Resource Allocation in the National Health Service: Access to drugs pending NICE Assessment

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Introduction

1. The NHS is not a bottomless pit; yet new treatments continue to emerge at an ever-increasing rate. The decision regarding which drugs are available on the NHS is not a new one, and the primary responsibility for assessment of the clinical evidence lies on the National Institute for Health and Clinical Excellence. But what is a patient to do if a drug is licensed for use, but is not due for consideration by NICE for a substantial period of time?

The General Approach

2. Traditionally the courts have been reluctant to interfere with decisions as to healthcare resource allocation. In *R v Cambridge Health Authority, ex parte B* [1995] 1 WLR 898 the patient was a 10 year old girl who had been diagnosed with non-Hodgkin’s lymphoma with common acute lymphoblastic leukaemia. This was treated with chemotherapy over a period of months. Unfortunately she then developed acute myeloid leukaemia and was treated for the second time with a course of chemotherapy, including a course of total body irradiation. She then underwent a bone marrow transplant.

3. For a while her condition stabilized, but then she suffered a relapse of acute myeloid leukaemia. The child’s father consulted doctors at Addenbrookes in Cambridge, the Royal Marsden and the Hammersmith Hospital in London, and in the United States, at a stage when it was considered by her treating consultant that she had 6 – 8 weeks to live and there was no further treatment which could usefully be administered.

4. Professor Goldman of the Hammersmith Hospital then suggested a further course of chemotherapy called MAE, and if complete remission was achieved, a second bone marrow transplant could be considered. The chances of success with this
approach were assessed at less than 20%. The highest the Professor put it was that it would be “reasonable” to adopt this approach, and it was the “best palliative approach” although it was a “high risk strategy”.

5. After discussion with the private physician contemplated to be the treating physician, both doctors agreed that the treatment was of an “experimental” nature.

6. The Health Authority refused to provide funding, on the following grounds:

   (1) The clinical opinions of the treating physician and some other clinicians was that a further course of intensive chemotherapy with a view to a second transplant operation was not in the best interests of the child.

   (2) Taking into account the advice and directions of the Department of Health with regard to funding of treatments which have not been proved to be of benefit, and the fact that the proposed treatment was neither standard nor had been formally evaluated, the funding of such a treatment would not be an effective use of resources.

7. Laws J granted judicial review on four grounds:

   (1) The decision-maker had wrongly failed to have regard to the wishes of the patient.

   (2) The description of the treatment as “experimental” was not a fair or accurate description, given the estimates of success stated.

   (3) The Trust’s evidence relating to resources consisted only of grave and well rounded generalities. He stated:
“where the question is whether the life of a 10 year old child might be saved by however slim a chance, the responsible authority… must do more than toll the bell of right resources… it must explain the priorities that have led it to decline to fund the treatment”,

and he found that the Trust had not adequately done so.

(4) The authority had wrongly treated the problem as one of spending £75,000 when in the first instance the treatment only involved the expenditure of £15,000.

8. In overturning the first instance decision Sir Thomas Bingham MR said the following:

“I have no doubt that in a perfect world any treatment which a patient, or a patient's family, sought would be provided if doctors were willing to give it, no matter how much it cost, particularly when a life was potentially at stake. It would however, in my view, be shutting one's eyes to the real world if the court were to proceed on the basis that we do live in such a world. It is common knowledge that health authorities of all kinds are constantly pressed to make ends meet. They cannot pay their nurses as much as they would like; they cannot provide all the treatments they would like; they cannot purchase all the extremely expensive medical equipment they would like; they cannot carry out all the research they would like; they cannot build all the hospitals and specialist units they would like. Difficult and agonising judgments have to be made as to how a limited budget is best allocated to the maximum advantage of the maximum number of patients. That is not a judgment which the court can make. In my judgment, it is not something that a health authority such as this authority can be fairly criticised for not advancing before the court.

… furthermore think, differing I regret from the judge, that it would be totally unrealistic to require the authority to come to the court with its accounts and seek to demonstrate that if this treatment were provided for B. then there would be a patient C. who would have to go without treatment. No major authority could run its financial affairs in a way which would permit such a demonstration.” (p906D – G) (emphasis added)
A more Interventionist Approach?

9. However in *R v North West Lancashire Health Authority, ex parte A* [2000] 1 WLR 977 the court found against the Health Authority. The Applicants suffered from an illness called “gender identity dysphoria”, commonly known as transsexualism. Each was born with male physical characteristics, but psychologically has a female sexual identity. Each had been living as a woman for some years. At the material time two had been diagnosed by a specialist consultant to have a clinical need for surgery substituting female for male characteristics, a procedure called “gender reassignment surgery”.

10. The challenge was to the authority’s refusal to fund their treatment, including surgery, because of its policy not to do so in the absence of “overriding clinical need” or other exceptional circumstances. They maintained that they were ill and that the authority’s refusal to fund treatment was irrational. The authority sought to argue that it has a statutory obligation to care for all within its area and limited financial resources with which to do so, requiring it to give a lower priority to some medical conditions than to others, and that transsexualism rightly has a low priority.

11. There was only one specialist clinic in the country, with the starting point being a period of consultation with a specialist to diagnose the condition and assess suitability for treatment. If considered appropriate, this is followed by a course of administration of hormones and psychiatric “monitoring” and a period of living and working as a woman (the “real life test”). Finally, in appropriate cases, surgery is performed.

12. A preliminary point was whether transsexualism was an “illness” within the meaning of the National Health Service Act 1977. That Act imposes on the Secretary of State a duty:
"to continue the promotion in England and Wales of a comprehensive health service designed to secure improvement - (a) in the physical and mental health of the people of those countries, and (b) in the prevention, diagnosis and treatment of illness, and for that purpose to provide or secure the effective provision of services in accordance with this Act."

In section 3, it elaborates on that duty by obliging him:

"to provide . . . to such extent as he considers necessary to meet all reasonable requirements . . . (e) such facilities for the prevention of illness, the care of persons suffering from illness and the after-care of persons who have suffered from illness as he considers are appropriate as part of the health service; (f) such other services as are required for the diagnosis and treatment of illness."

13. Illness is defined (section 128) as including “mental disorder within the meaning of the Mental Health Act 1983 and any… disability requiring medical… treatment or nursing”.

14. Accordingly it was common ground that transsexualism was an illness in the nature of a mental disorder for the purposes of sections 1 and 3.

15. The court continued:

“The qualifications in the statutory duties imposed by the Act of 1977 to which I have referred make plain that it is for the authority to judge what services it should provide, and to what extent, to meet all reasonable requirements for them. In Ex parte Coughlan the court said as to the originating and corresponding obligations of the Secretary of State, at pp. 633-634:

"25. When exercising his judgment he has to bear in mind the comprehensive service which he is under a duty to promote as set out in section 1. However, as long as he pays due regard to that duty, the fact that the service will not be comprehensive does not mean that he is necessarily contravening either section 1 or section 3. The truth is that, while he has the duty to continue to promote a comprehensive free health service and he must never, in making a decision under section 3, disregard that duty, a comprehensive health service may never, for human, financial and other resource reasons, be achievable. Recent history has demonstrated that the pace of developments as to what is possible
by way of medical treatment, coupled with the ever increasing expectations of the public, mean that the resources of the N.H.S. are and are likely to continue, at least in the foreseeable future, to be insufficient to meet demand.

26. In exercising his judgment the Secretary of State is entitled to take into account the resources available to him and the demands on those resources. In *Reg. v. Secretary of State for Social Services, Ex parte Hincks* (1980) 1 B.M.L.R. 93 the Court of Appeal held that section 3(1) of the [National Health Service Act 1977](#) does not impose an absolute duty to provide the specified services. The Secretary of State is entitled to have regard to the resources made available to him under current government economic policy.”” (emphasis added)

16. In 1995 the Authority adopted a policy which permitted funding for gender reassignment surgery “except in cases of overriding clinical need”; but later on within the policy it stated that gender reassignment (surgical treatment and/or specialist counselling outside the district) will not be purchased.

17. In 1998 the policy changed:

“"Gender reassignment. Persons wishing to adopt the role of the opposite gender . . . have access to the general psychiatric and psychological services available within the contract portfolio. However, no such service will be commissioned extra-contractually. The health authority will not commission drug treatment or surgery that is intended to give patients the physical characteristics of the opposite gender.

"In the event of requests for special consideration, a diagnosis of a gender identity disorder . . . evidence that the person has successfully adapted to the opposite gender role, or clinical advice that the person is suitable for surgery, will not (separately or in combination) be regarded as overriding clinical need or exceptional circumstances . . .””

Paragraph 5.1, under the heading "Exceptions," underlines how limited the authority intended it to be:
“"the Director of Public Health and Health Policy is authorised to consider exceptions to this policy on the basis of overriding clinical need. Such exceptions will be rare, unpredictable and will usually be based on circumstances that could not have been predicted at the time when the policy was adopted. They cannot therefore be defined. However, except when indicated otherwise above, the following circumstances may contribute to a case for exceptional funding: (i)When there is evidence (including consultant advice) that the problem is the cause of serious mental illness, which can be expected to be substantially improved if the exception is granted. (This must be distinguished from the disappointment and reactive depression resulting from ineligibility for treatment, which would not be regarded as exceptional)."” (emphasis added)

18. Further evidence served by the Health Authority gave a different slant to their attitude to funding such treatment:

"42. It is the view of the . . . authority (paragraph 2 of the 1998 policy) that 'interventions on the human body are not always related to ill health, but may be related to a desire to achieve an ideal body image or a bodily function that cannot currently be achieved. This is complicated by the facts that their supporters often describe the desire for intervention in medical terminology.'

"43. Consequently, although a condition is recognised by a group of medical practitioners the . . . authority would not necessarily regard this as giving it the status of a disease.

"44. The . . . authority's view is that the comments above apply to gender dysphoria, and therefore that treatment for gender dysphoria is not a condition for which . . . authority funded treatment is appropriate. However, psychological distress (which may result from difficulties with gender identity) may be appropriate for . . . authority funded treatment, and therefore the . . . authority is willing to commission support for such cases within its contracts." (Namely, for limited consultation of local practitioners with a view to acceptance of their condition - see below.)"

19. The authority also doubted the literature on the effectiveness of such surgery.

20. Mr. Justice Hidden had found for the Applicant as follows:
"in formulating policy or in applying policy to a particular case before it
the authority has to consider whether there is a demonstrable medical need
for the treatment in question. The court will not seek to allocate scarce
resources in a tight budget but will ensure that the health authority
has asked the right questions and has addressed the right issues
before arriving at a policy that is lawful. The authority has to tackle the
vexed problem of transsexualism and it has decided that gender
reassignment 'will not be purchased.' It is true that it has come to that
conclusion subject to the proviso of overriding clinical need, but since
it is unable to define or exemplify what is meant by such words, such
words either add nothing or alternatively unlawfully fetter the
authority's discretion in the question it is seeking to answer. To
conclude that it will provide counselling but it will not provide hormone
treatment or surgery is a conclusion to which it is not entitled to come . . .I
am satisfied that the authority's decisions . . . are Wednesbury unlawful
and irrational. They were arrived at without consideration of relevant
matters, such as the question of what is a proper treatment or what is
recognised as the illness involved in gender identity dysphoria . . . or
transsexualism. Those decisions were equally arrived at by consideration
of irrelevant matters. The policy itself is unlawful because it fetters
the authority's exercise of its discretion in discharging its duty of
providing treatment and providing facilities for the prevention of
illness and the cure of persons suffering from that illness." (emphasis
added)

21. The Court of Appeal differed in its reasoning, if not in the result:

"It is proper for an authority to adopt a general policy for the exercise
of such an administrative discretion, to allow for exceptions from it in
"exceptional circumstances" and to leave those circumstances
undefined: see In re Findlay [1985] A.C. 318, 335-336, per Lord
Scarman. In my view, a policy to place transsexualism low in an order of
priorities of illnesses for treatment and to deny it treatment save in
exceptional circumstances such as overriding clinical need is not in
principle irrational, provided that the policy genuinely recognises the
possibility of there being an overriding clinical need and requires each
request for treatment to be considered on its individual merits.”
(emphasis added)

22. However the court continued:
“However, in establishing priorities - comparing the respective needs of patients suffering from different illnesses and determining the respective strengths of their claims to treatment - it is vital for an authority:

(1) accurately to assess the nature and seriousness of each type of illness;
(2) to determine the effectiveness of various forms of treatment for it; and
(3) to give proper effect to that assessment and that determination in the formulation and individual application of its policy.”

23. Thus it was held that the authority’s policies, read with the further evidence served, did not reflect its acceptance on the appeal that transsexualism was an illness.

24. That basic error, one of failure to evaluate such a condition as an illness suitable and appropriate for treatment, was not mitigated by the allowance in both policies for the possibility of an exception in the case of overriding clinical need or other exceptional circumstances. Auld LJ stated that:

“such a provision is not objectionable, but it is important that the starting point against which the exceptional circumstances have to be rated is properly evaluated and that each case is considered on its individual merits: see per Bankes L.J. in Rex v. Port of London Authority, Ex parte Kynoch Ltd. [1919] 1 K.B. 176; per Lord Reid in British Oxygen Co. Ltd. v. Board of Trade [1971] A.C. 610, 624-625; and per Lord Scarman in In re Findlay [1985] A.C. 318, 335-336. The authority's relegation of what was notionally regarded as an illness to something less, in respect of which an applicant for treatment had to demonstrate an overriding clinical need for treatment, confronted each applicant with a very high and uncertain threshold.” (emphasis added)

25. The Court concluded as follows:

“The 1995 policy gave no indication of what might amount to an overriding clinical need or other exceptional circumstances; nor did the 1998 policy, save in paragraph 5.1 in which it emphasised the likely rarity and unpredictability of such circumstances, and instanced as a possibility when “the problem” was the cause of serious mental illness. Expert assessment that a patient needs the treatment would not do; demonstration of the existence of some other illness was a necessary condition for consideration for treatment. The authority gave a hint in its consideration
of the case of A. that epilepsy caused by her untreated transsexualism, if established, might have qualified. But, given the authority's reluctance to accept gender reassignment as an effective treatment for transsexualism - and it would follow logically any condition caused by it - the provision for an exception in a case of "overriding clinical need" was in practice meaningless, as Mr. Blake observed. It was as objectionable as a policy which effectively excluded the exercise by the authority of a medical judgment in the individual circumstances of each case; cf. Reg. v. Secretary of State for Health, Ex parte Pfizer Ltd., The Times, 17 June 1999, per Collins J. Looked at in that light, Dr. Sudell's observation in paragraph 31 of his first affidavit that it was "difficult to imagine what an exceptional clinical need for" gender reassignment might be, is understandable.

…

In my view, the stance of the authority, coupled with the near uniformity of its reasons for rejecting each of the applicants' requests for funding was not a genuine application of a policy subject to individually determined exceptions of the sort considered acceptable by Lord Scarman in In re Findlay [1985] A.C. 318. It is similar to the over-rigid application of the near "blanket policy" questioned by Judge J. in Reg. v. Warwickshire County Council, Ex parte Collymore [1995] E.L.R. 217, 224-226, "which while in theory admitting of exceptions, may not, in reality, result in the proper consideration of each individual case on its merits." (See p. 227.)

…

Accordingly, given the authority's acknowledgement that transsexualism is an illness, its policy, in my view, is flawed in two important respects. First, it does not in truth treat transsexualism as an illness, but as an attitude or state of mind which does not warrant medical treatment. Second, the ostensible provision that it makes for exceptions in individual cases and its manner of considering them amount effectively to the operation of a "blanket policy" against funding treatment for the condition because it does not believe in such treatment.” (emphasis added)

Resources Irrelevant

26. In R (Rogers) v Swindon NHS Primary Care Trust [2006] EWCA Civ 392 [2006] 1 WLR 2649 the Claimant sought judicial review of the Defendant’s decision to refuse funding of Herceptin to treat her breast cancer.
27. Herceptin is a drug which was licensed to treat secondary or late stage breast cancer in March 2002, but was not then licensed for the treatment of early stage breast cancer; nor had it then been evaluated by NICE.

28. The National Cancer Research Institute guidelines dated 14 December 2005 recommended that women should be considered eligible for adjuvant Herceptin if they fit the following criteria:

   (a) have primary invasive breast cancer that is confirmed as HER2 positive …
   (b) are eligible for and receive adjuvant chemotherapy;
   (c) have normal left ventricular ejection fraction ('LVEF') (though particular care was recommended in the case of patients aged over 50 with an LVEF of 55% or less) …
   (d) have none of the [listed] … cardiac contraindications …
   (e) have an adequate baseline hepatic, renal and haematological function;
   (f) have no evidence of metastatic spread.

29. Although the PCT’s written general policy was not to fund off-license or unlicensed drugs subject to the exception that “where a patient has a special healthcare problem that presents an exceptional need for treatment” it will consider that case on its merits; and in doing so, it will have regard to the funds available.

30. The Court of Appeal saw nothing unlawful in such a general policy (para 24).

31. However that was not the policy adopted in the case itself. On 5 October 2005 the Secretary of State for Health made an announcement which was later republished as a press release headed "Hewitt fast-tracks cancer drug to save 1000 lives" in which she is recorded as saying:

"Herceptin has the potential to save many women's lives and I want to see it in widespread use on the NHS. Today I am asking Professor Mike Richards [the National Cancer Director] to ensure that the facilities are put in place to enable women who require it to be tested. I want the licence for
Herceptin to be granted as quickly as possible, without compromising people's safety, and to be available within weeks of the licence being given. I share the huge frustration of many women about the delays in getting Herceptin licensed. I am determined to take action, and this represents a major step forward in our fight against cancer."

32. The Department of Health e-mails a weekly bulletin to NHS and local authority chief executives and directors of social services. The Chief Executive Bulletin (Issue 294) for the week 4-10 November 2005 contained the following item:

"Herceptin for early stage breast cancer

"On 25 October 2005 the Secretary of State announced: 'It is down to individual clinicians to decide whether … to prescribe Herceptin for a woman who has tested HER2 positive … after discussions with the woman about potential risks and taking into account her medical history. I want to make it clear that PCTs should not refuse to fund Herceptin solely on the grounds of its cost.' This applies to women prescribed Herceptin for early stage breast cancer ahead of a decision on licensing or NICE appraisal. PCTs should not rule out treatments on principle but consider individual circumstances. Further information: Lindsay Wilkinson." (emphasis added)

33. The PCT then decided on a specific policy for Herceptin, in which it would consider cases individually, and grant funding in exceptional circumstances:

"Swindon PCT's current approach

"Swindon PCT's Commissioning Policy states that the PCT will not commission unlicensed drugs. However, following the direction of the Department of Health, Swindon PCT will review each patient's case, where the managing clinician believes trastuzumab should be considered as part of the patient's treatment. The purpose of this approach is to establish whether there are any extenuating circumstances surrounding an individual's case that would warrant an exception to the current policy of not commissioning unlicensed drugs."

34. Crucially, that policy did not involve taking into account resources.

35. Mrs. Rogers’ case was considered for funding, but no exceptional circumstances were identified, and funding was therefore refused.
36. The Claimant sought judicial review, and was refused at first instance.

“The judge observed in para 63 of his judgment that the Court of Appeal was there considering North West Lancashire's policy on the prioritisation of treatment because of scarcity of resources. He said that in that context it was to be noted that, as most people would expect, it gave the treatment of cancer as an obvious example of a top priority. However, he accepted a submission made by Mr Havers that the same principle applies to a policy based on the absence of regulatory approval. **He concluded that to decide that unlicensed use would not be funded save in undefined exceptional circumstances was not of itself unlawful.**” (para 61 of Court of Appeal judgment, Emphasis added)

37. The Court of Appeal allowed the appeal:

“62 We would accept that conclusion subject to this important qualification, which can in our view be seen from the passage just quoted. In it Auld LJ stresses that a policy which allows for exceptions in undefined exceptional circumstances is not unlawful "provided that the policy genuinely recognises the possibility of there being an overriding clinical need and requires each request for treatment to be considered on its individual merits". As we see it, that means that a policy of withholding assistance save in unstated exceptional circumstances (in the case addressed by Auld LJ, and no doubt in this case also, overriding clinical need) will be rational in the legal sense **provided that it is possible to envisage, and the decision-maker does envisage, what such exceptional circumstances might be. If it is not possible to envisage any such circumstances, then the policy will be in practice a complete refusal of assistance: and irrational as such because it is sought to be justified not as a complete refusal but as a policy of exceptionality.**

63 Thus we would not hold that the policy was arbitrary because it refers to unidentified exceptional circumstances. The essential question is whether the policy was rational; and, in deciding whether it is rational or not, the court must consider whether there are any relevant exceptional circumstances which could justify the PCT refusing treatment to one woman within the eligible group but granting it to another. And to anticipate, the difficulty that the PCT encounters in the present case is that **while the policy is stated to be one of exceptionality, no persuasive grounds can be identified, at least in clinical terms, for treating one patient who fulfils the clinical requirements for Herceptin treatment differently from others in that cohort.”** (Emphasis added)
“the PCT developed a policy which treated financial considerations as irrelevant. It thus had funds available for all women within the eligible group whose clinician prescribed Herceptin. Yet its policy is to refuse funding save where exceptional personal or clinical circumstances can be shown.

79 Mr Havers was naturally asked to give examples of personal circumstances which might justify funding one woman rather than another within the eligible group. He submitted that it was not necessary for the PCT to identify possible examples and relied upon the North West Lancashire Health Authority case [2000] 1 WLR 977. The only positive example he gave was that of a woman with a child with a life-limiting condition. For our part, we cannot see how that fact can possibly justify providing funding for that woman but not another when each falls within the eligible group and there are available funds for both. After all, once financial considerations are ruled out, and it has been decided not to rely on NICE without exception, then the only concern which the PCT can have must relate to the legitimate clinical needs of the patient. The non-medical personal situation of a particular patient cannot in these circumstances be relevant to the question whether Herceptin prescribed by the patient's clinician should be funded for the benefit of the patient. Where the clinical needs are equal, and resources are not an issue, discrimination between patients in the same eligible group cannot be justified on the basis of personal characteristics not based on healthcare.

80 As to clinical characteristics, it was suggested in argument that one woman in the eligible group might have a greater clinical need for Herceptin than another. We can see that that might be theoretically possible but there is no indication that any such possibility in fact exists. The PCT rejected the suggestion that a distinction might be made between one person within the group and another on the ground that the prognosis of each was different. As we understand it, that was on the basis that the research does not support such an approach. It was also suggested that one patient within the group might be unable for medical reasons to take another drug such as tamoxifen, whereas the rest of the group might be able to take it, and that such a case would be an example of an exceptional circumstance upon which a decision to fund Herceptin treatment for the former patient and not for the rest could be justified. There is, however, no evidence which supports such a possibility. In any event we accept Mr Pannick's submission that it could not be reasonable or rational to deny a patient Herceptin treatment because she can tolerate tamoxifen, where
there is no evidence that tamoxifen, or any other drug, is an alternative to Herceptin.”

39. Mr. Justice Ouseley has recently given permission in the case of *R (Gordon) v Bromley NHS Primary Care Trust* [2006] EWHC 2462 (Admin). Linda Gordon was seeking funding for a trial period of Tarceva, a new lung cancer drug. The judge granted permission on the basis that it was arguable that the Trust had misinterpreted the period of funding sought, and that there had been an over-rigid application of the Trust policy.

**Conclusion**

40. The recitation of resources is simply insufficient to justify refusal to provide treatment. There is a real question as to whether policies truly admit the possibility of exceptions, depending on the facts of an individual case; and it seems likely that such policies must be applied on a proper view of the medical evidence on effectiveness. Indeed, HSC 1999/176 states as follows:

“The overall context

...  
5. If a new intervention is not referred to NICE, this does not imply any judgment on whether the intervention(s) in question are clinically or cost effective. NHS bodies should continue to use exi[s]ting arrangements to access the publicly available evidence and to determine local policies for the managed entry of the new intervention. The same principle should apply if an intervention has been referred to NICE but guidance is not yet available at the point which the new intervention is first introduced…”

41. The Prime Minister wrote the following letter in answer to a question at Prime Minister’s Questions:

“As Tarceva is licensed for the treatment of non-small cell lung cancer, clinicians can prescribe it on the NHS. The National Institute for Health and Clinical Excellence (NICE) is currently appraising the use of Tarceva for this indication and expects to issue guidance to the NHS in September 2007.
The Government has made it clear that funding for newly licensed treatments should not be withheld because guidance from NICE is unavailable. In these circumstances, we expect PCTs to take full account of available evidence when reaching funding decisions.

However, the final decision about funding lies with local PCTs…”
(Emphasis added)

14 October, 2006

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