FPH Position Statement

Describing exceptionality for funding panels

The Faculty commends a series of NHS Confederation short reports on priority setting to all members working in this area of public health practice[1]. We further recommend that members who take part in or advise PCT decision panels should familiarise themselves with the good practice points in the third of this series, dealing specifically with the management of individual funding requests[2] This position statement summarises the concepts developed within the UK Commissioning Public Health Network on this topic and complements the forthcoming publications by the National Prescribing Centre on robust decision making.

It is important to distinguish between an exceptional case and an individual funding request. In an exceptional case, a patient seeks to show that he or she is an 'exception to the rule' or policy and so may have access to an intervention that is not routinely commissioned for that condition. In contrast, an individual funding request arises when a treatment is requested for which the PCT **has no policy**. This may be because:

- it is a treatment for a very rare condition for which the PCT has not previously needed to make provision *or*
- there is only limited evidence for the use of the treatment in the requested application *or*
- the treatment has not been considered by the PCT before because it is a new way of treating a more common condition. This should prompt the development of a policy on the treatment rather than considering the individual request unless there is grave clinical urgency.

More detailed advice on dealing with individual cases can be found elsewhere[2]. The rest of this paper provides advice on how to assess claims that **an individual is an exception to a policy.**

Considering exceptional cases

It is important to be clear about what the term 'exceptional' means in this context. Understanding the rationale behind policies not to fund certain interventions is central to this. In general the decision not to fund is because either:

1. The commissioners consider that the available evidence does not support a conclusion that the intervention is a reasonable use of NHS resources. This is usually because the intervention falls below commonly accepted thresholds of clinical effectiveness or cost effectiveness or a combination of both

or

[1]Priority setting: an overview; Priority setting:managing new treatments; ;.Priority setting: legal considerations
2008 NHS Confederation Publications. Available from www.nhsconfed.org/publications

[2] Priority setting:managing individual funding requests. Available from www.nhsconfed.org/publications

2. The commissioners believe that the intervention is a low priority for NHS resources when compared to the other health needs of the population.

1. Considering exceptions to a policy on an intervention with evidence of poor clinical or cost effectiveness.

In dealing with exceptional case requests for an intervention that is considered to be a poor use of NHS resources, the Faculty considers that in order for a patient to be considered as exceptional the PCT panel must be persuaded that

> *the patient has a clinical picture that is significantly different to the general population of patients with that condition* ***and as a result of that difference,*** *the patient is likely to derive greater benefit from the intervention than might normally be expected for patients with that condition.*

It is our opinion that, in essence, it is a question of equity. The PCT must justify the grounds upon which it is choosing to fund this patient when the treatment is unavailable to others with the condition.

The Faculty advises that exceptionality should be defined solely in clinical terms; to consider social and other non clinical factors automatically introduces inequality, implying that some patients have a higher intrinsic social worth than others with the same condition. It runs contrary to a basic tenet of the NHS namely, that people with equal need should be treated equally. This concept is expanded in section 2; an example of of the implications of considering these factors is given in box 1.

It must also be likely that the patient will derive greater benefit from the intervention than others in the patient group who cannot access the treatment. Again, this is a question of equity. If a panel is persuaded that a treatment is likely to be clinically and cost effective in a patient making an exceptional case request, then special consideration should be given to whether this patient may represent a small sub-group in whom the intervention may meet clinical and cost effective criteria. ***If this is the case, the original policy should be amended to include a provision for treatment of this subgroup.***

There may sometimes be only sparse evidence, to suggest improved outcome. This may simply be a biologically plausible mechanism for the intervention. This situation is similar to the individual funding request. In other cases the variation in the patient's condition may be so unusual as to make it unlikely that a significant body of research evidence on outcome will emerge in the foreseeable future. This presents a difficult decision for the PCT as the evidence may fall well below the standard usually required for service commissioning. We conclude that in reaching a decision in such circumstances, it is important to consider the following:

- the outcomes for best standard care and how the intervention relates to this
- the nature of the condition and its impact on daily function
- the likely outcome of the intervention i.e. cure; delay in progression; symptomatic relief with functional benefit etc.

- how does the intervention compare with accepted clinical and cost effectiveness thresholds

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BOX 1 Implications of including social circumstances in decision making

The PCT has decided to not fund Innovatomab, a newly licenced treatment for recurrent cancer. In reaching it's decision, the PCT considered that the 10 week median survival advantage of Innovavatomab over the standard treatment was not cost effective. This was based on quality of life measures during that 10 week period and the cost of the drug. P. H. is 67 and has had recurrence of cancer. He is the main carer for his disabled son aged 39. He points out that although the median survival is 10 weeks, survival of 45 weeks has been recorded in a very small number of patients. He argues that because it is impossible to predict which patients will attain this longer survival he should have access to Innovatomab because the costs to society of providing care for his son outweigh the costs of the drug. He also believes that even if he was only able to attain an additional 10 week survival, that would enable him to make better arrangements for his son after his death.

In agreeing to fund Innovatomab for Mr Hetherington the PCT acknowledges the value of the care he provides for his son. However, it would be difficult to argue that this care is of more worth than the care given to an elderly relative enabling that person to continue to live at home or the pivotal role played by the parent of a young family. Thus, the PCT would need to adopt a policy to fund Innovatomab in all those with a caring responsibility for a vunerable adult or children. This should be reflected in the other prioritisation policy documents of the PCT. The PCT should ensure that provider units are aware of this change in policy in order that all those who may be eligible for treatment come forward for treatment.

The decision also implies that the usual considerations of clinical and cost effectiveness do not apply to those with such a caring role and so access to medicines and treatments should be judged on a different basis for this group.

2. Considering exceptions to a policy on a low priority intervention.

Interventions are accorded low priority status for a variety of reasons. Commonly, such interventions have some of the following characteristics:

- Uncertain outcomes in the medium/longer term
- Paucity of research evidence to support their use
- The problem causes 'unhappiness' rather than ill health or functional impairment

Usually requests to be considered as an exception to these policies are based upon the psychological or social/functional implications for the individual.

If social and psychological factors are included in decision making, it becomes more difficult to prevent inequity. Agreeing to fund a case based on social or psychological factors almost inevitably sets a precedent for funding a sub group and so, should prompt policy review. ***PCTs should have an explicit policy on whether and how they view social and psychological factors in exceptional case decisions.***

There are three options for PCT panels dealing with claims for exceptionality to a policy on a low priortity intervention:

1. to remove the exceptional case option from policies governing procedures of low priority. and instead place a complete ban on the funding of these procedures. This is a legitimate stance but the PCT must be willing to review the policy if it becomes apparent that there are circumstances in which they will fund the

treatment. In addition the PCT must have a process by which such cases are identified.

2. to accept exceptionality claims but to review the existing policy on each occasion. As before, if circumstances emerge in which the PCT will fund the intervention, **the policy should be amended** rather than agreeing to fund an individual.
3. to allow exceptional case requests against a policy on low priority treatments on the basis of clinical, social and psychological factors.

Including these factors in decision making would require the PCT to have standardised criteria against which to judge psychological and social factors. Agreeing to fund for social reasons inevitably identifies a group the PCT believes have a greater social worth

A defensible decision to fund because of psychological distress, would need to demonstrate evidence that the distress was

- considerable,
- was beyond that seen in other patients in this situation
- and that the distress would be reversible as a result of the intervention.

The Faculty takes the view that because of the difficulties associated with obtaining normative values for the majority of patients for whom an intervention is not available and in the interests of equity, PCTs should exercise extreme caution in choosing this option in decision making. The Faculty considers that members would be best advised to encourage their organisations to adopt only options 1 or 2.

Box 2 illustrates the implications of funding a low priority treatment because of psychological distress

BOX 2

Mindful of health care messages S.J. has lost around 11stone in weight. She is very conscious of the large pendulous folds of excess skin especially on her upper arms and finds it impossible to expose them in public. She is the lone parent of young children and is anxious that they adopt a healthy lifestyle, however, she is so embarrassed by her arms that she cannot accompany the children in exercise such as swimming, parks, playgrounds and other leisure activities. She is also limited in the exercise she can take to maintain her new weight because she is aware of the movement of the skin folds. She is depressed because of the restrictions this places on her choice of clothes and regularly cries before getting ready to go out. She points out that she has saved the health service significant amounts of money by not accessing the bariatric surgery services and asks that the money that could have been spent on this should be used to help her now.

If the PCT chooses to fund this lady when others seeking cosmetic surgery are not funded, it would need to be sure that the functional impairment described is greater that found in both a general population but also that there is significantly different to the distress of others for whom cosmetic surgery is not available. If the PCT feel that the level of distress is proven then the cosmetic surgery policy should be amended to allow for the treatment of people who exhibit this level of functional disturbance on an objective scoring system. This criterion should then apply to all cosmetic procedures that have restricted access. The PCT should also ensure that there is equity with the PCTs position on cosmesis after bariatric

surgery. The PCT should ensure that provider units are aware of this change to the policy and of any psychological evidence it would require. The PCT should consider whether other policies should be amended to enable treatment of people who are distressed by lack of access to services.

Box 3 illustrates the implications of funding a low priority treatment based on social factors

Box3
J McF is a 40 year old man who is asking the PCT to fund reversal of his vasectomy. Eighteen months ago his children aged 11 and 8 were killed in a car accident. He and his wife, aged 36 would like to try to have another child or children. He cannot recall being told that there NHS funding would not be available for reversal at the time of the original procedure simply that it was technically possible but that results were variable. There is no documentation available from the original procedure

Choosing to fund J McF should prompt the PCT to amend its policy on reversal of vasectomy to include a provision for funding the procedure in the case of death of children. The PCT would need to be clear on whether it would fund reversal only when all living children had died or in circumstance in which a child/children survived. It would also to be appropriate to consider the position of a family in which a child is diagnosed with a terminal disease.

The PCT should establish the nature of the information given to those seeking vasectomy. It may wish to ensure that providers include information on the PCT's position on reversal of vasectomy. It may emerge that there is a cohort of men who were unaware of the PCTs position at the time of vasectomy. The PCT may consider funding reversal for this cohort.

The PCT should also consider its position on the funding of further fertility treatment for such couples should reversal of vasectomy prove unsuccessful.

General comments

We believe that because panels have a tendency to fund interventions for identified patients, the differences between the majority of patients for whom the treatment is not available and the patient in question must be abundantly clear. It is equally important that provider units and commissioners have a common understanding of exceptionality. In this way appropriate cases can be considered, inappropriate requests do not raise false expectations in patients and a funding route that circumvents the usual prioritisation processes can be closed.

This is a difficult area of Public Health practice because of the frequent lack of clarity and the highly charged, emotive nature of the applications. We would urge members to collaborate with commissioners, clinicians and legal advisors to establish common understanding of the principles and share best practice
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