NHS Consultation Duties

Richard Turney & Alistair Mills

1. This paper is divided into two parts. First, it considers the law relating to consultation generally. Second, it considers the specific duties imposed upon NHS bodies relating to patient involvement and consultation.

Part 1: Lawful consultation

What does lawful consultation involve?

2. Firstly, it important to establish whether a consultation process is required at all. The NHS context, there are various statutory duties to consult (see further below) as well as duties to "engage", which may be distinguished from a formal consultation obligation. Further, public bodies may have policies which require them to consult on certain matters. There are also circumstances where fairness requires a consultation process even if there is no specific duty. The source of the duty to consult is important, as what is required by way of consultation may be prescribed.

3. Regardless of the reason for consulting, it is a process which must be carried out lawfully. In *R v North and East Devon HA ex p Coughlan* [2001] QB 213, the Court of Appeal held:

> "[108] It is common ground that, whether or not consultation of interested parties and the public is a legal requirement, if it is embarked upon it must be carried out properly. To be proper, consultation must be undertaken at a time when proposals are still at a formative stage; it must include sufficient reasons for particular proposals to allow those consulted to give intelligent consideration and an intelligent response; adequate time must be given for

> this purpose; and the product of consultation must be conscientiously taken into account when the ultimate decision is taken: *R v Brent London Borough Council, Ex p Gunning* (1985) 84 LGR 168."

4. The true test is whether the consultation process is so unfair as to be unlawful, and whether something has "gone clearly and radically wrong". [1] What fairness requires depends on the context and the particular circumstances. [2]

What is meant by consultation at a "formative stage"?

5. The duty to consult at a formative stage means that it must happen at a point in the decision-making process where the consulting body has not made the final decision. In *R (Sardar) v Watford BC* [2006] EWHC 1590 (Admin) per Wilkie J at [29]:

> "The description "a formative stage" may be apt to describe a number of different situations. A Council may only have reached the stage of identifying a number of options when it decides to consult. On the other hand it may have gone beyond that and have identified a preferred option upon which it may wish to consult. In other circumstances it may have formed a provisional view as to the course to be adopted or may "be minded" to take a particular course subject to the outcome of consultations. In each of these cases what the Council is doing is consulting in advance of the decision being consulted about being made. It is, no doubt, right that, if the Council has a preferred option, or has formed a provisional view, those being consulted should be informed of this so as better to focus their responses. The fact that a Council may have come to a provisional view or have a preferred option does not prevent a consultation exercise being conducted in good faith at a stage when the policy is still formative in the sense that no final decision has yet been made. In my judgment, however, it is a difference in kind for it to have made a decision in principle to adopt a policy and, thereafter, to be concerned only with the timing of its implementation and other matters of detail."

[1] See *R (Greenpeace) v Secretary of State for Industry* [2007] Env LR 29; applied by the Court of Appeal in *R (Royal Brompton and Harefield NHS Foundation Trust) v Joint Committee of Primary Care Trusts* [2012] EWCA Civ 472

[2] See *R (Eisai Ltd) v National Institute for Health and Clinical Excellence* [2008] EWCA Civ 438, considered further below, at [27]

6. In *Sardar*, there had been a policy decision followed by a wide ranging consultation, which included possibilities other than the course adopted by the local authority. However, because there had been a prior decision, the decision making process lacked the appearance of fairness. [3]

What are "sufficient reasons for particular proposals to allow those consulted to give intelligent consideration and an intelligent response"?

7. The consulting body must set out its consultation document clearly, and it must provide adequate information to allow an informed response. The consultation document must facilitate effective responses, and be clear to the general body of consultees. The information must be presented fairly. A decision maker may set out its preferred option, but must also make clear what other options exist: see *R (Royal Brompton and Harefield NHS Foundation Trust) v Joint Committee of Primary Care Trusts* [2012] EWCA Civ 472, at [9]-[10].

8. In certain circumstances, it is incumbent upon the decision-maker to provide additional information to consultees to allow them to make informed responses. In *R v Secretary of State for Health, ex p United States Tobacco International Inc* [1992] 1 QB 353, the Secretary of State had purported to ban oral snuff without making available to the claimant the advice received from an expert committee which had led to the decision. The claimant, who had opened a factory in the UK for the production of the snuff, had previously agreed with the same committee how it would go about marketing the product. The committee's subsequent advice was found to be crucial to the Secretary of State's decision. Taylor LJ held:

[3] By way of contrast, note the case of *R (Gate) v Secretary of State for Transport* [2014] J.P.L. 383, where despite the consultation taking place after the formative stage had passed, there was found to be no unfairness as the scheme (a new link road) had been the subject of several earlier rounds of consultation and engagement when the proposed route had not been determined.

> "One cannot help feeling that the denial of the applicants' request was due to an inbuilt reluctance to give reasons or disclose advice lest it give opponents fuel for argument. One can understand and respect the need for ministers to preserve confidentiality as to the in-house advice they receive on administrative and political issues from their civil service staff. But here, the advice was from a body of independent experts set up to advise the Secretary of State on scientific matters I can see no ground in logic or reason for declining to show the applicants the text of the advice. In view of the total change of policy the Regulations would bring about and its unique impact on the applicants, fairness demanded that they should be treated with candour. To conceal from them the scientific advice which directly led to the ban was, in my judgment, unfair and unlawful."

9. However, there is no general duty to provide advice received by the decision-maker to consultees, or to share the responses of other consultees. In *Coughlan*, the health authority had commissioned a report from a Dr Clark in respect of its proposal to close the Mardon House facility. In consulting on the closure proposals, it had not made the report available to Miss Coughlan. The Court held that the report was an expert opinion which was itself part of the response to the consultation. The Court held (at [112]):

> "It has to be remembered that consultation is not litigation: the consulting authority is not required to publicise every submission it receives or (absent some statutory obligation) to disclose all its advice. Its obligation is to let those who have a potential interest in the subject matter know in clear terms what the proposal is and exactly why it is under positive consideration, telling them enough (which may be a good deal) to enable them to make an intelligent response. The obligation, although it may be quite onerous, goes no further than this."

10. Fairness may require the consulting body to disclose data and modelling which is available to it, to allow consultees to interrogate that information. In *R (Eisai Ltd) v National Institute for Health and Clinical Excellence* [2008] EWCA Civ 438, the claimant pharmaceutical company challenged the decision of NICE to adopt guidance relating to the use of Alzheimer's drugs produced by the claimant. During the consultation process, the claimant had asked to have access to an executable version NICE's economic model, but the request had been refused and the claimant had been

provided with a "read only" version. The claimant complained that the consultation process was unfair, because it had not been able to test the reliability of the model. The Court of Appeal agreed that the process had been rendered unfair. The modelling exercise had been central to the decision making process, and the claimant had been denied the opportunity to properly test it. As a result, the claimant had been limited in its ability to make an intelligent response to the consultation.

11. The following points are of note from the judgment of Richards LJ (with whom Jacob and Tuckey LJJ agreed):

    a. The mere fact that information is "significant" does not mean that fairness necessarily requires its disclosure to consultees (see [26]);

    b. The fact that external advice has been received does not automatically mean that it must be disclosed in the consultation process. The decision in United States Tobacco did not turn solely on the fact that input had been received from independent experts but from a combination of factors – including the high degree of fairness required in the context, the crucial nature of the advice, the lack of good reason for non-disclosure, and the impact on the applicants (see [30]);

    c. In deciding what amounts to a fair consultation, the Court may give some weight to the view of the consulting body (see [66]);

    d. The fact that a large amount of material had already been disclosed in the consultation process can "cut both ways" when a particular piece of material is excluded, because the amount of material serves the underline the importance of the process and makes the refusal to the disclose certain pieces of information stand out (see [66]).

12. Consultees will often have to be provided with the basis for the decision-maker's assessments. In *R (Save our Surgery) v Joint Committee of Primary Care Trusts* [2013] EWHC 439 (Admin), a challenge was brought to the identification of seven specialist centres for paediatric heart surgery which followed from the Kennedy Inquiry into deaths at the Bristol Royal Infirmary. The claimant's first ground was that the scores attributed to particular units for the "Quality" of their service provision by an independent panel had not been made public during the consultation. The defendant argued that because the detailed scores had not been seen by the decision maker they could not be material to the decision making process and thus fairness did not require them to be disclosed.

13. Nicola Davies J held that fairness did require that the claimant was provided with the scores. The scores had assumed increasing importance as the consultation process progressed, and ultimately the difference in score was determinative of the difference between two of the centres under consideration. The scores, whilst essentially being matters of professional judgment, would have provided a useful guide to the assessment being undertaken and could have given rise to requests for reappraisal.

How long is an "adequate time"?

14. The adequacy of the time provided will depend on numerous factors, including the complexity of the issues and the volume of the consultation materials. The Cabinet Office's latest statement of "Consultation Principles" states[4]:

> "Timeframes for consultation should be proportionate and realistic to allow stakeholders sufficient time to provide a considered response and where the consultation spans all or part of a holiday period policy makers should consider what if any impact there may be and take appropriate mitigating action. The amount of time required will depend on the nature and impact of the proposal (for example, the diversity of interested parties or the complexity

[4] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/255180/Consultation-Principles-Oct-2013.pdf

> of the issue, or even external events), and might typically vary between two and 12 weeks. The timing and length of a consultation should be decided on a case-by-case basis; there is no set formula for establishing the right length. In some cases there will be no requirement for consultation, depending on the issue and whether interested groups have already been engaged in the policy making process. For a new and contentious policy, 12 weeks or more may still be appropriate. When deciding on the timescale for a given consultation the capacity of the groups being consulted to respond should be taken into consideration."

How should the product of consultation "be conscientiously taken into account"?

15. The decision-maker must be able to demonstrate that consultation responses have been taken into account. That means the substance of the responses must be before the decision-maker itself – the knowledge of an official is not enough: see *R (National Association of Health Stores) v Department of Health* [2005] EWCA Civ 154, at [26].

16. However, that does not necessarily mean that every consultation response should be before the decision-maker, so long as the substance of the points made is known to it: see e.g. at *R (Buckinghamshire CC & ors) v Secretary of State for Transport* [2013] PTSR 1194, at [118]. For similar reasons, the failure to consult a particular person will not necessarily undermine the process if the substance of any points which would have been made have been considered. For that reason, the courts have held that rarely can a challenge to a consultation process succeed on the basis of a failure to consult others: see *R (Wainwright) v Richmond upon Thames LBC* [2001] EWCA Civ 2062, at [47].

17. Finally, the process of taking into account consultation responses may include re-consulting, and developing new proposals as views are taken into account. The courts have recognised that the consultation process may evolve, and that errors may as a result be "self-correcting": see *R (Royal Brompton and Harefield NHS Foundation Trust) v Joint Committee of Primary Care Trusts* [2012] EWCA Civ 472, at [93].

Part 2: Legislative Requirements: Patient Involvement and Consultation

Introduction

1. Consultation and patient involvement is an important part of the legal framework relating to the NHS. The legal duties are mainly set out in s.242 and ss.14Z2 and s.14Z11 of the National Health Service Act 2006 (as amended by the Health and Social Care Act 2012.

Section 242

2. Section 242 applies to NHS trusts and NHS foundation trusts. It is well established that it does not impose a duty upon the Secretary of State for Health: *R (Fudge) v South West Strategic Health Authority* [2007] EWCA Civ 803; *R (Unison) v Secretary of State for Health* [2010] EWHC 2655 (Admin), paragraph 33. By s.242(1B), each NHS trust and NHS foundation trust must:

   "make arrangements, as respects health services for which it is responsible, which secure that users of those services, whether directly or through representatives, are involved (whether by being consulted or provided with information, or in other ways) in–
   (a) the planning of the provision of those services,
   (b) the development and consideration of proposals for changes in the way those services are provided, and
   (c) decisions to be made by that body affecting the operation of those services."

3. In *R (LB Ealing) v NHS England* [2013] EWHC 3255 (Admin), it was common ground that Primary Care Trusts [16]:

   "were obliged to secure that "users" of health services for which they were responsible were "involved" in the development of the proposals for change set out in the consultation document and not merely consulted about them after they had been formulated."

4. The duty under s.242 is therefore relates primarily one of consultation, but involvement. Consultation is one of the ways in which this duty can be satisfied, but

it can also be satisfied through the provision of information. It was found, with reference to s.11 of the Health and Social Care Act 2001 (the predecessor to s.242) that consultation was not required in every instance: *R (Fudge) v South West Strategic Health Authority* [2007] EWCA Civ 803, paragraph 51. In *R (Lewisham London Borough Council); R (Save Lewisham Hospital Campaign Ltd) v Secretary of State for Health* [2013] EWCA Civ 1409, Sullivan LJ held at paragraph 16:

"It is a striking feature of the 2006 Act that it makes provision for an elaborate and lengthy process of public involvement and consultation in respect of proposals to reconfigure hospital services: see section 242 of the Act."

5. No obligation arises with respect to s.242 under proposals which are considered to be non-viable. Some possibilities can therefore be considered and discounted on clinical, financial or other grounds without consultation: *R (Enfield Borough Council) v Secretary of State for Health* [2009] EWHC 743 (Admin), [17] (a decision on permission by Geraldine Andrews QC, sitting as a Deputy High Court Judge – although this matter was not in dispute between the parties).

6. It is also notable that the duty can be satisfied through the involvement of representatives. Therefore, an NHS trust or foundation trust can engage patients through a focus group or patient representative group. This is different to the position of CCGs, which cannot satisfy the legislative requirements concerning patient involvement by representatives. The arrangements must relate to "users" of the services. In *R (Royal Brompton and Harefield NHS Foundation Trust) v Joint Committee of Primary Care Trusts* [2012] EWCA Civ 472, the Court of Appeal held at paragraph 7 that users of paediatric cardiac surgical services included the parents of the children to whom the services would be provided.

7. Section 242 (1C) provides that the duty to make arrangements for involvement in the development and consideration of proposals for changes in the way services are provided applies only:

"if implementation of the proposal would have an impact on–

(a) the manner in which the services are delivered to users of those services, or

(b) the range of health services available to those users."

8. The duty in s.242(IB)(c) concerning decisions to be made by an NHS trust/foundation trust affecting the operation of services applies only if the implementation of the decision would have an impact upon:

"(a) the manner in which the services are delivered to users of those services, or
(b) the range of health services available to those users."

Section 14Z2

9. Section 14Z2 of the NHS Act 2006, introduced by the Health and Social Care Act 2012, imposes a similar, but not identical, duty upon CCGs.

10. Section 14Z2(2) provides:

The clinical commissioning group must make arrangements to secure that individuals to whom the services are being or may be provided are involved (whether by being consulted or provided with information or in other ways)—

(a) in the planning of the commissioning arrangements by the group,
(b) in the development and consideration of proposals by the group for changes in the commissioning arrangements where the implementation of the proposals would have an impact on the manner in which the services are delivered to the individuals or the range of health services available to them, and
(c) in decisions of the group affecting the operation of the commissioning arrangements where the implementation of the decisions would (if made) have such an impact.

11. Unlike with s.242, there is no reference to representative bodies. It is not open to a CCG to satisfy its duties through focus groups.

12. Again, there is no duty to consult – the arrangements for involvement can relate to consultation, or to provision of information, or "other ways" of involvement. However, a CCG must have regard to guidance published by the NHS Commissioning Board. This Guidance is entitled *Transforming Participation in Health and Care: the NHS Belongs to us all*.

13. Section 14Z2(3) imposes requirements upon a CCG's constitution: it must have a description of the arrangements made under s.14Z2(2), and a statement of the principles which will be followed in implementing those arrangements.

14. The arrangements which a CCG has made under s.14Z2 must be explained in the CCG's annual commissioning plan, under s.14Z11.

Part 2, Chapter 5A

15. The consultation requirements under s.242 are excluded where the Secretary of State makes a direction under Part 2, Chapter 5A of the 2006 Act. In those circumstances, the requirements of consultation are more limited: *R (Lewisham Borough Council) v Secretary of State for Health* [2013] EWCA Civ 1409, paragraph 16.

16. In preparing a draft report, the trust special administrator must consult the board, and "any other person to which the trust provides goods or services under this Act and which the Secretary of State directs the administrator to consult" (s.65F(2)). He is required to publish a statement setting out the means of seeking responses to the draft report: s.65G(1), and to publish a notice stating that he is seeking responses to the draft report, and describing how people can give their responses: s.65H(2). He must hold a meeting seeking responses from the staff of the trust: s.65H(4), and another meeting for anyone else who may wish to attend to give their responses (s.65H(5)). The Secretary of State can direct an administrator to request a written response from any person, or hold a meeting to seek a response from any person. All responses to the draft report received must be attached to the final report: s.65I(2).

What are 'arrangements'?

17. Both s.242 and s.14Z2 concern a duty to make "arrangements". There is currently no case law on the meaning of "arrangements" under these sections. However, the meaning of making "arrangements" was considered by the House of Lords in the context of children with special educational needs in *Tandy v East Sussex CC* [1998] AC 714. Lord Browne-Wilkinson held:

> "The duty is to make arrangements for what constitutes suitable education for each child. That duty will not be fulfilled unless the arrangements do in fact provide suitable education for each child"

18. However, it is clear that the nature of "arrangements" is that there must be some generic planning for how patients will be involved in decision-making processes. There must be sufficient specificity in the arrangements so that they actually constitute arrangements, as opposed to vague expressions of intent. However, *ad hoc* patient involvement mechanisms for particular proposals also will not suffice as "arrangements".

The Importance of Patient Involvement

19. There are various high-level statements concerning the importance of patient involvement in NHS decision-making.

20. The NHS Commissioning Board's Guidance 'Transforming Participation in Health and Care: The NHS belongs to us all' begins:

> "The NHS is a cherished national institution. Its founding principle is to provide healthcare which is free at the point of delivery, to anyone who needs it, regardless of their circumstances. The NHS must be more responsive to the needs and wishes of the public, all of whom will use its services at some point in their lives.
>
> NHS England will ensure that public, patient and carer voices are at the centre of our healthcare services, from planning to delivery. Every level of our commissioning system will be informed by insightful methods of listening to those who use and care about our services."

21. There are clear references to the importance of patient involvement in the Parliamentary debates considering the Health and Social Care Bill 2012. Andrew Lansley, then Secretary of State for Health, said:

> "Under the Bill, patients will come first and will be involved in every decision about when, where, by whom, and even how, they are treated-"there must be no decision about me, without me." The 2002 Wanless report called for patient engagement, but that did not happen. Now it will. Because patients cannot be empowered without transparent information, an information revolution will give them more detailed information than ever before, showing them and their doctors the consultants who deliver the best care, giving them control over their own care records and enabling everyone to access the care they need at the right place and at the right time. Patients and their doctors and nurses will be able to see clearly which provider of health care offers the best outcomes and to make their decisions accordingly." [Hansard 31 January 2012, Col 608]

22. At Col 609, he said:

> "The general aims of reform are sound-greater role for clinicians in commissioning care, more involvement of patients, less bureaucracy and greater priority on improving health outcomes-and are common ground between patients, health professions and political parties."

Richard Turney

Alistair Mills

11 June 2014