same thing but which are priced differently. This does not seem a defensible position in a publicly funded system.

The NHS is facing a new challenge. There is an increasing number of treatments for common disorders that offer valued health gain and are considered cost effective but which are relatively expensive. If provided to all patients, the opportunity costs are so high that they are deemed unaffordable. The NHS has not yet worked out how to approach these drugs.

The role of R&D in commissioning

It has already been mentioned that PCTs might wish to fund research into experimental drugs. However, PCTs might also fund clinical research by providing a new treatment under ongoing evaluation. Again, this has to be carried out in a robust manner and it is likely that PCTs will need to collaborate in order to fund a large enough study. The circumstances in which they might like to do this include:

- where the evidence available at the time of licensing suggests that further research is needed to establish a treatment's true place in management or its cost effectiveness
- where there is potential for sizeable variation in clinical practice (often known as 'clinical creep') which would be difficult to control – but which might lead to less cost-effective practice
- where it is not know how best to deliver the treatment (for example, frequency of treatment)
- where a treatment is considered valuable but unaffordable, such that cheaper alternative solutions have to be explored (for example, treatment doses or intervals).

'It is possible to have a group of drugs that do roughly the same thing but are priced differently.'

In summary

Figure 6 provides a quick summary of some of the key decision points for assessing new treatments.

Figure 6: Quick-reference decision tree for new treatments

Assess whether there is sufficient evidence to assess the treatment	*If not, then*	*the PCT's policy on experimental treatments is engaged*
↓		
Assess whether the treatment is likely to deliver valued health outcomes	*If not, then*	*a long-term exclusion policy is drawn up*
↓		
Assess whether the treatment represents value for money / is cost effective	*If not, then*	*the PCT's policy on treatments above the cost-effectiveness threshold is engaged*
↓		
Assess a range of factors needed for prioritisation	*If new policy issues arise, then*	*a piece of work is undertaken that looks at these issues before proceeding*
↓		
Prioritise and make funding decisions	*If good but unaffordable, then*	*the PCT's policy on R&D funding is considered*
↓	*If good but not affordable this year, then*	*the treatment is not funded and is logged onto the bring-forward system to be reconsidered next year*
↓	*If low priority*	*a long-term exclusion policy is drawn up*
Funded	*If high priority*	*funding is agreed and a commissioning policy drawn up specifying what will be funded.*

Rationalising the assessment of treatments

Many PCTs do not have the capacity within their organisation to carry out all the necessary assessments of treatments and services. However, this would not matter if there were greater sharing of expertise across PCTs to pool information and minimise duplication of efforts.

There are aspects of assessing treatments that only need to be done once across the whole of the NHS. PCTs should give consideration as to how they can collaborate to develop efficient networks to ensure a continuous supply of high-quality assessments.

Disinvestment

This report has focused on new treatments. However, PCTs also need to review what is currently provided. Disinvestment does not have to mean stopping a treatment altogether. It can mean stopping treatment to groups of patients that benefit less or changing the threshold for treatment.

The process for assessing existing treatments is similar to that for new treatments, with one exception. An additional exercise is often needed to assess to what extent clinical practice has drifted from licensed practice.

'PCTs often need to assess whether current clinical practice has drifted from licensed clinical practice.'

Commissioning policies

One of the key rules of priority setting is good documentation.

Commissioning policies are part of the essential documentation that supports priority setting. They provide an explicit statement of what the PCT will and will not provide. They also facilitate consistent and efficient decision making. It is as important to develop commissioning policies for treatments that the PCT actively supports as it is for those that it wishes to restrict. Such policies are also useful to help shape a number of aspects of provision.

In developing a commissioning policy, the following components are worth considering:

- What, if anything, is to be provided? What are the access criteria? Are there specific exclusions?
- What controls are wanted? How can these be specified? For example, does the PCT want the treatment offered only by a nominated provider or clinician?
- What information does the PCT want and is its provision going to be a condition of funding?
- Does the PCT want to check compliance or monitor spending? If so, then a prior-approval process is required
- What exceptionality criteria operate? (It is also always worth reiterating the PCT's general policy on exceptionality and management of individual funding requests within a specific commissioning policy.)
- Who can make which decisions? Delegated functions need to be specified.

All policies must be ratified by the board of the PCT.

Key pitfalls to avoid when developing commissioning policies

- Don't buy a little bit just in order to avoid saying 'no'. 'Clinical creep' always happens and it is difficult to control.
- If a PCT does not wish to fund a treatment then it should say so in a policy document and not adopt case-by-case decision making through the individual funding request route. This latter approach is fraught with problems (this will be dealt with in greater detail in the Confederation publication, *Priority setting: managing individual funding requests*).
- Do not adopt a commissioning policy that does not match resources (for example, 100 cases are funded when the PCT knows 200 cases are expected). If a policy cannot be afforded then restrict access criteria or don't fund at all. This situation needs to be differentiated from those in which there is planned growth (for example, renal dialysis).

Key action points

Key action points

Step 1: Agree key principles to underpin priority setting

- Agree an overall approach to service developments.
- Adopt a clear definition of a service development.
- Agree the criteria for agreeing unplanned in-year funding.
- Agree how the PCT will manage treatments that fall above or below the cost-effectiveness threshold.

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

- Agree and document the process for screening new treatments for exceptionality for in-year funding. Document any delegated authority.
- Develop more efficient means to assess new treatments – do 'once only' where appropriate by co-operating with other PCTs.
- If outsourcing assessment, be very clear what is wanted and ensure each product is fit for purpose.
- Agree the status of recommendations coming from various bodies related to the PCT, such as clinical networks. It is also worth documenting how the PCT regards statements and documents endorsed by the royal colleges.
- Give careful regard to how the different stages of decision making will be documented.
- Agree what decisions have to go through the board.
- Ensure that there are bring-forward mechanisms for good treatments that are not funded in any given year.

Step 3: Consider how to approach key relationships

- Set out a strategy for informing and educating key stakeholders about the PCT's approach to priority setting.
- Ensure that local provider trusts understand the definition of a service development and how the PCT will manage new treatments. In particular, providers should understand what is expected of them in relation to managing new treatments.
- Consider adding how new treatments will be managed to contracts with providers.
- Be explicit and provide clear and honest communication with clinicians and patients.

Step 4: Produce key policy documents

- The overarching policy document on resource allocation should include the PCT's approach to new treatments.
- The PCT should routinely produce treatment-specific commissioning policy documents. These can be interim policies.

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

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Glossary

Opportunity costs – arise from alternative opportunities that are foregone in making one choice over another.

Affordability – the ability to do something without incurring financial risk or unacceptable opportunity costs. It is ultimately determined by the fixed budget of the PCT.

Service development – 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 protocols that have cost implications; changes to treatment thresholds; and quality improvements, such as reduced waiting times. It also refers to other types of investment that existing services might need, such as pump priming to establish new models of care, training to meet anticipated manpower shortages and implementing legal reforms.

Service disinvestment – the mirror image of service developments.

The 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.

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Priority setting: managing new treatments

This report is the second 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.

Also available in this series: *Priority setting: an overview*.

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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