Consultation response

The King's Fund response to the Health Select Committee's inquiry into the purchase of additional drugs by NHS patients (top-up fees)

10 December 2008

This paper is a formal response to the Health Select Committee's inquiry into the purchase of additional drugs by NHS patients (top-up fees).

The King's Fund is a charity that seeks to understand how the health system in England can be improved. Using that insight, we help to shape policy, transform services and bring about behaviour change. Our work includes research, analysis, leadership development and service improvement. We also offer a wide range of resources to help everyone working in health to share knowledge, learning and ideas.

1. Overview

1.1 In its evidence to the Inquiry conducted by Professor Mike Richards into the consequences of additional private drugs for NHS care, The King's Fund acknowledged that the government had to resolve a conflict between two views of the fairness. However, The King's Fund suggested that if patients chose to purchase a drug not funded by the NHS they should not, as a consequence, be denied the NHS care they would ordinarily have received. This was also the view taken by Professor Richards in his report and by the government in its response. (Recommendation 8]

1.2 Richards' recommendations and the Department of Health consultation document are based on the principle that NHS resources should be devoted solely to NHS patients and should not be used to subsidise private care. They therefore propose that patients who choose to pay for part of their care privately will also be required to pay all associated costs. Again this is in line with the recommendation in our submission to the Richards review. In order that such patients are not denied care they would ordinarily have received, Richards suggests that the private and public elements of care will need to be not only clearly identified but also kept separate. In effect, this strengthens existing guidance on this matter.

1.3 At the same time the Richards' review has aimed to contain the demand for private purchase of additional drugs by:

- speeding up NICE processes (Recommendation 1)
- negotiating with the pharmaceutical industry, seeking to introduce more pricing flexibility (Recommendation 5)
- ensuring that the scope for NHS funding is fully explored before purchase of private drugs is considered (Recommendation 9)
- ensuring that patients are made fully aware of the clinical and financial implications of doing so (Recommendations 12 and 13).

We agree with all these recommendations.

1.4 In addition, the possibility, raised in the Richards review, that certain patient groups near the end of life could have the health benefits of any potential drug treatment weighted more highly than other patient groups is also designed to reduce demand for topping up by making drugs that would ordinarily fall above NICE's 'acceptability range' more cost effective. We comment further on this below.

1.5 In its consultation paper, the Department of Health seeks to define a line between publicly and privately funded care on the basis of 'separation'. This is designed to ensure that the costs of administering drugs paid for privately fall entirely on the patient (or the insurer) and that the NHS itself does not pay for care that has been assessed by NICE as being not cost effective. There is a variety of ways in which 'separateness' could be created but the Department has chosen a physical concept of separateness.

1.6 A commonly used argument for physical separation is that it would be undesirable for patients on the same NHS ward to be receiving different levels of treatment. Using a 'specially designated area within an NHS trust' for private care could, Richards suggests, constitute separateness. But it is unclear whether guidance along these lines will secure against patients in the same ward being treated differently- the notion of 'separateness' is not precise enough to ensure it. But even if physical separation was clear, this would not ensure that patients would be unaware of the differences in treatment being offered. The real argument in favour of physical and thereby temporal separation is to ensure that NHS and privately funded care can be clearly identified and are not mixed up.

1.7 As an example of something that would fall outside the permitted scope for top-ups, the Department's consultation paper uses the example of an improved lens for cataract surgery – on the grounds that the extraction of the cataract and the insertion of the lens must be carried out during the same operation and hence in the same place. In other words, separation of publicly and privately funded care in a physical sense is not achievable. However, as the Richards review and its recommendations are confined to drugs this is a somewhat strange choice of example.

1.8 The example does, of course, illustrate how 'separation' could be achieved in a financial sense. Although the operation is one procedure, it would be easy to allow the improved lens to be paid for by the patient and the rest of his or her care provided by the NHS. This point has already been recognised by, for example, Age Concern, which is seeking clarification for other similar situations. There are likely to be more arguments for allowing patients to pay privately for elements of their care in cases where financial separation is easily defined, as in the case of upgraded implants, aids, and devices. The current rules around spectacles already permit patients both to mix NHS lenses with private frames and to buy more expensive glasses than NHS vouchers will cover.

1.9 The Richards report concludes (Recommendation 14) that the government should confirm how situations in which patients wish to purchase additional non-drug interventions should be handled. We agree with this.

2. Other issues

2.1 The Richards report (Recommendation 5) proposes that the Department of Health together with NICE should [re]consider the value to be attached to extra time at the end of life.

2.2 The government is right to look again at the value attached to giving extra time to patients with life-threatening conditions. If media coverage and political interest is anything to go by, there does appear to be public support for the idea that a patient who has been given just a few months to live may well regard the time left to them as particularly precious and that it is reasonable for the state to place additional value on that time compared to say someone who can expect to have say 20 years left. However, more work does need to be done to explore public attitudes and to have a wider and more considered debate than hitherto. There does not seem to have been much research

in this area - the Review identified just two studies on patients' notional willingness to pay for an extended, or improved, quality of life.

2.3 However, any such move to introduce differential valuations of life must be taken cautiously. For NICE to move away from the principle that a 'QALY is a QALY is a QALY' - that is, treating everyone's lives of equal value - represents a significant step. The central ethical question here is who should decide any differential valuation?

3. Variations

3.1 The Richards report makes a number of recommendations (1,3,10) designed to reduce variations between PCTs in their decisions on exceptional cases. We agree with most of these. However, the proposed collaboration between PCTs within SHAs or care networks, while offering the possibility of more rigorous and robust assessments, still leaves room for differences to emerge across the country as a whole, which will be challenged and which in a national health service may be hard to justify.

3.2 Making a case for exceptional treatment must inevitably involve the use of information specific to the case concerned. The proposals for a more transparent process will clearly help to promote some degree of consistency as they will allow both patients and clinicians to see what information and arguments have been used in similar cases.

3.4 If the government is successful in reducing the number of patients seeking access to non-approved drugs on the NHS, a national appeals system may be feasible. But if administrative practicalities suggest that local arrangements should be retained, then a system more accountable to the operation of the courts may be preferable. This would allow precedents and case law to be developed and used nationally and would reduce (though not eliminate) the scope for variation between areas.

3.5 The issue of individual hospitals choosing to top up NHS care on behalf of their patients –as one foundation trust is currently doing – should also be addressed, particularly where it is not just individual clinicians making exceptional case decisions based on the clinical circumstances of each patient. Although topping up is within their vires, and hospitals would not be able to bill their PCTs for the funding involved, they are, arguably, using NHS funds and introducing a form of inequity that the Richards' proposals are designed to reduce.

4. Drug approvals

4.1 The Richards report (Recommendation 1) supports the measures already being taken to speed up the approval process. The example of the Scottish Medicines Consortium does suggest that at least some decisions can be made more quickly than they are now. But the risk is that speedier appraisals may be of lower quality as less information will be available. If a speedier process is adopted then it will be necessary to ensure that effective arrangements are in place for monitoring the effectiveness of the drugs concerned when they are in day-to-day use.

4.2 However, there is a case for a more radical policy that would eliminate the time drugs are 'in limbo' by formally adopting a stage 4 approach to all new drugs. This would mean that they could be used as soon as they are licensed but that they should, immediately after licensing, be subject to systematic evaluation until a definitive evaluation was possible. This would have the advantage of allowing speedy take-up of new drugs but at the same time ensuring that when they are evaluated the financial and clinical evidence base for doing so is much more substantial than is the case now. In principle PCTs are already allowed to pay for drugs that have not been assessed by NICE, but there are no arrangements for monitoring the impact of their decisions. Our proposal would ensure that this interim period was used effectively to generate the information required for a full appraisal to be carried out when the evidence base is adequate.

5. Audit

5.1 Recommendation 11 - that the use of non-approved drugs should be audited – is sensible and is in line with what we suggest above. However, the government needs to make clear what the purpose of such an audit is: is it intended to provide information that might be used by NICE to review its position; to help clinicians identify the patients who might benefit from non-approved drugs and hence make the case for them being treated as exceptional cases; or to provide patients with better information on the cost and clinical implications of deciding to pay for them?

5.2 It may be possible to support this process through targeted research. NICE evaluations aim to identify the overall benefit of using a drug over the population it is applied to. Typically, however, the benefits of a drug are unevenly distributed, with some people gaining a lot and others, nothing. If those likely to benefit could be better identified in advance – as is the case now in some instances as the Richards report notes (para 2.19)- the cost-effectiveness of the drug concerned would be transformed. The government has recently begun to support, through its Biomarkers programme, research that aims at the more effective identification of the patients who have a good chance of benefiting from a particular intervention. It would be desirable to ensure that this programme is linked to the proposed audit process - or even better our proposed stage 4 approach.

6. The needs of patients

6.1 Recommendation 11 in the Richards report proposes that the Department of Health should consider the needs of patients for soundly based information. We agree with this but consider that the government should give more consideration to those patients who do opt for expensive top-ups. Although the proposals for better informed consent are sound, they do not deal with the financial risk to patients of their treatment being more successful than forecast. A stop-loss provision should be introduced to protect such patients from severe financial hardship. This would be justifiable in cost-effectiveness terms as longer-than-expected survival would mean that the drug concerned was cost effective for this particular patient.

7. Concluding comment

7.1 Although we agree with the broad approach the government has taken to minimise the number of patients seeking to top up their care in the sense defined in the Richards report, this, and the government's response to it, represent the beginning rather than the end of a debate about access to treatments that the NHS decides not to fund.

7.2 The current economic climate and the prospect of a sharp reduction in the rate of growth of the NHS budget from 2010 onwards combined with continuing technical progress in medicines and other technologies means that the number of occasions when patients wish to supplement their NHS care by paying for additional or superior treatments may grow, despite the measures Richards proposes to limit them. It is important therefore that any 'solution' is designed for the future, as well as to meet current difficulties.