Neutral Citation Number: [2015] EWHC 3752 (Admin)

Case No: CO/2887/2015

**IN THE HIGH COURT OF JUSTICE**
**QUEEN'S BENCH DIVISION**
**ADMINISTRATIVE COURT**

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 21 December 2015

**Before** :

**THE HONOURABLE MR JUSTICE FOSKETT**

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**Between :**

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| **THE QUEEN ON THE APPLICATION OF QSRC LIMITED ("QSRC")** | **Claimant** |
| **- and -** | |
| **THE NATIONAL HEALTH SERVICE COMMISSIONING BOARD ("NHS ENGLAND")** | **Defendant** |
| **- and -** | |
| **UNIVERSITY LONDON COLLEGE HOSPITALS NHS TRUST** | **Interested Party** |

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**Robert Palmer** (instructed by **Brooks & Co**) for the **Claimant**
**Simon Taylor** (instructed by **Blake Morgan**) for the **Defendant**
**The Interested Party did not appear and was not represented**

Hearing dates: 1 December 2015

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# Approved Judgment

**Mr Justice Foskett :**

## Introduction

1. This matter comes before the court pursuant to an order of Mr Neil Cameron QC, sitting as a Deputy High Court Judge, dated 28 July 2015 whereby he ordered that the Claimant's application for permission to apply for judicial review should be heard at a "rolled up" hearing.

2. Although there is a dispute between the parties about whether the Claimant's application is truly a challenge to a decision of the Defendant dated 20 March 2015, that is the way the proposed application is advanced. The Defendant asserts that the relevant decision was made much earlier and that the Claimant's application is, accordingly, out of time (see paragraphs 109 - 120 below).

3. The proposed challenge is to the Defendant's decision not to conclude any form of interim contract with the Claimant concerning the provision of "gamma knife treatment" (see paragraphs 8 - 14 below) for NHS patients at the National Hospital for Neurology and Neurosurgery ('the NHNN') at Queen Square in London pending the completion of the Defendant's national procurement exercise. Since the Defendant was created (see paragraph 17 below), it has declined to fund gamma knife treatment provided at the NHNN by the Claimant and will provide funding for such treatment for NHNN patients at the gamma knife facilities only at the BUPA Cromwell Hospital ('the Cromwell') or St Bartholomew's Hospital ('Barts').

4. It should be emphasised that the challenge concerns the position from 1 April 2013 until the procurement exercise is complete. It is not about the long-term issue of whether gamma knife treatment should be available under the NHS at NHNN. Equally, of course, the question of whether, either on an interim or long-term basis, NHS-funded gamma knife treatment should be available at NHNN is not a decision for the court. The court's involvement is purely with the legality of the decision not to agree an interim position.

5. The NHNN in association with the Institute of Neurology is a world-renowned centre for teaching, training and research in neurology and allied clinical and basic neurosciences. The NHNN itself is a neurological and neurosurgical hospital and forms part of the University College London Hospitals NHS Foundation Trust ('UCLH').

6. The Claimant alleges that the failure to fund the treatment identified above on an interim basis is unlawful. The Defendant denies this and says that it has ample justification for taking the position it has.

7. In my judgment, the Claimant's case meets the relatively low threshold of arguability and, accordingly, I grant permission to pursue the application for judicial review.

## The nature of the treatment concerned

8. Before turning to the parties and the background to the dispute, the nature of the treatment in issue should be identified.

9. Stereotactic radiosurgery ('SRS') and stereotactic radiotherapy ('SRT) are means by which precisely targeted radiotherapy treatment, in a precisely measured target volume, is delivered. SRS is delivered in one fraction; SRT is delivered in two or more fractions. One means by which each can be delivered is by 'gamma knife technology'.

10. Gamma knife radiosurgery involves the use of very precisely focused beams of radiation to treat tumours or lesions within the brain. The radiation beams are directed solely at the targeted area so that surrounding healthy tissue is not damaged. It can be used to treat malignant and benign tumours, as well as various functional and vascular disorders. The advance reflected by this form of treatment means that previously inoperable tumours can now be treated. One of the major benefits of gamma knife treatment is that it is minimally invasive and can often be carried out on an outpatient basis. That does not, of course, mean that the delivery of the treatment is necessarily to be regarded as a straightforward procedure or that specialist oversight is not required (see paragraph 12 below).

11. One feature of the apparatus that constitutes the gamma knife is essentially a metal helmet shaped in such a way that when the head is inserted the radiation beams (derived from radioactive cobalt) can be focused on a particular point within the skull. The equipment provided by the Claimant delivers 192 such beams all of which are focused accurately upon the lesion or tumour to be treated.

12. The following has been agreed between the parties as a description of what and who is ordinarily involved in the treatment:

    1. The initial step is for a stereotactic frame to be fitted to the patient; this frame is screwed to the skull to ensure precise measurements under local anaesthetic. The patient's head is immobilized in this stereotactic frame. The frame is fitted by the treating consultant as it breaks the skin, but does not penetrate the skull.

    2. The next step is for the patient to be transferred to radiology for imaging, accompanied by the radiographer. The specific target in the head is imaged via an MRI Scanner (and if a Vascular lesion, also an Angiography machine), and then the image or scan is transferred electronically to the planning system. The use of the frame allows the use of a fixed grid to map and plan the tumour treatment via the necessary x, y and z co-ordinates so that the cobalt sources/beams from the Gamma Knife can all be precisely focused.

    3. The scan within the planning system is then reviewed by the treating consultant, the medical physicist and neuroradiologists. The treatment is planned or calculated to provide the most effective dose to the tumours/ lesions etc. but with minimal radiation outside the target area and especially critical structures adjacent to the area (e.g. the Trigeminal Nerve is located alongside the brain

stem). The consultant is crucial in deciding the best ways of delivering radiation to the target area.

4. The treating consultant has to sign the agreed plan before any treatment can occur; it is his/her responsibility as in any surgical procedure. (In practice, the Medical Physicist and Neuroradiologist would also countersign the treatment plan.)

5. The plan allows for the 192 beams to coincide at the fixed focal point of the tumour or lesion. Each beam will contribute a small dose of radiation and have a minimum impact on the tissue on its way to the target. However, when all the beams meet at the target point, the resulting dose has the effect of destroying or removing the tumour. The treatment planning software is able to accommodate irregular shaped tumours.

6. The planning system transfers the agreed plan for treatment to the Gamma Knife console and the treatment is then delivered by the radiographer. Treatment times vary between 25 minutes to 1-2 hours depending on the condition being treated (multiple Cerebral Metastases are usually the longest treatment times and are dependent on the number of tumours scanned on the day of treatment, as each small metastases would need to be planned and treated)

7. The patient's frame is fixed into the Gamma Knife, immobilising the patient's head, and treatment can then occur. Whilst the patient is alone in the treatment room, the radiographer can chat and reassure the patient via the communication system.

8. At the end of the treatment, it is not the role of the radiographer to remove the frame: this need to be the treating consultant or a clinical registrar.

9. Once the frame has been removed the patient is provided with pain relief for the pressure headache that usually occurs and is allowed to rest. After 1-2 hours depending on the individual, the treating consultant would assess that the patient was ready to leave and allow for the patient to be discharged. A vascular patient would normally be transferred to a ward overnight for observations due to a heightened risk of further bleeding.

13. This treatment is, of course, of immense importance to the patients who require it. The evidence suggests that it is a technique that is employed nationwide with a frequency currently of approximately 7 patients a day. The cost varies but a gamma knife treatment at NHNN under the auspices of the Claimant currently costs £9,250.

14. The agreed position reflected in paragraph 12 above is said by the Claimant to be significant because it corrects, it is contended, an important misconception at one stage entertained by the Defendant about the personnel who need to be on hand on the day any such treatment is carried out. I will return to this in due course (see paragraph 106).

15. It will be appreciated that gamma knife surgery constitutes one of the "specialised services" provided under the NHS, those services currently accounting for approximately 14% (£14 billion) of the NHS England budget. It will be obvious from that bare statistic that any national review of specialised services will be a complex process (see paragraphs 56, 59 and 84 below.)

**The parties involved in this case and other relevant bodies**

16. The Claimant ('QSRC') is a wholly-owned subsidiary of Medical Equipment Solutions Limited ('MESL'). According to the first witness statement of Lynn Brooks, the Chief Executive of QSRC and of MESL, MESL is "an investor in niche medical equipment solutions, particularly within radiotherapy and radiosurgery." She says that the company "has investments and involvement in a number of schemes, including an upright specialist MRI for spine and claustrophobic patients … and two centres providing radiosurgery via a gamma knife solution." In February 2011 MESL and UCLH began negotiations with a view to MESL becoming the provider of the gamma knife services at NHNN. On 31 January 2012 a contract relating to these services was concluded between UCLH and QSRC (which, as foreshadowed above, was a newly formed special purpose subsidiary of MESL). Between then and October 2012 QSRC built the gamma knife suite (inclusive of the gamma knife itself) within NHNN at a total cost of well over £4 million leading to the gamma knife being ready for use at the end of October 2012.

17. NHS England ('NHSE') is the name under which the NHS Commissioning Board operates. NHSE has responsibility for commissioning clinical services (including SRS and SRT) throughout England within a budget set by the government on behalf of the NHS. Its actions are governed by the statutory powers and duties set out in the Health and Social Care Act 2012 ('the 2012 Act') and various NHS Regulations. NHSE was created by section 9 of the 2012 Act and has been operative since 1 April 2013.

18. Prior to 1 April 2013 services such as SRS and SRT were commissioned by Primary Care Trusts ('PCTs') by working collaboratively through Specialised Commissioning Groups (SCGs). There were 10 regional SCGs that operated in different ways resulting in variations in the commissioning arrangements throughout the country. In London the London Specialised Commissioning Group ('the London SCG') was the body generally responsible for commissioning these services until 1 April 2013. The London SCG became part of NHSE on 1 April 2013 and the personnel previously employed at London SCG joined NHSE. PCTs were abolished on 31 March 2013 and replaced by clinical commissioning groups ('CCGs').

19. One feature of the arrangements obtaining both prior to 1 April 2013 and thereafter is the Individual Funding Request ('IFR'). Pre-April 2013 IFRs feature in the background to the Claimant's claim and it is as well to highlight its meaning at this stage. Essentially, they were used primarily in the pre-April 2013 period in order to secure treatment for a patient who did not fulfil the requirements of what Mr Peter

Huskinson, the National Commercial Director for Specialised Commissioning for NHSE, called in his witness statement the "routinely commissioned standards of eligibility". In other words, they provide the basis for permitting treatment for a patient under the NHS in exceptional circumstances. Mr Huskinson also said this in his witness statement:

> "Before NHS England came into being, Primary Care Trusts also had a system where they authorised IFRs. For some PCTs the IFR system was also used for a quite different purpose, in addition to [authorising treatment on grounds of patient specific clinical exceptionality]. It was possible, either in the absence of a policy for treatment or any established contracted providers for care, or for treatments that are high cost, to institute an 'Individual prior approval' process, whereby rather than billing for all patients treated on a monthly basis, each request to treat with standard care is authorised one by one. It is important to understand that NHS England's IFR process has never been used for the additional function of an individual prior approval process to manage expenditure for routinely commissioned care, as our policies make clear. It is important that the historical IFR system and the current NHS England system are not conflated."

20. In April 2013 NHSE issued a document entitled 'Interim Commissioning Policy for IFRs'. This made clear the basis of IFRs for the future:

> "1.1. This policy applies to any patient who is in circumstances where the NHS CB is the responsible commissioner for NHS care for that person or needs medical treatment where the NHS CB is the responsible commissioner for the provision of that medical treatment as part of NHS care to that person.
>
> 1.2. Clinicians, on behalf of their patients, are entitled to make a request (an "individual funding request") to the NHS CB for treatment that is not normally commissioned by the NHS CB under defined conditions:
>
> The request does not constitute a request for a service development;
>
> AND
>
> The patient is suffering from a medical condition for which the NHS CB has commissioning responsibility and a commissioning position and the patient's particular clinical circumstances falls outside the criteria set out in an existing commissioning policy for funding the requested treatment
>
> OR

> The patient is suitable to enter a clinical trial which requires individual explicit funding by the NHS CB as opposed to being part of a group of such trial patients
>
> OR
>
> The patient has a rare clinical circumstance, thus rendering it impossible to carry out clinical trials, and for whom the clinician wishes to use an existing treatment on an experimental basis."

21. A "service development" is said to include, but is not limited to, new services, new treatments including medicines, surgical procedures and medical devices, developments to existing treatments including medicines, surgical procedures and medical devices, new diagnostic tests and investigations, quality improvements, requests to alter an existing policy (called a "policy variation" and which could involve adding in an indication for treatment, expanding access to a different patient sub-group or lowering the threshold for treatment), requests to fund a number of patients to enter a clinical trial and the commissioning of a clinical trial are considered as service developments in this context as they represent a need for additional investment in a specific service area.

22. I will return to the significance of IFRs in this case in due course, but Mr Huskinson also added this:

> "Since NHS England's establishment and operation of the policy, data I have reviewed shows that fewer than 5 treatments per week across the entire country and the entire £14 billion specialised commission portfolio take place as a result of an IFR application."

23. It will be appreciated that the discussions between MESL and UCLH concerning the provision of the gamma knife services at NHNN and the subsequent installation of the gamma knife suite took place against the background of the impending changes in the organisation of NHS commissioning. I will trace below (at paragraphs 35 - 85) the history of how the various bodies interacted during the relevant period because it lies at the heart of the challenge brought by the Claimant.

24. From 1 April 2013 NHSE was subject to the duties set out in the National Health Service (Procurement, Patient Choice and Competition) (No.2) Regulations 2013 ('the 2013 Regulations') concerning the way in which services under the NHS were to be procured. I will return to those obligations below (see paragraphs 28 - 30).

25. Those duties may be enforced by Monitor, the sector regulator for health services in England (see paragraphs 31 - 33 below), by a variety of means one of which is to publish guidance on the effect of the Regulations with which commissioners are expected to comply.

**The statutory and regulatory framework**

26. As indicated above, section 9 of the 2012 Act created the NHS Commissioning Board and conferred upon it the function of arranging for the provision of services for the purposes of the health service in England in accordance with the 2006 Act. This was achieved by inserting a new section 1H into the National Health Service Act 2006 ('the 2006 Act'). The Board was established formally as from 1 October 2012.

27. Section 75(1) of the 2012 Act now provides as follows:

> "Regulations may impose requirements on the National Health Service Commissioning Board and clinical commissioning groups for the purpose of securing that, in commissioning health care services for the purposes of the NHS, they -
>
> (a) adhere to good practice in relation to procurement;
>
> (b) protect and promote the right of patients to make choices with respect to treatment or other health care services provided for the purposes of the NHS;
>
> (c) do not engage in anti-competitive behaviour which is against the interests of people who use such services."

28. The relevant parts of the 2013 Regulations are as follows. Regulation 3, so far as material, provides -

> "(1) When procuring health care services for the purposes of the NHS (including taking a decision referred to in regulation 7(2)), a relevant body must comply with paragraphs (2) to (4).
>
> (2) The relevant body must—
>
> (a) act in a transparent and proportionate way, and
>
> (b) treat providers equally and in a non-discriminatory way, including by not treating a provider, or type of provider, more favourably than any other provider, in particular on the basis of ownership.
>
> (3) The relevant body must procure the services from one or more providers that—
>
> (a) are most capable of delivering the objective referred to in regulation 2 in relation to the services, and
>
> (b) provide best value for money in doing so.
>
> (4) In acting with a view to improving quality and efficiency in the provision of the services the relevant body must consider appropriate means of making such improvements, including through—

> (a) the services being provided in a more integrated way (including with other health care services, health-related services, or social care services),
>
> (b) enabling providers to compete to provide the services, and
>
> (c) allowing patients a choice of provider of the services ….”

29. The expression “relevant body” means a CCG or the NHS Commissioning Board.

30. Regulation 7, so far as material, provides as follows:

> “(1) For the purpose of taking a decision referred to in paragraph (2), a relevant body must establish and apply transparent, proportionate and non-discriminatory criteria.
>
> (2) The decisions are—
>
> (a) determining which providers qualify to be included on a list from which a patient is offered a choice of provider in respect of first outpatient appointment with a consultant or a member of a consultant’s team,
>
> (b) determining which providers qualify to be included on a list from which a patient is otherwise offered a choice of provider,
>
> (c) determining which providers to enter into a framework agreement with, and
>
> (d) selecting providers to bid for potential future contracts to provide health care services for the purposes of the NHS ….”

31. Section 61(1) of 2012 Act now provides as follows:

> “The body corporate known as the Independent Regulator of NHS Foundation Trusts—
>
> (a) is to continue to exist, and
>
> (b) is to be known as Monitor.”

32. So far as material, section 62 of the 2012 Act provides as follows:

> “(1) The main duty of Monitor in exercising its functions is to protect and promote the interests of people who use health care services by promoting provision of health care services which -
>
> (a) is economic, efficient and effective, and

(b) maintains or improves the quality of the services.

(2) In carrying out its main duty, Monitor must have regard to the likely future demand for health care services.

(3) Monitor must exercise its functions with a view to preventing anti-competitive behaviour in the provision of health care services for the purposes of the NHS which is against the interests of people who use such services …."

33. The following provisions of the Regulations relate to Monitor:

"13. (1) Monitor may investigate a complaint received by it that a relevant body has failed to comply with a requirement imposed by regulations 2 to 12, or by regulations 39, 42 or 43 of the 2012 Regulations (choice of health service provider).

(2) Monitor may on its own initiative investigate whether a relevant body has failed to comply with a requirement imposed by regulation 10.

(3) Monitor may not investigate a matter which is raised by a complaint under paragraph (1) where the person making the complaint has brought an action under the Public Contracts Regulations 2006 in relation to that matter.

(4) A relevant body must provide Monitor with such information in its possession as Monitor may specify for the purposes of an investigation carried out by virtue of paragraph (1) or (2).

(5) The power of Monitor under paragraph (4) includes—

(a) power to require the relevant body to provide an explanation of such information as it provides, and

(b) in relation to information kept by means of a computer, power to require the information in legible form.

14. (1) Monitor may declare that an arrangement for the provision of health care services for the purposes of the NHS is ineffective.

(2) Monitor may only make a declaration under paragraph (1) where it is satisfied that—

(a) in relation to that arrangement, a relevant body has failed to comply with a requirement imposed by regulation 2, 3(1) to (4), 4(2) and (3), 5 to 8 or 10(1), and

(b) the failure is sufficiently serious.

(3) Monitor may declare that a term or condition of an arrangement for the provision of health care services for the purposes of the NHS is ineffective where is it satisfied that—

(a) in relation to that term or condition, a relevant body has failed to comply with regulation 10(2), and

(b) the failure is sufficiently serious.

(4) On a declaration being made under paragraph (3), the term or condition is void; but that does not affect—

(a) the validity of anything done pursuant to the term or condition,

(b) any right acquired or liability incurred under the term or condition, or

(c) any proceedings or remedy in respect of such a right or liability.

15. (1) Monitor may direct a relevant body—

(a) to put in place measures for the purpose of preventing failures to comply with a requirement imposed by regulations 2 to 12, or by regulations 39, 42 or 43 of the 2012 Regulations;

(b) to put in place measures for the purpose of mitigating the effect of such failures;

(c) to vary or withdraw an invitation to tender for the provision of health care services for the purposes of the NHS to prevent or remedy a failure to comply with a requirement imposed by regulations 2 to 8 and 10;

(d) to vary an arrangement for the provision of health care services for the purposes of the NHS made in consequence of putting the provision of services out to tender to remedy a failure to comply with a requirement imposed by regulations 2 to 8;

(e) to vary an arrangement for the provision of health care services for the purposes of the NHS to remedy a failure to comply with regulation 10;

(f) to otherwise remedy a failure to comply with a requirement referred to in sub-paragraph (a).

(2) Monitor may not direct a relevant body under paragraph (1) to hold a competitive tender for a contract for the provision of health care services for the purposes of the NHS."

34. I will revert to how it is said that the Defendant has breached its obligations under the statutory and regulatory framework in due course, but it is necessary to trace in some detail the chronology of events to understand the nature of the Claimant's case and the Defendant's response to it.

## The detailed background

35. It is necessary to set out the background in some detail, both for the substance of what has happened, for an understanding of the arguments advanced on both sides and for the chronology of events given the limitation/delay points taken by the Defendant. The chronology can begin for this purpose with the events described in paragraph 16 above.

36. During that period the Claimant and UCLH (through the NHNN) set up a specific gamma knife radiosurgery multi-disciplinary team ('MDT') to collaborate in making treatment recommendations for patients. This was presumably necessary to enable the gamma knife suite to be up and running as from the end of October 2012.

37. In the meantime, it seems that overtures were made towards the end of September 2012 by the Claimant to certain PCTs (Ealing and Harrow) for funding on an IFR basis (see paragraphs 19 - 22 above) of radiosurgery for various patients to be carried out at the NHNN, presumably later in October when the facilities at NHNN were in place. Ms Brooks, who was pursuing these applications, was apparently re-directed to the part of the London SCG responsible for the North West sector and sent an e-mail about this (together with two IFRs) on 31 October 2012.

38. A meeting was arranged for 8 November between Ms Brooks and Claire Foreman, the "SRS lead" at the London SCG. In the meantime on 6 November Ms Foreman sent an e-mail explaining that the London SCG was unable to consider the IFRs because for 2012/2013 the SCG "commissions gamma knife for head and neck indications at Barts and the Cromwell only." Outside those indications, she explained, "IFRs need to be raised with the relevant PCT." Ms Brooks replied expressing disappointment that the e-mail did "not address any of the many issues raised by QSRC and NHNN on SRS and patient treatments" and saying that the meeting on 8 November would be helpful. Following the meeting Ms Foreman spoke to a representative of one of the PCTs who informed her that the PCTs had not funded the cases because they were not considered "exceptional". In those circumstances, Ms Foreman told Ms Brooks that the patients should be advised to go to Barts or the Cromwell. Ms Brooks replied that following day saying that the two patients had been so advised by the NHNN team, but they did not wish to do so. She also said that the meeting had been helpful "in clarifying the differing roles within the PCT and LSCG" and went on to say that she was sure "you will shortly receive a submission from us regarding the service at NHNN/UCLH for consideration."

39. The Claimant's case, set out in the Statement of Facts and Grounds and supported by Ms Brook's first witness statement, is that at the meeting on 8 November 2012 -

> "… UCLH and QSRC were told that the relevant specialist commissioners would not award a new contract to any new entrant under the then current regulatory regime, given the expected changes under the Health and Social Care Act 2012

> that were expected to come into effect on 1 April 2013. QSRC and UCLH were therefore advised at the same meeting to seek approval of the service by way of [IFRs] from local commissioners, the then [PCTs] for patients to be treated in the period between opening 31 October 2012 and 31 March 2013; and to prepare a business plan for 2013/14 to be considered by NHS England, which would be taking over responsibility for specialised commissioning thereafter."

40. Ms Brooks asserts that –

> "The IFR arrangements were clearly intended to provide an interim commissioning arrangement until NHS England came into being and conducted a proper procurement for SRS under the new arrangements to be introduced by the 2012 Act (although in the event no mention of a national SRS procurement exercise was made by NHS England until July 2013)."

41. The factual background to this aspect of the Claimant's case is not controverted by the Defendant (see paragraphs 92 - 94 below), but it seeks to put a different gloss on the significance of the IFRs during this period from that put upon it by the Claimant. I will deal with the global picture concerning the NHNN patients in this context during this period below, but the chronology after the meeting on 8 November 2012 shows that shortly thereafter one of the Consultant Neurosurgeons at NHNN, Mr Neil Kitchen, submitted IFRs concerning SRS treatment for Trigeminal Neuralgia on behalf of 3 patients. The response of the North and East London Commissioning Support Unit (which gave approval in respect of all three cases) on 18 December 2012 was expressed in the following terms:

> "The application was considered on 15 November 2012 by the Individual Funding Request (IFR) for NHS East London and the City, which considers cases of patients who are registered with GPs in City, Hackney, Newham and Tower Hamlets. The IFR Panel considers, on an individual basis, those treatments and procedures that are not routinely NHS funded or for which prior approval needs to be sought. The panel is comprised of a director of public health, local GPs, medicines management lead and a commissioner. The IFR panel assesses the effectives of the treatment, grounds for exceptionality, as well as equality considerations in relation to previous decisions made by the sector and implications for the funding of other similar patients in the future.
>
> The panel clarified that the London Specialised Commissioning Group commission on behalf of London PCTs against the criteria set out in their guidance document (Advice to London Primary Care Trust Services Specification: Radiosurgery and Radiotherapy, endorsed May 2010) and there is a potential inequity if this is not applied consistently across all gamma knife providers. The panel agreed therefore that all three cases

> should be funded on clinical grounds as there is sufficient information to demonstrate that the London SCG criteria are met, and refusal to fund would increase inequality between these patients and previous patients treated at approved centres if these criteria were not adhered to. The panel noted that UCLH is not an SCG approved centre for gamma knife treatment. The panel asked for the commissioning arrangements to be clarified after the meeting to ensure that there is consistency of approach. As the lead commissioner for UCLH has funded gamma knife treatments at UCLH and the SCG criteria were met, commissioning approval was given after the meeting for the treatment to proceed for all three patients at UCLH."

42. It appears that further IFRs were submitted by the Claimant on behalf of NHNN to CCGs in North West London in the period after November 2012. There is a letter to Ms Brooks dated 11 March 2012 (which is plainly a mistyping for 2013) from the Chair of the Ealing CCG "on behalf of NWL CCG Chairs" referring to these IFRs. He noted that the IFRs cited "continuity of care" and "patient choice" as the exceptional reasons to justify the funding. He noted also two of the patients had already been treated because of "clinical circumstances". The substance of his reply was as follows:

> "… Our definition of exceptionality is as below.
>
> *Unusual or unique clinical factor about the patient that suggests that they are:*
>
> *(i) Significantly different to the general population of patients with the condition in question*
>
> *(ii) Likely to gain significantly more benefit from the intervention than might be expected from the average patient with the condition.*
>
> Using these parameters, patient continuity (something the NHS should strive to provide for all patients as far as possible) does not suffice as *clinically exceptional* circumstances. You have stated that all patients meet the LSCG commissioned criteria. Therefore, it is a reasonable expectation on our part that the patients are referred to an LSCG commissioned service and are not taken down the Gamma Knife pathway at Queen's Square.
>
> The NWL IFR service has kept the CCGs Chief Operating Officers and Chairs informed of your funding requests and the basis for the requests and no CCG has indicated they wished to consider funding outside the IFR framework.
>
> Given the number of requests received so far, it is very clear that you are seeking to take this via IFR route when it should be discussed as a service development. It is not appropriate to put

requests for service development through the IFR process. As you know, the LSCG commission gamma knife and so are responsible for considering adding providers to the list. I understand that the LSCG/London Commissioning board are considering your request to be added to the providers lists from April 2013 but there has been no agreement to fund in the interim. I understand that you may have had discussions with your lead commissioners (North Central London CCGs) about becoming a provider.

I wish to be very clear that the NWL CCGs' position on this matter.

- CCG will routinely fund funding Gamma Knife treatment within the LSCG commissioned pathway.

- Treatment outside the LSCG commissioned pathway will be funded via the IFR route only i.e. exceptionality or rarity must be demonstrated and agreed by an IFR panel. This is clear in our published policy that has been emailed to you (attached again with this letter).

- If, as part of the triage processes for individual requests (which includes clinical review), the IFR service feels that exceptionality or rarity is not likely to be demonstrated, the IFR team will not take the requests to panel for consideration.

- All requests that you have submitted have been triaged and reviewed by clinicians and the grounds you have stated (continuity of care and patient choice) are not considered to demonstrate exceptionality according to our definition and so have not been, and will be, taken to panel for consideration.

- CCGs are not willing to consider funding Gamma Knife treatment at Queens Square outside the IFR framework. This includes funding for patients you have already treated. The treatment was not authorised and will not be funded retrospectively.

- You are clearly seeking to have Queens Square added to the providers list for Gamma Knife and this can only be discussed with the LSCG.

I trust this clarifies why the funding requests you have sent in will not be considered by the IFR team and will not be considered by CCGs for funding. We are not willing to commission outside of the LSCG contracts unless on an exceptional basis. I would request the Trust to not send in any further requests to the IFR team unless exceptionality can be

> demonstrated. There are existing commissioned services for Gamma Knife treatment and the Trust should refer patients to these services." (All emphasis as in original.)

43. It would seem, therefore, that the CCGs in the North West region of London were not prepared to permit the IFR process to be adopted for the obtaining of funding other than in exceptional circumstances as defined. The final sentence indicates that the destination for patients for whom "exceptionality" could not be demonstrated was "the existing commissioned services", namely, Barts and the Cromwell.

44. Shortly before receipt of the reply from the NWL CCG Chairs, on 12 February 2013 Ms Brooks sent by e-mail to Mr Simon Williams, a commissioner of the London SCG, a detailed proposal for "Gamma Knife services" at NHNN. It would seem that it followed up a meeting held at NHNN on 21 December 2012 which Mr Williams attended and, on Ms Brooks' account, was put together by the Claimant at his suggestion. The proposal appears to have been designed to comply with the NHS Commissioning Board's publication "Prescribed specialised services: commissioning intentions for 2013/14" published in November 2012. It was published by what was known as the Specialised Services Commissioning Transition Team. The purpose of the document was described within it as follows:

> "2. From 1st April 2013 the NHS CB, as part of its portfolio of directly commissioned services will be responsible for the commissioning of all 'specialised' services (referred to as prescribed services in this report). This document sets out our commissioning intentions for 2013/14 and beyond for these services.
>
> 3. The commissioning and contracting of prescribed services will radically change for 2013/14; however, this is in the context of the phased transition programme for these services which has been underway since 2011. In addition, the changes being implemented are also in support of the direction of travel set out by Sir David Carter's 2006 independent review of specialised commissioning arrangements[1]."

45. The Carter review said this about the role of those responsible for specialist clinical commissioning:

> "Specialised services commissioners have an additional role in preventing the proliferation of specialist centres to the point where there are too many centres, each treating too few patients, to provide a safe, high quality, value for money service.
>
> Designation of specialised service providers by SCGs would secure an appropriate concentration of clinical expertise and activity at designated centres located to maximise geographical access. Designation would safeguard patient access to high

[1] Review of Commissioning Arrangements for Specialised Services May 2006.

> quality, cost effective services and prevent unsafe and unplanned proliferation of services.
>
> Commissioners should be able to choose how many providers to designate for each service so as to promote choice for patients but maintain sufficient critical mass in each provider to ensure clinical safety, quality and value for money."

46. The 'Commissioning Intentions' document (see paragraph 44 above) went on to say that all "prescribed services" would be commissioned and contracted for by the NHS CB and that this was be organised as follows:

> "There will be a single operating model for the commissioning of all Prescribed services, operationally delivered via ten nominated Local Area Teams (LATs). Within these arrangements London will have a more integrated structure with the LATs working as an essential part of the overall pan-London arrangements for direct commissioning. In addition, these arrangements will also include the integration of highly specialised services currently commissioned via NHS London/National Specialised Commissioning Team (NSCT), and high secure psychiatric services."

47. The proposal advanced by the Claimant (referred to in paragraph 44 above) indicated also that 5 draft papers published in December 2012 concerning the clinical commissioning policies in respect of SRS and SRT for particular conditions to be followed in due course by the NHS CB had been considered and taken into account in drafting the proposal, as was a further draft paper concerning the service specification for SRS and SRT.

48. The proposal was for the year 2013/2014 and was put forward plainly in an effort on the part of the Claimant and NHNN to secure an agreement for that period. The proposal indicated that the anticipated flow of patients from April 2013 would be 17-19 patients per month at the price of £9250 each (the price being charged during the current year).

49. There was no immediate response and Ms Brooks did not follow it up (reflecting an understanding on her part that the period was one involving "unprecedented change") until an e-mail of 22 April. It appears that a meeting between Mr Williams and Mr Mike Foster, the Deputy Chief Executive of UCLH, then took place on 26 April. An internal exchange of e-mails between Mr Williams, by then the Acute Programme of Care Lead (London Region) for NHSE, and Ms Sue McLellen, Head of Specialised Commissioning (London Region), on 29 April demonstrates Mr Williams' position taken at the meeting:

> "… The gamma knife business case and the IFRs were discussed separately and not explicitly linked.
>
> On the gamma knife we ran through our concerns given the late inclusion plus the fact that there are a number of other business cases up for consideration at other Trusts. Hence risk of over

> capacity. We agreed that UCLH would continue to submit IFRs for cases which would be mapped against existing commissioning policies (and the Trust suggested draft service specifications) whilst a more robust assessment of service need across London was carried out.
>
> Mike was quite happy with this and given he wasn't clear himself on the Trust's relationship with the actual service provider thought quite reasonable and we'd given him a roll forward on how to manage requests.
>
> Mike raised the concern about IFRs and the fact that to date they'd had no acknowledgments for requests made. Although they didn't think anything was clinically urgent they didn't think this was a reasonable position especially as it meant they didn't know where the patient was in the process. He did say he did feel constrained to mention this to Anne Rainsbury (sic)[2] this afternoon when she visits."

50. In answer to a query from Ms McLellen, Mr Williams said the "more robust assessment of service need across London" was then anticipated to take no longer than 6 months. He noted the complication of the position of UCLH in the context of the "existing services at Barts", something he mentioned to Mr Foster. I will return to those "existing services" below (see paragraphs 57 and 64).

51. On 29 April 2013 a series of letters from Ms Caroline Walton, the CDF and IFR Lead for NHSE (London Region), to Mr Kitchen (see paragraph 44 above) were sent in relation to IFR requests for Gamma Knife radiosurgery sent by him on various dates to NHSE (London Region) between 5 and 26 April. The standard reply was as follows:

> "It was found that your patient meets the current policy NHSCB/D05/P/d access criteria. Please refer your patient to one of the two NHSE commissioned providers in London, the BUPA Cromwell Hospital or Barts Health NHS Trust to carry out the required treatment."

52. As the Claimant alleges, NHSE continued to approve IFRs in respect of patients who met the access criteria, but on the basis that payment would only be made if the patients were treated at either the Cromwell or Barts.

53. I should interrupt this part of the narrative to observe that at about this time the Claimant (albeit in a different corporate manifestation) had been engaging in correspondence with NHSE (South Yorkshire and Bassetlaw Area Team) concerning the arrangements for Gamma Knife treatment at Thornbury in Yorkshire. I will say more about this below (see paragraphs 68 - 69), but the point to be noted at this juncture is that the Thornbury Radiosurgery Centre (where the facilities were provided by the Claimant to the Sheffield Teaching Hospitals Trust) lodged a complaint with Monitor in May 2013. Monitor accepted it and investigated it. As

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[2] Dr Anne Rainsberry was the Region Director (London) for NHSE.

will appear below (see paragraph 70), it resulted in guidance being given by Monitor in April 2014 which the Claimant asserts is relevant to the present case.

54. Returning to the narrative, Ms Walton sent a similar letter to those referred to above (see paragraph 51) to Mr Kitchen dated 30 May 2013 in respect of a particular patient. Although addressed to Mr Kitchen, Mrs Pauline Richardson, the Claimant's Director of Operations, appears to have responded to the letter and wrote to Ms Walton on 31 May expressing her "dismay" at the request to transfer the patient to the Cromwell or Barts. Her letter continued thus:

> "I believe it would be appropriate for you to explain the reasoning for the decision made by NHSE to commission services from these providers to the exclusion of NHNN. I believe a similar letter was sent recently by our Medical Director, Mr Neil Kitchen, but no response was given.
>
> Therefore please note that QSRC requests a formal and detailed written response on the rationale why preference has been made in commissioning these other providers in preference to NHNN. Is this made on clinical grounds? Has your commissioning of these providers been subject to transparent procurement? We await an expeditious response before transfer of this patient can be considered further."

55. This period was an intense period of e-mail and other communications with, as I read those communications, a degree of "posturing" by all those involved. The answer to Mrs Richardson's letter would seem, at least in substance, to have come in an e-mail from Ms McLellen to Mr Foster of 18 June, the essential part of which was in these terms:

> "I note that you describe the service at [NHNN] as an established service. I reiterate the request made in my email to you of 6 June to provide evidence of commissioner support for this service development. To the best of my knowledge, there has been no business case approved for the development of SRS by any commissioners and the SRS service at UCLH has not been formally commissioned, although some London PCTs have approved treatment via their IFR process.
>
> From April 2013, SRS became the commissioning responsibility of NHS England for which it has agreed policies and guidance and NHS England made appropriate arrangements to commission the provision of this service.
>
> As I have previously stated, NHS England has two contracted providers for Gamma Knife in London, to whom all activity has been referred in the past and should continue to be referred until such time as we have completed the needs assessment and determined, from this, what additional capacity, if any, is required. Should we reach that position, we will need to follow an appropriate procurement route to secure this additional

> capacity. It is our intention to complete the activity and capacity analysis by the end of August, following which, all providers who have an interest in providing SRS/SABR, will have the opportunity to be considered for this additional capacity.
>
> I trust that this also addresses the issue you raise regarding Procurement, Patient Choice and Competition. As you are aware, the act does provide for circumstances where a provider may not be included, and an excess of providers to be included is one determinant. Equally, commissioners should not favour one provider over another and I am aware of other London Providers who wish to undertake this work."

56. The Claimant had been seeking legal advice at this time. On 27 June Ms Brooks wrote to Ms Walton, referring to the response to Mr Kitchen referred to above (see paragraph 54). She complained that despite the fact, as she asserted, "more than 50 patients" had been treated with gamma knife treatment between late October 2012 and 31 March 2013, the funding for which had been provided in each case by way of an IFR, from 1 April 2013 onwards treatment at the NNNH was no longer approved. She suggested that no reason had been given for this and said that NHSE would be contacted shortly with details of the "illegality" of the position it had taken. She said that, notwithstanding this position, the Claimant had tried to persuade patients to go to one or other of the two hospitals named by NHSE as providers of this treatment, but had failed. She said that NNNH was proposing to treat these patients in any event and that NHSE would be invoiced. Ms Walton effectively replied on the following day saying that this would be at the Claimant's own financial risk. Ms Brooks responded refuting that suggestion and then on 5 July sent, as promised, details of the alleged breaches of the 2013 regulations that the Claimant's solicitors had advised her had occurred. Her letter indicated that she had scheduled a meeting with representatives of Monitor on 22 July. Her letter also contained a list of questions concerning the contract with Barts and the Cromwell which she had been advised to raise. The reply to these questions did not emerge until a letter from Ms McLellen dated 30 September 2013. I will set out the relevant facts below (see paragraph 64). However, in the meantime (in August 2013) it seems that a decision was made by NHSE to conduct a "demand and capacity review for all forms of innovation radiotherapy services, including SRS and SRT." This was to be a nationwide review and presumably an expansion of the needs assessment previously contemplated in relation to such services in London (see paragraphs 49 - 50 above).

57. The letter replying to the various questions raised by Ms Brooks indicated that the contracts with Barts and the Cromwell then current were contracts for one year commencing on 1 April 2003, initial discussions concerning which started in December 2012. Reference was made to the commissioning intentions document referred to at paragraph 44 above which, it was said, made clear that existing contracts would transfer into the 2013/14 year within "financial envelopes based upon historic expenditure". It was said that one of the operational business rules for 2013/14 was that no new service developments would be considered and this was why the business case submitted by the Claimant (see paragraphs 47 - 48 above) was not considered because it amounted to a new service development.

58. I assume that the matters thus raised are to be derived from the following paragraphs in the commissioning intentions document, some of the language of which is, at least to the uninitiated, somewhat opaque:

> "11. There are currently not only variations in price for the same services across providers, but also differential pricing arrangements and currencies in existing contracts for the same providers. With the new model for a nationally commissioned portfolio of services, there will be a requirement for consistent pricing, currencies and contracting arrangements. This could therefore represent significant risk in 2013/14 for both providers and the NHS CB, therefore, in order to avoid destabilising services in the transition to consistent pricing and currencies, a financial envelope will be set with each provider based on historic expenditure. Consistent prices will be set for each provider based on net zero impact at 2012/13 prices. The envelope will then be adjusted for net tariff deflator (inflation less efficiency deflator) and QIPP programmes[3]. This will be a time limited transitional arrangement to avoid destabilising any part of the system. The NHS CB will work with providers to rebase currencies and prices on a national basis for the 2014/15 contracting round.
>
> …
>
> 77. The move to a national model for specialised commissioning has a range of implications and potential financial impacts. Specialised services will be funded via a finite budget that will be set by the NHS CB, rather than on a subscriptions basis funded by PCTs. This has significant potential impacts for providers which are detailed below. It is essential that providers note the changes and ensure that they are prepared to respond with effect from 1st April 2013. It is acknowledged that the move to consistent pricing across the specialised services portfolio has significant inherent risk with the potential to destabilise providers. In order to introduce this in a planned and managed way and to give providers and the NHS CB sufficient time to move towards this, 2013/14 will be a preparatory year. Financial envelopes will be set based on historic expenditure adjusted for Operating Framework requirements. The NHS CB and providers will work collaboratively to ensure that costs are managed within these envelopes."

59. Translated, it would seem that this means that the policy of NHSE in the interim period until completion of the transition to a "nationally commissioned portfolio of services" was not to commission gamma knife services from any provider other than an existing provider. As will become apparent (see paragraph 88 et seq below), what constituted an "existing provider" is an important feature in this case. The

[3] The Quality, Innovation, Productivity and Prevention programme.

background, from the perspective of NHSE, is set out in Mr Huskinson's witness statement:

> "62. Given the very significant system change at that time it was simply not possible to re-procure from first principles all specialised services immediately following the reorganisation. At its starting point for 2013/14 NHS England thus adopted the position arrived at by its predecessor specialised commissioning groups (SCGs).
>
> 63. To ensure critical mass of patients and infrastructure, specialised services needed to be concentrated in a managed number of providers, with appropriate geographic distributions to optimise patient access. Where there were existing contracts in place before March 2013 services would continue to be procured from those providers on an interim basis until a review of commissioning for the relevant service. There were 200 specialised services and it was not going to be possible to carry out national reappraisals of all of those services and indeed issue tenders for the provision of those services in time for the new NHS contract year starting on 1 April 2013."

60. Reverting to the chronology of events in the present case, there had been attempts to reach a compromise solution in September 2013, but no overall resolution was achieved (other than in relation to the payment for certain patients who had been treated by September) and each communication from NHSE was to the effect that all patients who achieved the access criteria for SRS or SRT treatment "should be referred to one of the two NHS England commissioned providers for this service in London" (letter from Ms McLellen to Mr Foster of 6 November 2013) - in other words, they were to be sent to the Cromwell or to Barts.

61. On 20 December 2013 Ms Brooks wrote to Ms McLellen (and others) notifying her of the Claimant's intention to make a formal complaint to Monitor. The complaint was made on behalf of the Claimant, not UCLH as such. The complaint was lodged on 30 January 2014. It was a detailed document setting out the history as the Claimant saw it and specifying the grounds upon which it was said that there had been a breach or breaches of the regulations.

62. In the same month, NHSE published (as I understand it, in draft) to various parties its 'Needs Assessment and Service Review'. It was obviously not an immediately acceptable document to the SRS Clinical Reference Group. With the papers before the court is a letter from the Chair of the CRG dated 21 February 2014 rejecting the findings in the draft document.

63. The lodging of the complaint placed a temporary halt in communications between the Claimant and NHSE, but those communications did resume in February/March 2014 when further (unsuccessful) efforts were made to resolve issues over payment for treatments already carried out. It is unnecessary to set out the substance of those communications for present purposes.

64. The disclosure process in these proceedings has revealed that the NHSE London Area Team met with Monitor on 26 February 2014 for a preliminary meeting in advance of Monitor deciding whether to open a formal investigation. It appears to have been a thorough meeting judging by the notes disclosed. The London area team was asked to provide a history of gamma knife services in London, which it did. In summary it was to the effect that Barts had provided to the Department of Health such services from no later than April 1993 and by 2000 the Cromwell had been added as a provider. In 2009 the commissioning of gamma knife services was passed to the London SCG and the existing contracts were passed to the London SCG in April 2009. The London SCG commissioned gamma knife services on behalf of the London PCTs until April 2013 when the existing contracts were transferred to the NHSE London area team. It was said that there was "no difficulty in managing demand between the two existing providers who provided continuity of provision for London." It was said on behalf of the London area team that the first awareness of the Claimant was in October 2012 and that the receipts by North West London PCT of a number of IFRs (see paragraphs 42 - 43 above) prompted questions by that PCT as to whether the Claimant was a contracted provider.

65. The notes also indicate that the London area team relayed to Monitor the message it had been relaying to the Claimant to UCLH as set out above. One feature of what was said by the London area team concerning the existing contractors was as follows:

> "When signing contracts with Barts [and the Cromwell] the former SCG agreed expected levels of activity. These contracts were rolled over on 1 April 2013 and expected levels of activity agreed with the providers (in line with NHS England commissioning policy to permit time for a fundamental review of the commissioning of radiostatic surgery services …). NHS England would be breaking its existing contracts with the existing London providers of gamma knife as having three providers rather than two when two already provide sufficient capacity, would reduce the expected levels of activity for the existing contract providers. There is no penalty for NHS England if the expected levels of activity fall below those agreed, but NHS England has an interest in the sustainability of the providers with which it contracts."

66. The Claimant draws attention, in particular, to the passage in the notes that suggests that the "prescribed pathway" did not harm patients for the following reasons:

- There is no waiting time to be seen at the contracted Gamma Knife services.
- The patient's own consultant will perform the operation at the contracted Gamma Knife services.
- There is no break in clinical care or diminution of the quality of that care.

67. It is now acknowledged that the second of these bullet points is not correct because, at least so far as NNNH is concerned, not all Consultants based primarily there had or

have clinics at either Barts or the Cromwell. Accordingly, most patients transferred from NNNH to either of the foregoing hospitals must be treated under the supervision of a different Consultant.

68. As will appear below (see paragraph 72), Monitor's decision on the complaint was communicated to the Claimant in June 2014. In the meantime Monitor had issued guidance in April 2014 on the commissioning of radiotherapy services following its decision, given on 26 February 2014, to close its investigation into the Thornbury case (see paragraph 53 above). The purpose of the proposed guidance, as set out in the closure decision, was as follows:

> "We have decided to close our investigation into the commissioning of radiosurgery services. This document explains our reasons for closing the case. To assist commissioners facing similar circumstances in the future, we also intend to publish guidance on some of the issues raised in this investigation."

69. The reasons for closing the case were given as follows:

> "To ensure we use our resources in a way which delivers the greatest potential benefit to patients, we apply a prioritisation framework when deciding whether or not to open an investigation. We also apply this framework when we consider whether or not to continue an investigation once under way.
>
> Since we opened our investigation, NHS England has confirmed that it has now entered into a contract with Thornbury. In the circumstances, it appears to us that closing our investigation and issuing guidance is the course of action likely to create the greatest potential benefit to patients and is a proportionate means of achieving our objectives. This will enable us to support commissioners facing similar issues in the future and ensure that patients benefit from what we have learned in this case.
>
> Closing our investigation prior to a final decision being taken means that we have not made findings in relation to the matters under investigation. In particular, we have not determined whether or not the conduct carried on by NHS England or its predecessor was consistent with the applicable rules. The decision to close our investigation does not prevent us from opening a new investigation in relation to the commissioning of radiosurgery services if concerns arise. Any decision to open a new investigation would be made in line with our duty to protect and promote the interest of patients."

70. The guidance issued in April 2014 ('Commissioning of radiosurgery services: guidance following case closure Case CCD 01/13') was under four headings: prioritisation and commissioning, using evidence in decision-making, acting

transparently and publishing details of all contracts awarded. The parts to which I have been referred are as follows:

1. Under 'prioritisation and commissioning'

> "Commissioners may sometimes decide, in the face of competing priorities, that it is not practical to undertake a comprehensive commissioning exercise to choose their providers; they may instead adopt an interim position using a simple, expedient process. However, in these circumstances, commissioners must still act within the framework of the Regulations[4].
>
> For example, it may appear to be a reasonable commissioning decision to only procure services from providers that held an NHS standard contract in the previous commissioning year. However, under the Regulations, commissioners must treat all providers equally, not favouring one provider (or type of provider) over another. Differential treatment between providers requires objective justification. In this example, if the commissioner's decision had the effect of excluding some existing providers from being able to provide a service (because they had provided direct services to NHS patients under other arrangements than an NHS standard contract), commissioners would need an objective justification for this. The objective justification would need to be well reasoned and based on evidence. If commissioners did not have a well reasoned objective justification based on evidence, we would normally expect them to also procure services from the other existing providers (those that had provided services under other arrangements than an NHS standard contract), under their interim commissioning position …."

2. Under 'using evidence in decision-making'

> "Under the Regulations, a commissioner must procure services from providers most capable of delivering its objectives and that provide best value for money. Commissioners should ensure that they evaluate objectively the ability of different potential providers to deliver the service specification and to improve quality and efficiency. Not doing so may mean that commissioners do not contract with the providers best placed to deliver high quality and efficient healthcare services. It may also mean commissioners do not create incentives for the selected providers to invest in improving quality and efficiency …."

3. Under 'acting transparently'

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[4] The 2013 (No. 2) regulations.

> "Commissioners must ensure that they conduct all their procurement activities openly, in a way that allows their behaviour to be scrutinised. Transparency is necessary for proper accountability. It should also mean that providers better understand how commissioners make decisions, and ultimately benefit patients by creating a more stable commissioning environment …."

71. I will return to the argued relevance of these matters below.

72. The decision of Monitor on the Claimant's complaint was communicated to the Claimant by letter dated 23 June 2014. The substance was in the following terms:

> "Having reviewed your complaint and the documentation you provided we took a number of steps to obtain further information. As well as speaking with you, we spoke with and sought information from NHS England. We also spoke with University College London Hospitals NHS Foundation Trust on the matters set out in the complaint.
>
> We have considered whether we should investigate the matter further based on our administrative priorities having regard to our published prioritisation criteria and have assessed the complaint with reference to the likely benefit for patients and the likely costs of taking action. Having considered all the information in the round, we have decided not to investigate this matter further. This assessment does not constitute a view on the substance of the complaint.
>
> Our prioritisation criteria are intended to ensure that we make the right choices about which projects and programmes of work we undertake to ensure that we use our resources in a way that creates the greatest potential benefit to patients
>
> The essence of the complaint we received in January is that NHS England had prevented Queens Square Radiosurgery Centre Limited from providing gamma knife services by only funding this treatment in London if it is undertaken at London Barts Health NHS Trust or at the Bupa Cromwell Hospital.
>
> We have decided it would not be a good use of our resources to investigate this complaint further. This is because our substantive guidance on the Procurement, Patient Choice and Competition Regulations and the further guidance published following our investigation into the commissioning of radiosurgery services, a case involving similar services, set our expectations on how commissioners should behave. We expect commissioners to consider proposals from providers on their merits having regard to our published guidance.

> We realise this may be disappointing news for you, but we nevertheless appreciate the time you have taken in bringing this matter to our attention. Monitor is keen to ensure that choice and competition in the NHS continues to work well for patients and the complaints we receive are used to help assess and the shape our future work programme."

73. This decision letter referred back to the guidance issued in April 2014 and the combined effect of the decision letter and the guidance prompted a renewed attempt by the Claimant to seek a resolution of the issues as it saw them. By June 2014, Ms McLellen had retired and Mr Will Huxter had taken her place. On 26 June 2014 Ms Brooks e-mailed him asking if there could be a meeting at which some or all of the following could be discussed: payment under IFRs for treatment at NHNN initially approved in early 2014, payment for patients covered by the agreement involving UCLH in 2013 and, as she put it, "a discussion - as suggested by the guidance and the Monitor letter - on the contractual situation, which is likely to be both a retrospective and a prospective discussion."

74. Mr Huxter replied on 4 July 2014 saying that he did not see any value in meeting to discuss the complaint made to Monitor because Monitor had decided not to investigate the complaint any further. He said that he had asked his team to process payment of six invoices concerning treatment at NHNN under approved IFRs, but asserted that NHSE had not agreed to pay for any patient except those approved as IFRs because, whilst it had a contractual relationship with UCLH as a provider of a range of services those services did not include gamma knife treatment. Furthermore, he said that, in light of Monitor's decision not to investigate the Claimant's complaint further, "and the fact that we are awaiting the outcome of a national review on commissioning of radio surgical treatments, it would not be appropriate for us to meet." Ms Brooks replied the same day, expressing disappointment at the rejection of the proposed meeting. She said that the Claimant would be considering its position with its advisers.

75. On 28 July 2014 Mr Andrew Taylor of Aldwych Partners wrote a detailed letter to Mr Huxter on behalf of the Claimant. In the first instance, he drew attention to that part of the guidance quoted under paragraph 1 of paragraph 64 above and the need for "objective justification" for differential treatment between providers in the absence of which commissioners would normally be expected to procure services from "other existing providers (those that had provided services under other arrangements than an NHS standard contract), under their interim commissioning position." He contended that the Claimant had been providing radiosurgery services since October 2012 and that the decision not to contract with the Claimant was inconsistent with that guidance and also with regulation 3(2). He also suggested that since commissioners are required, under the regulations, to act so as to secure the needs of healthcare service users, improve the quality of services and improve the efficiency with which services are provided, permitting gamma knife treatment at NHNN was consistent with that approach. Finally, he suggested that not contracting with the Claimant represented a restriction of competition between the Claimant and other providers of gamma knife facilities in London and elsewhere.

76. Mr Huxter replied on 14 August 2014 reiterating that both Barts and the Cromwell had been long standing providers of gamma knife services under contract with PCTs

that there was no waiting list for this kind of treatment at either hospital and no concerns had been raised about the quality of service provided. He, therefore, contended that pending decisions on the outcome of the national review, NHSE considered that, for the time being, patient interests were "best met by continuing with the two contracted London providers." He also said that whilst individual PCTs might previously have approved treatment by the Claimant at NHNN "on an IFR basis", it would not create an ongoing contractual relationship between the provider and a responsible commissioner, even when they were repeated approved IFR treatments: all it evidenced was a sequence of individual agreements. His concluding paragraph was as follows:

> "We would not therefore wish to meet to discuss the April 2013 commissioning decision or the rejected IFRs which [the Claimant] treated without authorisation. Once the national procurement process has been scoped and timetabled, we would be keen to meet with [the Claimant] and other potential providers as part of plans for market development."

77. The position taken by NHSE resulted in a further complaint by the Claimant to Monitor. It would seem that the complaint was put together by Aldwych Partners and it was despatched to Monitor on 23 September 2014. It essentially repeated the substance of the matters referred to in Mr Taylor's earlier letter.

78. On 16 October 2014, Monitor wrote to NHSE referring to the complaint that had been made and to the guidance previously given and the letter contained the following paragraph:

> "In its complaint [the Claimant] says that following our letter it has tried unsuccessfully, to engage with NHS England regarding its proposal to provide gamma knife services. [The Claimant] says that NHS England has been unwilling to meet with [the Claimant] and its correspondence has not addressed the issues raised by [the Claimant]. If that is accurate, it is not the outcome we had in mind when sending our letter."

79. It would seem that, in light of Monitor's indication, a meeting was arranged. It took place on 6 January 2015 and attended by Mr Huxter and another NHSE representative, Mr Foster and another UCLH representative and Ms Brooks and Mr Taylor on behalf of the Claimant.

80. A note concerning the discussion at that meeting was substantially agreed. The only disagreement was over a paragraph introduced by Mr Taylor as follows:

> "It was agreed that the most likely solution would be to award a contract in the interim period, but that any proposal would need to be reviewed in the light of the responses received by NHS England in relation to the National SRS consultation to sure (sic) there were no major conflicts."

81. Mr Huxter said that the note suggested that "all agreed that an interim contract was the most likely solution" whereas his recollection was that Mr Taylor and UCLH had

made the case for this, but that no agreement had been made other than that NHSE would review any proposal made.

82. The interim proposal was made on 3 February 2015. The essential provisions of the proposal were as follows:

> - A contract between NHS England and QSRC Limited for the delivery of gamma knife services at Queens Square Radiotherapy Centre with UCLH as the clinical lead and research partner.
>
> - These services will cover the following in delivery of the service: (a) SRS intracranial MDT for all patients; (b) all relevant treatment activities including inpatients services (if required); (c) scanning (MRI, CT and Angio); (d) guaranteed treatment dates; and (e) compliance with the SRS Service Specifications.
>
> - This contractual arrangement should date from 1 April 2013 (i.e. from the establishment of NHS England), and until such time as NHS England seeks to re-commission these services either by way of a national tender or some other mechanism.
>
> - Payment should be as per the relevant national tariff for the services in question.
>
> - All outstanding requests for payment to NHS England for the treatment of patients for which an IFR was submitted will be met in full by NHS England.

83. This was eventually rejected in the letter the subject of the present challenge dated 20 March 2015 (although not received by the Claimant until 8 April 2015). The terms of that letter need to be recorded:

> "We are unable to accept your proposal. I have set out the rationale for this below:
>
> - NHS England is content that your proposed interim solution is not consistent with the Section 75 Regulations or the Public Contract Regulations 2006.
>
> - The proposal would require NHS England London to treat QSRC differently to all other London providers of SRS which are not contracted under a Standard Contract. Barring special circumstances, such as unforeseeable patient need, this would be in breach of the S75 Regulations.
>
> - NHS England cannot issue a contract backdated by almost two whole financial years. In determining

whether to offer QSRC a contract NHS England would need to comply with the S75 Regulations which require NHS England to treat all providers equally, or to be able to objectively justify why we are not treating all providers equally. NHS England cannot determine any objective justification for providing UCLH/QSRC a contract without running a procurement process.

- There are in London multiple potential providers of SRS, which can be delivered via a number of platforms. QSRC makes its case based on its assessment that it is one of only three potential gamma knife providers. However, SRS can be delivered via a number of platforms (gamma knife, cyberknife, linear accelerator), and there are at least 9 potential providers of SRS in London. Our national review is agnostic about the most appropriate platform to be used, and our approach to procurement has to be broader than only gamma knife.

- We have legal advice explicitly stating spot purchases used for IFR patients cannot be considered as giving the provider the right to ongoing supply. As a result, we do not accept your contention that IFR arrangements with PCTs for individual patients prior to the establishment of NHS England make QSRC an existing provider.

- We have no contract in place with QSRC. The only contractual arrangement we have in place is with UCLH. This does not include gamma knife services, and does not name QSRC as a sub-contractor.

- UCLH is not complying with NHS England's defined pathway for these patients, and is instead sending this work to QSRC as a sub-contractor. Given that NHS England has in advance refused to pay for work where there is no clinical necessity to break the prescribed pathway, this is a matter between UCLH and QSRC only. We therefore do not accept that QSRC has any claim under the Section 75 Regulations.

- It is not for the provider to decide that its services should be provided to NHS patients, that is a matter for the commissioner. As the commissioner, NHS England has not given QSRC a contract to provide services to NHS patients and therefore it will not pay the provider for services provided in direct contravention of the commissioner's wishes.

As you know, we are progressing the national procurement for stereotactic radiosurgery, which provides an opportunity for

> QSRC to put itself forward as a potential contracted provider with NHS England.
>
> Our procurement capacity is finite, and we therefore have to prioritise strategic change at a national level above an alternative parallel procurement arrangement for London; given the timescales for any procurement, a London process would not be any quicker than joining the national procurement.
>
> Our review of the national commissioning of SRS demonstrated that despite having vast overcapacity (23 providers chasing 7 patients treated per day across England) half of the population of England must travel over 60 mins to an SRS provider. The high capital costs spread over a very small number of patients also mean very high prices per patient for treatment. NHS England therefore plans to take a strategic, national approach to fixing a broken market. This will widen patient access (lower clinical threshold, 7 day services and better geographic equity) by reducing the number of providers, so reducing the cost per treatment, thereby improving cost effectiveness. Notice of this was given to the market on 3 November 2014 via a three month consultation."

84. I will turn shortly to the challenges to this letter, but it is a convenient point at which to note the evidence of Mr Huskinson (see paragraph 19 above) about what is involved in the "national procurement for stereotactic radiosurgery" referred to in the letter which, of course, has to be seen as only one part of the overall review of specialised services. He said this in his witness statement:

> "28. The process of reviewing all specialised services, nationally and regionally, is a mammoth task. The workload required in doing this, by gathering evidence, consulting with patients and providers, dealing with other relevant stakeholders including Monitor and NICE, developing service specifications, running fair and transparent procurements, developing new contracts and addressing any TUPE issues is a significant undertaking. NHS England has to ensure it focusses on opportunities to review services in a structured way. That permits concentration upon those services where changes would have the greatest benefit for patients.
>
> 29. There are restrictions placed (by central government) on NHS England management expenditure which includes the costs of service reviews and procurements and there are finite staff with the expertise to undertake this work. Accordingly NHS England has had to prioritise and stage its different service reviews and has not been able to complete a review of every specialised service undertaken since NHS England came into being on 1st April 2013. A key part of the role of my team is to ensure that we focus on opportunities to provide services in a structured way so that we can consider all services in the

> fullness of time. We cannot simply review services on the basis of prioritising those who make the greatest noise, nor create instability for existing service providers by undertaking repeated reviews in a short space of time. We believe we will achieve the best results for patients from a thorough and considered process which allows for durable solutions."

85. He added this:

> "… Low volume yet capital intensive services such as SRS/SRT are best undertaken with a national footprint to assess the total market requirement, rather than based on decisions in one region or town that have knock on effects on the sustainability of adjacent services."

## The grounds of challenge

86. As I have indicated (see paragraph 2), the Defendant says that the Claimant's challenge, though framed as a challenge to the decision reflected in the letter of 20 March 2015, ought properly to be seen as one to a much earlier decision (made in April - June 2013) and is out of time. It is also suggested, in any event, that the Claim Form, which was issued on 18 June 2015, was unnecessarily delayed after receipt of the letter of 20 March 2015 on 8 April 2015 which was the trigger point for the running of time. The Claim Form was thus issued some 10 weeks after receipt of the decision letter.

87. I propose to consider the merits of the challenge in the first instance and will, if necessary, return to the limitation/delay argument in due course.

Ground 1

88. The first and most substantial challenge is that NHSE has failed to comply with regulation 3(2) of the 2013 Regulations (see paragraph 28 above) by not acting in a transparent and proportionate way and, it is alleged, treating some providers of gamma knife services more favourably than others. Part of this challenge involves the suggestion that Monitor's guidance in relation to radiosurgery services (see paragraph 70 above) has been ignored, the contention being that the Claimant was an "existing provider" and that no "well-reasoned objective justification based on evidence" has been advanced for treating NHNN less favourably than Barts and the Cromwell in connection with these services. The justification advanced, namely, that Barts and the Cromwell each held an NHS standard contract in the previous commissioning year is said to be an insufficient basis to exclude the Claimant from providing such services given that the Claimant, it is contended, fell within the category of "other existing providers (those that had provided services under other arrangements than an NHS standard contract)" as set out in Monitor's guidance. It is contended that this aspect of the guidance applied directly to the Claimant's position because it had provided gamma knife services to NHS patients "under other arrangements than an NHS standard contract" and it was, accordingly, entitled not to be excluded from providing a service under NHS England's in the interim pending the unless there was a "well reasoned and evidence-based objective justification for doing so".

89. NHSE asserted in the decision letter (on the basis of legal advice) that it did not accept the contention that "IFR arrangements with PCTs for individual patients prior to the establishment of NHS England make [the Claimant] an existing provider".

90. The first question, therefore, is whether the Claimant is correct in its contention that it was properly to be regarded as "an existing provider" within Monitor's guidance. Plainly, the guidance is not to be read as a statute and must be read in its proper context and, of course, guidance is guidance and, whilst persuasive is not prescriptive. Mr Simon Taylor, who appears for NHSE, argued that "it was likely that Monitor had sub-contracted providers in mind when it referred to "existing providers" under the guidance" because MESL's position in the arrangements at Thornbury (see paragraphs 53 and 68 - 69 above) as at April 2013 was as a nominated subcontractor of Sheffield Teaching Hospitals Trust. The evidence does indeed point to that being MESL's status vis-à-vis the Trust at the time. After the initial refusal to enter into a contract with MESL and the lodging of a complaint to Monitor, a direct contract between NHSE and MESL was concluded for 2013/2014. It was against that background that Monitor decided not to investigate further.

91. Mr Robert Palmer, for the Claimant, accepts that an existing subcontractor may well be included in the umbrella description of "other existing providers" but submits that the expression has a more broadly directed focus and should not be seen as excluding providers that have been providing services directly to NHS patients under arrangements other than a standard contract or subcontract. Those "arrangements" should, he submits, include the procedure of the submission of IFRs to PCTs which have thereafter been accepted and processed. This occurred in relation to the gamma knife treatment at the Claimant's facility at the NHNN. He submits that if commissioning during the interim period is confined to those providers that already have NHS standard contracts, the expression "other existing providers", as defined in parenthesis in Monitor's guidance, is meaningless.

92. The factual basis upon which the Claimant's case in this regard is advanced is set out in paragraph 30 of the Statement of Facts and Grounds:

> "Between 31 October 2012 and 31 March 2013, QSRC treated a total of 51 (42 NHS and 9 private) patients. All bar two NHS patients were approved for treatment by local commissioners. Further, from 1 April 2013 until August 2013, QSRC treated patients for whom QSRC had already obtained approval for the treatment from PCTs prior to 1 April 2013. This was for a further 10 NHS patients, which were paid for by NHS England."

93. The suggestion is, therefore, that the gamma knife treatment for a total of 50 patients was funded by the NHS by way of acceptance of the IFRs relating to those patients in "arrangements" that were entered into before 1 April 2013. Some of the treatment was carried out before that date and some after, but all treatments were paid for by the NHS and, of course, whilst NHSE was in existence.

94. I do not understand the factual premise to be disputed, but its relevance for the purposes of this case undoubtedly is.

95. Mr Palmer submits that these (for want of a better expression) "transactions" made the Claimant an "existing provider" of gamma knife services to the NHS as at 1 April 2013. He submits that this is consistent with what NHSE agreed with UCLH at the meeting on 26 April 2013 (see paragraph 49 above) and that Mr Taylor's contention that the meaning of the expression "would be mapped against existing commissioning policies" was simply a reference to Barts and the Cromwell must be wrong (a "commissioning policy" being different from a "commissioned provider") and could not, in any event, stand with the reference in the internal e-mail to the suggestion by UCLH that any IFR should be mapped against the "draft service specifications" (which had nothing to do with Barts or the Cromwell). The draft commissioning policies and service specification were those issued in December 2012 and taken into account in the Claimant's proposal dated 12 February 2013 (see paragraph 47 above).

96. I am not sure to what extent it can be said that an internal e-mail concerning a conversation between representatives of NHSE and UCLH (with no representative of the Claimant present) can truly be said to reflect an agreed position upon which the Claimant can rely, but irrespective of that observation the fact is that the history of events thereafter concerning submitted IFRs was that all those patients who met the access gateway were expected by NHSE to be transferred to Barts or the Cromwell for treatment (see, e.g., paragraph 51 above). However, as I will indicate below, I am not persuaded that what happened in practice at this time helps in determining the meaning of the expression "existing provider".

97. Resolution of the question of what constitutes an "existing provider" as at 1 April 2013 within the meaning of the expression as used by Monitor is not entirely easy. For my part, reading the expression in the full context of the passage in the guidance entitled "Prioritisation and Commissioning" (see paragraph 70 above) does suggest that those who had supplied specialist services to the NHS prior to 1 April 2013 by some arrangement other than under a standard NHS contract were not to be excluded from being considered for commissioning purposes in the period between 1 April 2013 and when the national appraisal of the services was completed. Whilst I can see the force of Mr Huskinson's observation that it is important not to conflate the IFR process as it existed before 1 April 2013 with the process that operated thereafter (see paragraph 19 above), that does not of itself prevent a provider that had, via the IFR process, supplied gamma knife services on a more than minimal basis for NHS patients prior to 1 April 2013 from being an "existing provider" within the Monitor guidance. It would require a strained interpretation of the expression to conclude otherwise.

98. As foreshadowed above (see paragraph 96), I do not find what has happened in practice particularly revealing. It is clear in the Claimant's case that some PCTs were prepared to entertain IFRs in the transitional period leading up to 1 April 2013 whereas others were not. A wholly consistent pattern, one way or the other, might have helped to conclude the matter, but I can detect no such pattern on the evidence. The same observation applies to the information that has been provided about how other providers have been treated on an interim basis by NHSE in connection with other SRT services. I am inclined to think that, as with any process that involves a very significant change in approach (which the inception of NHSE heralded) there will be some inadvertent (or even uninformed) inconsistencies in how things are handled during the transitional stage. With that consideration in mind it would be

imprudent to draw too many hard and fast conclusions from what happened "on the ground" when what happened was somewhat variable. To my mind, however, to the extent that it matters to the outcome of this application, it is sufficiently clear that the Claimant was "an existing provider" of gamma knife services within the terms of Monitor's guidance such that it should not without more have been excluded from consideration for the commissioning of such services in the interim period. If that guidance is to be followed, then a decision by commissioners not to commission services from an existing provider should be capable of being justified objectively on the basis of evidence. In the absence of justification of that kind, Monitor would "normally expect" the commissioners to procure services from that existing provider. As expressed, however, Monitor's expectation is not phrased in mandatory terms.

99. It should, of course, be noted that NHSE could only be in breach of the Monitor guidance once that guidance had been given. It was not in existence on 1 April 2013. NHSE's case is that it declined legitimately to enter into any interim contract with the Claimant as from 1 April 2013 for reasons that are articulated in its various communications. It does, however, contend that it acted in accordance with the guidance once promulgated even if it was wrong not to have treated the Claimant as "existing provider" as at April 2013.

100. Since the decision letter of 20 March 2015 reflects the decision formally under challenge in this application, I will "fast forward" to the decision letter and consider whether it meets the Monitor guidance or, as the Claimant contends, it fails to do so.

101. On the basis that the letter rejects the status of the Claimant as an "existing provider", then it is wrong to have done so. Until the guidance from Monitor it would, as it seems to me, have been a legitimate position for NHSE to take that a provider simply through IFRs would not have been a party with which, on an interim basis, NHSE would have been obliged to treat given the national policy of simply maintaining the status quo with existing contracted providers whilst a national review was undertaken. This would have meant that existing services were maintained to meet existing patient needs and that the "market" retained stability whilst the review took place. Whilst new structures were in place on 1 April 2013 it would be unrealistic to expect an immediate transition on that date to the practical realisation of new arrangements. However, the Monitor guidance changed the landscape, certainly so far as SRS/SRT services were concerned, in relation to the way the issue of other providers needed to be addressed.

102. Nonetheless, the question is whether, notwithstanding the mistaken view taken of the Claimant's status in the letter of 20 March 2015, the letter contained an objective justification for not procuring services from the Claimant on an interim basis. The letter was in one aspect not drafted felicitously because it said that the NHSE could not "without running a procurement process" see any objective justification for providing the Claimant with a contract. The onus was to have articulated positive reasons for not providing the Claimant with a contract. However, that may simply be a matter of semantics because NHSE's substantive reasoning for not doing so is encapsulated in, in particular, the second and fourth bullet points (concerning "all other London providers of SRS" and "multiple providers" respectively) and the final two paragraphs of the letter. In essence it was said that entering into an interim contract with the Claimant two years down the line from NHSE's inception would be treating the Claimant preferentially compared with "at least 9 potential providers of

SRS in London" against the background of there being no "unforeseeable patient needs" to justify doing so. It would involve the entry into a contract whilst the national commissioning review (which had revealed "vast overcapacity") was still continuing.

103. It is, of course, for the decision-maker to make judgments of the nature reflected in the letter (subject to *Wednesbury* unreasonableness), but there can be no realistic challenge to such an assessment in this case unless it was unlawful for any other reason. As an encapsulation of the reasons for rejecting the Claimant's proposal, it affords a sustainable basis for not providing an interim contract with the Claimant and, in my judgment, would have provided a sustainable reason for doing so from the outset and I cannot see that, certainly at an interim stage, it would constitute a breach of section 75 or the regulations. Indeed to do so would have preferred the Claimant over other potential providers which itself would have breached the regulations. The reasoning in the letter is explained further in Mr Huxter's witness statement which contains these paragraphs:

> "36.4 … awarding a contract to another London provider would have exacerbated the problem of oversupply in London, would have failed to address the issue of unmet demand outside London and could also undermine the viability of commissioned providers. It would have added another commissioned provider to the market in London without tackling the problem of oversupply. The national review of SRS/SRT undertaken by NHS England demonstrated the need to rationalise the overcapacity by taking a national approach;
>
> 36.5 NHS England made a decision that it was not going to commission any additional providers of existing services, except where there were known problems with supply, cost or quality. There were no known problems with supply, cost or quality in relation to SRS/SRT in London;
>
> 36.6 NHS England is committed to a national procurement for these services; there is no financial or service justification for undertaking a separate London procurement for a short term contract ahead of this. And without procurement there is no fair basis on which to award a contract to QSRC and not to any of the other non-commissioned London providers."

104. I do not consider that this represents unsustainable reasoning or reflects some illegality in approach.

105. The letter does not suggest (as Mr Taylor had suggested) that the Claimant had been "abusing" the IFR process and, in my view, rightly so. Whilst it is possible for some to take the view that the Claimant was trying to "steal a march" on others in the field by using the IFR process, it does have to be acknowledged that there did appear at various stages to be some encouragement to do so from some (though not all) sources in the early stages of the Claimant's involvement with the PCTs and indeed the NHSE. However, it became very clear early on that this was not a process that ultimately would secure the Claimant's position.

106. I should say that none of the other arguments advanced on the Claimant's behalf causes me to alter that view. The misconception that there was about the need for a "Consultant presence", at least in the building, when gamma knife treatment is given was unfortunate, but I do not consider that it had any material bearing on the decision.

107. It is also unfortunate that the national procurement exercise for SRS/SRT has been considerably delayed and the results of the exercise commenced in November 2015 are not expected to lead to contracts coming into effect until April 2016 at the earliest. That will be 3 years after the inception of NHSE and the delay is bound to have caused difficulties and uncertainties in this market-place in particular. However, it cannot affect the legality of the approach taken in the decision letter.

108. These conclusions concerning the letter of 20 March 2015 must result in my rejection of the Claimant's application for judicial review of the decision reflected in that letter. That being so, I do not have to consider whether any of the Defendant's arguments concerning the time limits for bringing these proceedings are valid. I will, however, express my tentative views on those arguments briefly.

**Limitation/delay**

109. The first contention is that this is a "procurement case" and is governed by the 30-day time limit to which I will refer.

110. CPR 54.5(6) is as follows:

> "Where the application for judicial review relates to a decision governed by the Public Contracts Regulations 2006, the claim form must be filed within the time limit within which an economic operator would have been required by regulation 47D(2) of those Regulations (and disregarding the rest of that regulation) to start any proceedings under those Regulations in respect of that decision."

111. Regulation 47A, so far as material, reads as follows:

> (1) This regulation applies to the obligation on—
>
> (a) a contracting authority to comply with—
>
> (i) the provisions of these Regulations …
>
> (2) That obligation is a duty owed to an economic operator.

112. Regulation 47D, so far as is material, is as follows:

> "(1) This regulation limits the time within which proceedings may be started where the proceedings do not seek a declaration of ineffectiveness.
>
> (2) Subject to paragraphs (3) to (5), such proceedings must be started within 30 days beginning with the date when the

> economic operator first knew or ought to have known that grounds for starting the proceedings had arisen …."

113. Regulation 5 of the Public Contracts Regulations 2006, so far as material, reads as follows:

> 5.—(1) … these Regulations apply whenever a contracting authority seeks offers in relation to a proposed public supply contract, public works contract, Part A services contract, framework agreement or dynamic purchasing system other than a contract, framework agreement or dynamic purchasing system excluded from the application of these Regulations by regulation 6 or 8.
>
> …
>
> (2) Whenever a contracting authority seeks offers in relation to a proposed Part B services contract other than one excluded by virtue of regulation 6 or 8 …."

114. It is common ground that a "Part B services contract" includes a "health and social services" contract.

115. The issue, therefore, is whether, as the Defendant contends, the decision made not to contract with the Claimant was "governed by the Public Contracts Regulations 2006" or whether, as the Claimant contends, it was not. Mr Taylor submitted that the essence of the claim is that the Defendant should have procured SRS services from the Claimant instead of merely from Barts and the Cromwell over the period from April 2013 to April 2015 and contends that "the refusal to do so is a decision the legality of which may be affected by duties owed to [the Claimant] under" the 2006 Regulations. It seems to me that the issue is not whether the decision "may be affected" by the Regulations, but whether they <u>are</u> governed by them. Mr Palmer submits that they are not so governed, but they are governed by the 2013 Regulations. He accepts that in some respects there may be a degree of overlap, but argues this was not a situation where the "contracting authority" was seeking offers in relation to a proposed public supply contract (see Regulation 5) and, accordingly, the Regulations did not apply. Indeed he emphasises that no offers have yet been sought. He submits that no decision was taken under the 2006 Regulations which is or was capable of challenge pursuant to its terms.

116. The need for expedition in challenging procurement decisions is clear, but on balance I think that Mr Palmer's submissions are correct in the circumstances of this case.

117. The next issue is whether the decision was made much earlier and should, in any event, have been challenged within the usual three month period.

118. It would, I think, be fair to say that the decision in principle not to contract with the Claimant had been made in, say, the period between April and June 2013 as Mr Taylor has contended – indeed arguably before that. However, in the particular circumstances of this case, I do not think it unreasonable for the Claimant to have sought to negotiate in the first instance with the Defendant and then, before

commencing judicial review proceedings, to make a complaint to Monitor. The Claimant had to wait until June 2014 for the final response from Monitor and, against the background of Monitor's decision not to take the complaint further but to refer the Claimant to its guidance given in April 2014, it was not unreasonable in the circumstances for the Claimant to have sought to engage again with Defendant. When the Defendant expressed an unwillingness to do so in the first instance, a further complaint to Monitor was made resulting in the meeting on 6 January 2016. There was an express invitation from the Defendant at that meeting to make a proposal, which the Claimant did, and it was that proposal that led to the decision of 20 March 2015.

119. Overall, it seems to me that the Claimant was entitled to await that response before bringing judicial review proceedings. Any earlier institution of proceedings could have been met by the argument that the proceedings were premature. Whilst it might have been instituted more quickly given the prolonged history, the claim was brought within the 3-month period and I would not have seen any reason not to permit it to proceed.

120. For my part, therefore, I would not have held that the proceedings were out of time as such, though I have considerable reservations as to whether any relief granted could have resulted in a back-dated contract until 1 April 2013. However, that is academic for present purposes.

Ground 2

121. This ground alleges that NHSE has unlawfully interfered with the Claimant's protected rights under Article 1 of the First Protocol to the European Convention on Human Rights ('A1P1') on the basis that the continued decisions to place a condition on the approval of IFRs made by UCLH for gamma knife treatment for its patients that it must be provided either at Barts or the Cromwell (and would not be funded if it was provided at NHNN) was unlawful.

122. This claim is essentially parasitic on a successful claim under Ground 1 which set out to establish that the condition attached to IFR approvals was unlawful.

123. Since Ground 1 has not been made out, this ground falls away and, in the circumstances, I do not consider it necessary to express any view about it.

## Conclusion

124. For the reasons I have given I do not consider that the primary ground upon which it is alleged that NHSE acted unlawfully in this case has been made out. Everything else falls by the wayside in consequence.

125. I emphasised at the outset (see paragraph 4) that this case has nothing to do with any decision about the long-term provision of NHS-funded gamma knife treatment at NHNN. Looking at it through the eyes of the patients sent to what is undoubtedly regarded as one of the leading, international centres of excellence for neurological and neurosurgical treatment, often on a tertiary referral basis, it will undoubtedly have been an unwelcome discovery to find that any gamma knife treatment prescribed for them would not be funded by the NHS at NHNN even though high-standard facilities

existed there and that the transfer to Barts or the Cromwell may have led to their Consultant no longer being available to supervise their treatment. That has been the effect of the decisions made concerning the interim period from 1 April 2013 to date. Whether it remains so once the national procurement exercise has run its course remains to be seen.

126. I should express my gratitude to Mr Palmer and Mr Taylor for their helpful and comprehensive written and oral submissions.