Healthcare

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Patient funding request for life-saving treatment

The case of *R (on the application of Wallpott) v Welsh Health Specialised Services Committee and Aneurin Bevan University Health Board* [2021] EWHC 3291 (Admin) [2022] ACD 27 involved a challenge to a refusal to fund potentially life-saving medical treatment. It concerned Maria Wallpott, a 50-year-old woman with a rare form of appendix cancer. Ms Wallpott's clinicians had recommended that she undergo cytoreductive surgery with hyperthermic intraperitoneal chemotherapy (CRS with HIPEC). This treatment, involving the surgical removal of visible tumour and flushing with a heated chemotherapy agent, was not routinely available in Wales, in contrast to England, Scotland and Northern Ireland. An individual patient funding request (IPFR) was therefore made by Ms Wallpott's doctor to the Welsh Health Specialised Services Committee (WHSSC), which acted on behalf of the local health board. A WHSSC panel refused the request and maintained its decision on review.

Ms Wallpott brought an urgent application for judicial review of this decision. The claim was heard on an expedited timetable and was decided around a month after issue.

When deciding funding requests, the WHSSC applied an NHS Wales policy, which set out three criteria for a successful application:

- The clinical presentation of the patient's condition is significantly different in characteristics to other members of that population;
- This presentation means that the patient will derive a greater clinical benefit from the treatment than other patients with the same condition at the same stage; and
- The value for money of the intervention for the particular patient is likely to be reasonable.

The WHSSC had also adopted a policy position for this treatment and category of patients, in a document numbered PP90. PP90, issued in 2015, stated that there was insufficient data on clinical and cost effectiveness to consider routine funding of HIPEC and CRS for peritoneal carcinomatosis. The WHSSC was additionally required to have regard to guidance from the National Institute of Health and Care Excellence (NICE), which had been updated in March 2021.

Four of the claimant's grounds of challenge to the WHSSC decision succeeded, and Mrs Justice Steyn's reasoning on the fifth supported her conclusions elsewhere.

First, the judge found that the WHSSC had misinterpreted the IPFR policy. When considering clinical benefit, it compared the claimant with other patients with advanced cancer for whom the treatment would be recommended, but who would not receive it because of the WHSSC's policy not to provide routine funding. This was inconsistent with the terms of the policy. The comparator population was patients with the same condition at the same stage. Further restricting the comparator to patients for whom the treatment was recommended appeared to introduce a test of uniqueness.

Second, the WHSSC had breached its duty to give reasons. The contemporaneous reasons failed to address the principal important issues and were insufficient to enable the claimant to have a fair opportunity to request a review. New reasons, provided in the defendants' witness evidence, were *ex post facto* and inadmissible, going 'well beyond elucidating the reasons given contemporaneously'.

Third, there was a lack of clarity in how the WHSSC had interpreted the NICE guidance, which supported the conclusion that the panel's reasons were inadequate.

Fourth, the WHSSC had made a mistake of fact by suggesting that another form of treatment was available. It relied on a treatment – antibody therapy – which the claimant's clinicians did not consider to be clinically appropriate for her.

Fifth, when considering value for money, the WHSSC had failed to offset the cost of the only potential alternative (systemic chemotherapy). It thereby failed to have regard to a material consideration or, if it did not consider that the cost should be offset, failed to say so or provide any reasons. The reasoning in the defendants' witness evidence on this issue was also new rather than elucidatory, and therefore inadmissible.

In addition, Steyn J forcefully rejected the defendants' submission that relief should be refused on the basis of section 31(2A) of the Senior Courts Act 1981. The threshold for applying that section – that it was 'highly likely' that the outcome would not have been substantially different but for the errors in the decision – was 'nowhere close to being met in this case'.

The decision was therefore remitted for reconsideration. Happily, this resulted in a positive outcome: the WHSSC granted funding for the claimant's treatment.

A review of PP90, delayed from March 2021, is scheduled for July 2022. Patients with this rare form of cancer will no doubt hope that the review prompts a change in the WHSSC funding position. This would bring Wales in line with the rest of the UK, reflect developing clinical evidence, and avoid the uncertainty and difficulty of the IPFR process.

In the meantime, this judgment provides a number of wider lessons:

- Judicial review of unsuccessful IPFR applications can be a highly effective remedy for patients.
- Decision-makers should ensure that their decisions are consistent with the wording of their IPFR policy: notwithstanding the leeway given to a public authority in interpreting its own policy, ultimately the interpretation of a policy is for the court. They must avoid setting the bar for a successful application too high by introducing a test of uniqueness, or fettering their discretion by interpreting the evidence in such a way that no patient could expect to be granted funding.
- Decision documents must explain the decision-maker's reasoning on the important issues, and enable patients to exercise any right to a review effectively. If new reasons are provided for the first time in witness evidence, there is a real risk they will be rejected.

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