MILLS & REEVE

briefing

June 2014

What does *Rose v Thanet* tell us about the status of NICE guidelines in priority setting?

In *Rose v NHS Thanet Clinical Commissioning Group* (2014) the Administrative Court considered whether the CCG had acted unlawfully in failing to implement a clinical guideline issued by the National Institute for Health and Care Excellence, despite there being no statutory duty to do so.

As so often happens, the most interesting judicial observations in this case were not, ultimately, central to its disposal. And, just as words were famously said to be more volatile than deeds, so the obiter dicta of Mr Justice Jay seem to have caused much of a stir. In this briefing, we look at the judgment and its consequences for commissioners.

Background

The Claimant, Ms Rose, had suffered from a severe form of Crohn's disease for some ten years. In view of the deterioration in her condition, her clinicians recommended bone marrow transplantation and chemotherapy. Because this would, in all likelihood, render her infertile, she sought NHS funding to preserve her eggs prior to treatment. Oocyte cryopreservation not being funded routinely by NHS Thanet CCG ('the CCG') for those receiving gonadotoxic treatments, an individual funding request ('IFR') was submitted on the Claimant's behalf on 24 May 2013, seeking to establish that her clinical circumstances were exceptional, so as to justify funding in her particular case.

The CCG's IFR Applications Triage Team considered the application on 4 June 2013 and concluded that clinical exceptionality had not been established ie: the patient was not significantly different from other patients with the same condition at the same stage of development and not significantly more likely to benefit from treatment. The Group's notes recorded that the CCG's 2009 policy on the funding of oocyte cryopreservation was under review in light of the National Institute for Health and Care Excellence ('NICE') having updated and replaced its clinical guideline relating to fertility treatment (ie: CG156, previously CG11, published February 2004) in February 2013.

Although the Claimant did not have a right of appeal from this decision to reject the application for funding, a request for reconsideration was acceded to by the CCG, albeit with the same conclusion on funding being reached on 9 July 2013. This was communicated to the patient's clinician on 19 July 2013.

On 17 March 2014 a pre-action protocol letter from the Claimant's solicitors was received by the CCG, relying in the alternative on two key points:

- That, although CG156 was published in 2013, the policy relied upon to refuse funding for oocyte cryopreservation was published in 2009 (initially by the predecessor PCT and subsequently adopted by the CCG) and due for review in 2011; the 2009 policy was accordingly unlawful for failing to adhere to the

NICE guidelines without rational explanation and for appearing to be based on out of date information in a rapidly evolving area of medicine.

- That the nature of the Claimant's Crohn's disease was significantly different from the general population of patients suffering from Crohn's and that, because of the planned chemotherapy – an 'exceptionally new' treatment only to be used in extremely severe cases – the Claimant was likely to gain significantly more benefit from preservation of her eggs.

The Claimant's solicitors sought a response within 48 hours. The Triage Group reconvened on 18 March 2014 but noted that they could not re-triage the case because no new clinical information had been submitted. This was communicated to the Claimant on 19 March 2014. As regards the Claimant's allegations of 17 March, the Defendant rejected these on the grounds that NICE guidelines were not mandatory, the 2009 policy was accordingly not unlawful, and commissioning priorities, in general, were a matter for the CCG to decide, taking into account the needs of its patient population and clinical evidence relating to the efficacy of potential interventions.

Judicial review proceedings were commenced on 21 March 2014.

Obligations with respect to guidance produced by NICE

It is the role of NICE to give advice or guidance, provide information or make recommendations about any matter concerning or connected with the provision of NHS, public health or social care services in England[1]. In addition to such generic 'advice' (regulation 5), NICE also makes "technology appraisal recommendations" (regulation 7) and "highly specialised technology recommendations" (regulation 8), with which a CCG/NHS England and NHS England alone, respectively, must comply – usually within three months of the date of publication.

There is no explicit statutory obligation upon CCGs (or, indeed, NHS England), however, to comply with the "regulation 5" type of advice or guidance, which includes clinical guidelines published by NICE, such as CG156. The Defendant CCG in this case conceded that such guidance constituted a "public law relevant consideration" ie, something to which a public body should pay heed in reaching a lawful decision. Received wisdom to date, however, has long held that public bodies may depart from such guidance if there is a good reason for doing so and resources – or, rather, the lack of them – have long been recognised as just such a "good reason". All the more compelling, you might think, when times are tough and CCGs cash-strapped.

NICE guidance, priority setting and individual funding requests

Part 7 of the National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012/2996 sets out the duties of NHS commissioners with respect to decision-making about drugs and other treatments, in the broader context of priority setting as a whole.

Regulation 34(1) provides that "a relevant body" (ie, a CCG or NHS England) "must have in place arrangements for making decisions and adopting policies on whether a particular healthcare intervention is to be made available for persons for whom the relevant body has responsibility". In other words, the body must have a prioritisation process leading to an annual plan and specific commissioning policies. Those "arrangements" must ensure that the CCG or NHS England, as appropriate, implements NICE technology appraisal recommendations and highly specialised technology recommendations. They must also include arrangements for the determination of "any request for the funding of a health care intervention for a person where there is no relevant NICE recommendation" (ie, no technology appraisal recommendation or highly specialised technology recommendation) and the relevant body's

[1] The National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013/259 ('the 2013 regulations') set out the functions conferred upon NICE by the Secretary of State.

general policy is not to fund that intervention'. In other words, the body must have an individual funding request process.

Regulation 35(1) provides that "a relevant body must publish on its website a written statement of its reasons for any general policy it has on whether a particular healthcare intervention is to be made available" for its patients or, "where it has not published such a statement, provide a written statement of the reasons for any such policy when a person makes a written request for such a statement". Similarly, under regulation 35(2), where a body refuses to accede to an individual funding request, it must provide that person with written reasons for the refusal.

Interwoven with these express statutory obligations, the judge in *Rose v Thanet* inferred the following implied obligations, saying they were imposed "by force of public law and/or the true constructions of the regulatory scheme":

- The duty to have regard to NICE recommendations which constitute "generic" guidance – as opposed to technology appraisal recommendations or highly specialised technology recommendations – must bear on the formulation of the CCG's[2] general policies (as per regulation 34(1)) rather than its exceptional policies; and

- The duty to give reasons for any general policy not to fund a particular intervention must encompass the giving of a reasoned explanation of why a NICE recommendation made under regulation 5 of the 2013 regulations (ie, a NICE recommendation which does <u>not</u> constitute a technology appraisal recommendation or highly specialised technology recommendation) is not being followed.

The broad "ethical" framework

The Claimant's specific assertions as to the CCG's obligations were set in the broader context of the rights set out in the NHS Constitution and the Equality Act 2010.

Accepting that the CCG had a duty under section 3 of the National Health Service Act 2006 to commission medical services to such extent as it considered necessary to meet the reasonable requirements of its patients and a parallel duty under section 223H to break even financially each year, the Claimant nonetheless focused on the section 14T duty on the CCG to reduce inequalities between patients with respect to their ability to access health services and the outcomes achieved for them by the provision of such services, and the section 14P duty to act with a view to securing that health services are provided in a way which promotes the NHS Constitution.

Specifically, Ms Rose relied on the following section of the NHS Constitution:

> ***<u>"Nationally approved treatments, drugs and programmes:</u>***
>
> ***You have the right*** *to drugs and treatments that have been recommended by [NICE] for use in the NHS, if your doctor says they are clinically appropriate for you.*
>
> *You have the right to expect local decisions on funding of other drugs and treatments to be made <u>rationally following a proper consideration of the evidence.</u> If the local NHS decides not to fund a drug or treatment you and your doctor feel would be right for you, they will explain that decision to you." [Emphasis added].*

She argued that the perceived vice to be tackled was the so-called 'postcode lottery'. The judge went further than this, stating that *"any system which has the duty of distributing finite resources must do so not merely on a basis*

[2] The same would apply to NHS England but for ease of reading, this briefing refers henceforth only to CCGs.

which is not arbitrary (cf. the happenstance of the postcode) but also on a basis which recognises the patient's fundamental human right to be treated in exactly the same way as anyone else with the same clinical need". But what, you ask, about the tension between the distribution of finite resources to all patients equally, regardless of geography, and the recent restructuring of the NHS to provide for bespoke local decision-making? Local decision-making v the *National* Health Service? Ah, yes indeed…….

NICE Guidance and the CCG's ART policies

In February 2004 NICE published CG11 relating to fertility treatment. Whereas cryopreservation of semen was described as "a realistic option to preserve fertility, regardless of diagnosis and treatment", cryopreservation of oocytes was reported, on the basis of case studies and clinical opinion, as having had 'very limited success'. CG11 provided that women preparing for medical treatment likely to make them infertile should be offered oocyte cryostorage as appropriate if they were well enough to undergo ovarian stimulation and egg collection but should be informed that the procedure had 'very limited success'.

In July 2009 the body responsible for reviewing the then PCT's ART policies described oocyte preservation as a new technique with a low success rate. Their recommendation was, accordingly, to continue not to fund oocyte cryopreservation, this to be reviewed in 2011[3]. Evidential reasons for not following the NICE recommendation were recorded. The resulting policy recommendation did, however, state that PCTs in the NHS South Coast area would always consider appropriate individual funding requests.

By February 2013, just before Ms Ros made her first IFR application, NICE had published CG156, recommending (again) that oocyte preservation should be offered to women about to undergo gonadotoxic treatment but (this time and on the basis of new evidence) that they should no longer be advised that the treatment had very limited prospects of success. NICE classified this as a "strong" recommendation, because it was confident that the intervention would do more good than harm for the vast majority of patients and would also be cost effective. NICE also favoured the separation of the policy on access to cryopreservation found in the general fertility pathway from that within the treatment of cancer patients, with the latter not having to satisfy eligibility criteria.

On 2 May 2013 Kent and Medway Commissioning Support Unit (KMCS) published a briefing note explaining that they had been commissioned by local CCGs to review local policy in the light of CG156 and other recent legislation and that any new policy would be implemented for 2014/15. The final report of their working group ('the report') published in October 2013 explained that there would be no additional funding available for ART as it had not been prioritised for additional investment. The report reviewed the available evidence for oocyte preservation in the case of patients who had undergone gonadotoxic treatment, considered it 'lacking', and recommended that the intervention should not be funded. This was formally recorded in KMCS's policy recommendation in 2013 and adopted as policy by the Defendant with effect from 1 April 2014.

By the time of the hearing, the allegation that the 2009 policy was unlawful was no longer being pursued. Rather, the Claimant sought to assert that the 2009 policy should have been updated in light of the publication of CG156 and the 2014 policy should not have rejected NICE's view of cryopreservation for patients in the Claimant's circumstances.

The decision and allied observations

The difficulty in identifying the ratio (ie, the nub) of the decision arises from the fact that the Claimant's pleadings seem to have been the subject of ongoing development throughout the proceedings. As the judge put it: "On one view the target is oscillating so much it can hardly be identified at all". However, he said that if the decision under

[3] It was not in fact reviewed in 2011 because by then it had become known that NICE was reviewing CG11 – although the revised guideline did not, ultimately, appear until 2013.

challenge was the decision of the Triage Group of 18 March 2014 not to re-open the Claimant's case, it was legally unobjectionable because the Claimant had advanced no further clinical reasons for establishing exceptionality. Moreover, if the focus was solely on the decision of the Triage Group, the Claimant was unable to bring into play a whole raft of considerations bearing on the legality of the defendant's ART policies, because there was no link between the IFR policy and the general policy. In formulating its IFR policy, as opposed to its general policy, there could be no public law requirement for the CCG to have regard to NICE guidelines. And yet a further difficulty for the Claimant was that on 18 or 19 March 2014, the new ART policy was not yet in force, yet she had not (and could not legitimately have) challenged the 2009 policy. Trying to overcome this by alleging that the CCG had delayed unreasonably in deciding how to react to CG156 was a further argument with no mileage in it, the judge said: the publication of CG156 could not legally demand an *immediate* change of policy within the CCG. No doubt unreasonable, to the point of irrational, delay could give rise to a public law challenge, but the Claimant was a long way from establishing that.

Although this was sufficient to dispose of the case before him in the Defendant's favour, the judge went on to consider several other issues raised before him, including the manner in which the CCG had purported to engage with CG156 in revisiting its ART policy. It is these comments that have, perhaps, aroused the most interest, although they are arguably obiter dicta and, accordingly, not binding on future courts revisiting these issues.

The judge looked carefully at the 1997 case of *R v North Derbyshire Health Authority, ex part Fisher*, which arose from the refusal of the health authority to fund beta interferon for Mr Fisher's relapsing/remitting multiple sclerosis. The issue was whether the health authority properly took into account a circular issued by the Secretary of State referred to as ('national policy') for managing the entry into the NHS of this (then) new drug. Mr Justice Dyson said: *"If the Circular provided no more than guidance, albeit in strong terms, then the only duty placed upon health authorities was to take it into account in the discharge of their functions. They would be susceptible to challenge only on Wednesbury principles[4] if they failed to consider the Circular, or they misconstrued or misapplied it whether deliberately or negligently"*. In other words, there was no legal obligation on the health authority to follow the circular; special factors might exceptionally justify departure from the national policy within it, but what the health authority could not do was refuse to consider it or to depart from it merely because they disagreed with it altogether.

The CCG in Ms Rose's case, according to Mr Justice Jay, was not seeking to justify its 2014 policy as a rational exception to CG156. Rather, it was disagreeing with NICE that the evidence base was sufficiently strong to justify funding oocyte cryopreservation and, given that NICE's recommendations were based on an evaluation of the evidence, health benefit and cost, and that NICE is 'the pre eminent body', "*the CCG could not disagree with NICE";* to do so would be simply irrational. On this basis, the 2014 ART policy was unlawful. In the alternative, and on the assumption that other reasons (other than rational disagreement with the evidence base) *could* lawfully be adduced for departing from CG156's recommendation on oocyte cryopreservation, the CCG had just manifestly failed to document any.

The judge also looked at the Claimant's failure to bring her claim promptly *("the nature of this litigation did not lend itself to such a peremptory approach")*, whether a two stage exceptionality test such as that adopted by the CCG was appropriate *("I do have some difficulty with [this]")*, and whether the impossibility of establishing what a patient would have to demonstrate in order to be considered exceptional was a cause for concern *("I would not be troubled by [this]")*, as well as whether the CCG has discharged its duty under s149 Equality Act 2010 and whether there were any breaches of the Claimant's Convention rights, neither of which he elected to address in any depth.

[4] ie: For having acting irrationally, in a way that no reasonable body could possibly have done.

Judicial and non-judicial musings

So, what are we to make of this decision? The 2014 ART policy was not in force when the Claimant brought her claim for judicial review yet the judge analysed its failure to implement CG156 in its entirety at some length, ultimately pronouncing the policy unlawful and urging the CCG to go away and reformulate it. The central rationale regarding the lawfulness of the Triage Group's decision-making is wholly uncontroversial and disposed of the case in short order, but not without leaving the potentially most important part of the judgment – certainly the most interesting and hotly contested observations – residing within the dicta and therefore of questionable status.

Certainly there is no explicit statutory duty upon CCGs to 'have regard', even, to guidance issued by NICE under regulation 5, still yet to implement it in full with all the concomitant costs implications, as if it were a technology appraisal recommendation. The remit of the review undertaken by the ART Working Group was clearly stated to be *"to advise CCGs on how best to meet the requirements of NICE CG156 and the Equality Act 2010 within the available resources. There will be no additional funding available as CCGs have not prioritised ART for additional investment". [Emphasis added].* The unspoken consequence of the judgment must, therefore, be that lack of resources cannot constitute a lawful basis for departing from a NICE guideline. Where does this, then, leave the words of the then Sir Thomas Bingham?

> *"I have no doubt that in a perfect world any treatment which a patient, or a patient's family, sought would be provided if doctors were willing to give it, no matter how much it cost, particularly when a life was potentially at stake. It would however, in my view, be shutting one's eyes to the real world if the court were to proceed on the basis that we do live in such a world. It is common knowledge that health authorities of all kinds are constantly pressed to make ends meet. They cannot pay their nurses as much as they would like; they cannot provide all the treatments they would like; they cannot purchase all the extremely expensive medical equipment they would like; they cannot carry out all the research they would like; they cannot build all the hospitals and specialist units they would like. Difficult and agonising judgments have to be made as to how a limited budget is best allocated to the maximum advantage of the maximum number of patients. That is not a judgment which the court can make. In my judgment, it is not something that a health authority such as this Authority can be fairly criticised for not advancing before the court." (R v. Cambridgeshire Health Authority ex parte B [1995]) [Emphasis added]*

Perhaps it leaves the warning of Lord Pearce, known to law students all around the commonwealth jurisdiction, ringing in our ears:

> *"Words are more volatile than deeds. They travel fast and far afield. They are used without being expended and take effect in combination with innumerable facts and other words. Yet they are dangerous and can cause vast financial damage."*

Obiter dicta – remarks in passing – likewise, perhaps…

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