WHO KNOWS BEST (INTERESTS)?: THE CASE OF CHARLIE GARD

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INTRODUCTION

The judicial decision that it was in baby Charlie Gard's best interests for artificial ventilation to be withdrawn was devastating for his parents, Chris Gard and Connie Yates, and difficult for their supporters to fathom. Many found it incomprehensible that a treatment option proposed and funded by united parents that carries a chance, however small, of improving a child's future could be rejected. Interventions came from commentators across the globe, including the Pope, Donald Trump and US Congress. The legal principles were all but lost in the debate. We will argue that they were compassionately and correctly applied.

Charlie Gard was born at full term on 4th August 2016. When he was a few weeks old, his parents grew worried about his development and he was admitted to Great Ormond Street Hospital (GOSH). He was found to have a rare genetic condition called infantile onset encephalomyopathic mitochondrial DNA depletion syndrome, referred to as MDDS. Mitochondrial disease results in a build-up of oxygen and fuel molecules in the cells which leads to progressive muscle weakness. Charlie also had congenital deafness and severe epilepsy disorder. No proven treatment exists for Charlie's condition, but there was a theoretical possibility that nucleoside therapy might improve Charlie's outlook. GOSH considered making a referral[1] but declined to do so when tests indicated that Charlie's brain had been severely affected by the disease,[2] in all likelihood reaching the stage of severe epileptic encephalopathy.[3] GOSH considered nucleoside therapy to be contrary to Charlie's best interests. The parents accepted that Charlie's quality of life was not worth sustaining if there was no prospect of improvement, but they believed nucleoside therapy offered hope, located a Professor of Neurology in the United States willing to provide it and successfully raised £1.3 million through crowd funding.

The dispute between GOSH and Chris Gard and Connie Yates could not be resolved through mediation and the matter was referred to Mr Justice Francis in the High Court. A guardian was appointed to represent Charlie. Four declarations were sought by GOSH: that Charlie lacked capacity, that it was in his best interests for artificial ventilation to be withdrawn, that palliative care should be administered

[1] *Great Ormond Street Hospital v Yates, Gard and Gard* [2017] EWHC 972 (Fam), [17].
[2] See *Great Ormond Street Hospital's Position Statement Issued at High Court on 13 July 2017*, FD17P00103 <http://www.gosh.nhs.uk/search?s=charlie%20gard> accessed 30 October 2017.
[3] [2017] EWCA Civ 410, (n 3) [20].

and that it was not in his best interests to undergo nucleoside therapy.[4] Francis J granted the declarations and over the following months, his decision was upheld at three levels of appeal.[5] A stay of the High Court declaration permitting withdrawal of life-sustaining treatment was issued until the European Court of Human Rights heard the application. The stay itself was controversial given the finding that continued treatment was contrary to Charlie's best interests.[6] The Strasbourg Court ruled by a majority that the application was inadmissible.

In July 2017, claims of fresh evidence from the US neurologist saw the case returned to the High Court. A declaration is not a court order, but rather a judicial opinion of what is in the child's best interests. In this case, however, the new evidence was not convincing and Francis J confirmed the declarations made in April. At this point, Chris Gard and Connie Yates no longer opposed the declarations.[7] They believed that earlier intervention would have given Charlie a chance to improve, but that window of opportunity had passed. The High Court was called upon one final time to rule on the various options for withdrawal of treatment in light of difficulty honouring the parents' wish for Charlie to be ventilated at home for a number of days.[8] Charlie was moved to a hospice where he died on 28 July, aged 11 months.

LEGAL PRINCIPLES – FROM PROCESS TO SUBSTANCE

We lack the space to engage with many of the ethical issues the case raises.[9] Instead, we will follow the approach of the courts and confine our analysis to legal principle. Though we will focus on substantive law, there are five procedural issues we cannot ignore: Firstly, the lack of legal aid for Charlie's parents is a travesty.[10] Francis J opined that a case where an NHS Trust is applying for a declaration that life-support be withdrawn is precisely the sort of case that should come within the scheme.[11] The commitment of lawyers representing Connie Yates and Chris Gard on a pro bono basis is remarkable.

The second issue is the unprecedented media involvement in the case. At one time, medical treatment disputes of this nature would have been held *in camera*. The decision by Connie Yates and Chris Gard to sacrifice anonymity was beneficial to their crowd funding campaign. However, interviews, newspaper articles, the charliesfight.org media campaign and participation of Pope and President led

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[4] [2017] EWHC 972 (Fam), (n 1) [27].
[5] [2017] EWCA Civ 410 (n 3); Supreme Court decision declining permission to appeal <https://www.supremecourt.uk/news/permission-to-appeal-hearing-in-the-matter-of-charlie-gard.html> accessed 30 October 2017; *Gard and Others v the United Kingdom* - 39793/17; Decision [2017] ECHR 605 (27 June 2017).
[6] Consider *Aintree University Hospitals NHS Foundation Trust v James* [2014] AC 591, [22] per Lady Hale: 'If the treatment is not in his best interests, the court will not be able to give its consent on his behalf and it will follow that it will be lawful to withhold or withdraw it. Indeed, it will follow that it will not be lawful to give it'.
[7] [2017] EWHC 1909 (Fam), (n 7) [1].
[8] *Great Ormond Street Hospital v Yates, Gard and Gard* <https://www.judiciary.gov.uk/wp-content/uploads/2017/07/cg-order.pdf> accessed 30 October 2017.
[9] See for example, D Wilkinson, J Savalescu, 'Hard lessons: learning from the Charlie Gard case' (2017) J Med Ethics. Published Online First: 02 August 2017, doi: 10.1136/medethics-2017-104492.
[10] See K Holt, N Kelly, 'The right to free and fair legal representation: Re Charlie Gard' (2017) 47(9) Family Law 1031.
[11] [2017] EWHC 1909 (Fam), (n 7) [17] and [2017] EWCA Civ 410, (n 3) [54] per McFarlane LJ.

to a mob mentality that put pressure on the judiciary, the staff at GOSH and the family. The GOSH legal team responded to misperceptions of the hospital's position and powers through increasingly detailed and emotive updates and position statements.[12] Threats and abuse perpetuated on both sides of the debate, and social media involvement poured fuel on the flames. It is lamentable that some of the commentary might have offered false hope to Charlie's family. Greater transparency might reduce the inaccuracies and misconceptions perpetuated. But extensive social media attention in cases involving young children also provokes concern around their privacy.[13]

Thirdly, the case highlights uncertainties around the availability of unauthorised medicines for compassionate use. Drugs must be licensed before they can be marketed,[14] but novel therapies are made available through clinical trials, expanded access and compassionate use programmes, or on a named patient basis. The Medicines and Healthcare products Regulatory Agency launched an early access to medicines scheme in 2014,[15] and though the NHS rarely funds unproven treatment, the NHS Commissioning Policy[16] makes exceptions where clinical trials are not possible and there is a biologically plausible benefit and available funding. In Charlie's case the requisite funds had been raised, but crowdfunding is not without ethical issues given its potential to perpetuate inequalities.[17] Nor are the ethical issues limited to resourcing. The Committee for Medicinal Products for Human Use, part of the European Medicines Agency, makes recommendations for compassionate use of medicines, encouraging documentation of use so as to generate evidence.[18] It restricts its recommendations to cases where use is 'expected to help patients'.[19] In Charlie's case, the only doctor giving evidence who did not believe that the prospect of benefit from the nucleoside treatment was 'effectively zero' was Professor Michio Hirano MD, from Columbia University, USA.[20] Whilst there was no suggestion in the judgments that Professor Hirano was motivated by anything but a desire to help Charlie and his parents, GOSH stated to the court on 24 July that 'it was concerned to hear the Professor state … that he retains a financial interest in some of the NBT compounds he proposed

[12] Great Ormond Street Hospital Press Releases <http://www.gosh.nhs.news/press-releases> accessed 30 October 2017.

[13] M Oswald, H James, E Nottingham, 'The Not-so-Secret Life of Five Year Olds: Legal and Ethical Issues Relating to Disclosure of Information and the Depiction of Children on Broadcast and Social Media' (2016) 8 Journal of Media Law 198; M Oswald, H Ryan, E Nottingham, R Hendry and S Woodman, 'Have 'Generation Tagged' Lost Their Privacy? A report on the consultation workshop to discuss the legislative, regulatory and ethical framework surrounding the depiction of young children on digital, online and broadcast media' (2017) <http://www.winchester.ac.uk/newsandevents/Documents/Have%20Generation%20Tagged%20lost%20their%20privacy%20Report%20August%202017.pdf> accessed 30 October 2017.

[14] Directive 2001/83/EC, Article 6.

[15] See MHRA, Guidance: Apply for the early access to medicines scheme (EAMS) 2014 (updated 2017). <https://www.gov.uk/guidance/apply-for-the-early-access-to-medicines-scheme-eams> accessed 30 October 2017.

[16] NHS Commissioning Board, Commissioning Policy – Experimental Treatments NHSCB/CP/06 (2013). And see The Human Medicines Regulations 2012, SI 2012/1916, Reg 46(7).

[17] J Snyder, 'Crowdfunding for medical care: Ethical issues in an emerging heath care funding practice' (2016) 46(6) Hastings Centre Report 36.

[18] And see Access to Medical Treatments (Innovation) Act 2016 which makes provision for a national database though progress since its enactment is limited.

[19] In accordance with Regulation (EC) 726/2004, Article 83. See European Medicines Agency website <http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000293.jsp> accessed 30 October 2017.

[20] [2017] EWCA Civ 410, (n 3) [15].

prescribing for Charlie.'[21] As the recent scandal involving Paolo Macchiarini demonstrates,[22] controls over access to innovative medicine are important to protect patients vulnerable to unsubstantiated promises of hope.

Fourth, the use of mediation, whilst encouraged in professional guidance,[23] arguably requires more by way of facilitation.[24] It also raises questions about the scope of parental powers and rights which we will argue have varying force in the different arenas of the hospital and the courtroom. This is a substantive issue to which we shall return.

Finally, questions were raised over the jurisdiction of the court.[25] It was submitted that the court has no jurisdiction where a choice must be made between two viable treatment options. Whilst GOSH might refuse to deliver the nucleoside therapy, it could not, it was argued, prevent alternative arrangements for the therapy in the absence of proof of significant harm. As we shall see, the argument was rejected and the result was to limit parental rights to determine their child's best interests.

PARENTAL RIGHTS

The scope of parental rights in determining the treatment outcome for their child was central to the case. In particular, Chris Gard and Connie Yates relied in the Court of Appeal on Article 8 of the European Convention on Human Rights to assert that the best interests test had been wrongly applied. Their argument was defeated, and we would suggest that to have decided otherwise would have perpetuated a line of reasoning that would frustrate progress in protecting children's rights.

The starting point is section 1(1) of the Children Act 1989, which dictates that the welfare of the child must be the paramount consideration. This is the guiding principle whether the decision is taken by parents, doctors or the court. Section 3 of the Children Act 1989 sets out a definition of parental responsibility that counterbalances 'rights' and 'powers' with the 'responsibilities' owed to the child. Disputes between parents and medical professionals that cannot be resolved by mediation or otherwise must be determined by the court with respect to the welfare principle. In addressing the welfare of the child, the court considers what is in the child's best interests from the child's perspective. Whilst the parental view is a relevant consideration, the court is not obliged to act in accordance with the wishes of parents.[26]

The argument that the court lacked jurisdiction to prevent the parents seeking viable alternative treatment was based on the premise that treatment would not cause Charlie 'significant harm'. It was

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[21] GOSH, Latest statement on GOSH patient Charlie Gard' 24 July 2017, para 10 <http://www.gosh.nhs.uk/news/latest-press-releases/gosh-position-statement-issued-high-court-24-july-2017> accessed 30 October 2017.

[22] See N Hawkes, 'Nobel official resigns in wake of storm over Italian surgeon' (2016) BMJ 352.

[23] See for example General Medical Council, *Consent: Patients and Doctors Making Decisions Together* (2008), [77].

[24] [2017] EWHC 972 (Fam), (n 1) [130]; [2017] EWHC 1909 (Fam), (n 7) [20].

[25] [2017] EWCA Civ 410, (n 3) [83]-[88].

[26] *Re T (Wardship: Medical Treatment)* [1997] 1 WLR 242 at 250 per Lady Butler-Sloss; *Wyatt v Portsmouth NHS Trust* [2006] 1FLR 554; *NHS Trust v MB and B* [2006] EWHC 507 (Fam), [16].

argued that interference with the parental choice in these circumstances would be neither necessary nor proportionate and would therefore breach Article 8 of the European Convention on Human Rights.[27] The aim was not to challenge existing case law on the application of the best interests test, which clearly establish that the reasonableness of the parental decision is not definitive.[28] Rather, counsel sought to establish a special category of cases on the basis that adherence to parental rights under Article 8 requires a distinct approach where they propose a viable treatment option that will not cause significant harm.[29] In seeking to establish this special category of cases, counsel for Charlie Gard's parents sought to rely on the High Court decision in *Re Ashya King.*[30] *King* concerned a choice between treatment options for a five-year-old boy, Ashya, who suffered from medulloblastoma, a form of brain tumour. Granting Ashya's parents permission to take him to Prague for Proton Therapy, Baker J put considerable emphasis on the parental viewpoint:

> It is a fundamental principle of family law in this jurisdiction that responsibility for making decisions about a child rest with his parents. In most cases, the parents are the best people to make decisions about a child and the State – whether it be the court, or any public authority – has no business interfering with the exercise of parental responsibility unless the child is suffering or is likely to suffer significant harm as a result of the care given to the child not being what it would be reasonable to expect a parent to give.[31]

In the *Gard* case, McFarlane LJ in the Court of Appeal offered alternative readings of this passage. The first puts some strain on Baker J's dicta, attempting as it does to explain it on its facts as an example of the application of the best interests test. On this argument, there is no separate threshold of 'significant harm' where parents propose a viable treatment alternative. At the point at which the court in *King* was called upon to make a decision, the alternative options were considered equal in terms of their benefits and detriments and only for this reason were the parents free to make the choice.[32] As it was possible to accommodate either choice within the best interests test, the argument that *King* established a new category of cases is unfounded. In contrast, the options were not equal in Charlie Gard's case: it could not be established that the alternative treatment option in Charlie's case *was* viable.

McFarlane LJ gives an alternative and arguably more plausible reason for rejecting a separate threshold of 'significant harm'- namely, that Baker J had erred:

> If, contrary to my primary reading, Mr Justice Baker did intend to state, where a parent puts forward a viable option for treatment, that the High Court only has jurisdiction to interfere with a parent's choice of that medical treatment if the child is likely to suffer significant harm

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[27] [2017] EWCA Civ 410, (n 3) [82].

[28] Consider [2006] EWHC 507 (Fam) (n 26) per Holman J: 'I am not deciding what decision I might make for myself if I was, hypothetically, in the situation of the patient; nor for a child of my own if in that situation; nor whether the respective decisions of the doctors on the one hand or the parents on the other are reasonable decisions.'

[29] [2017] EWCA Civ 410, (n 3) [56].

[30] *Re Ashya King (A Child)* [2014] EWHC 2964 (Fam).

[31] *ibid*, at [31].

[32] [2017] EWCA Civ 410, (n 3) [96].

> as a result, then, in my view, such a statement has no foundation as a matter of law, is contrary to established authority and is therefore plainly in error.[33]

The unproven nature of the treatment was given scant attention in *King*,[34] and one of us has expressed concern elsewhere that accommodating parental preferences for an option that is clinically suboptimal may stretch the boundaries of best interests.[35] As we have argued above, dicta supports the application of best interests from the child's rather than the adults' perspective. We welcome McFarlane LJ's firm rejection of a separate threshold of 'significant harm'. The Court of Appeal found that best interests is the 'established yardstick'[36] which should apply to all cases:

> The judge decides what is in the best interests of the child by looking at the case entirely through eyes focused on the child's welfare and focused upon the merits and drawbacks of the particular options that are being presented to the court.[37]

This is not to say that the parental view is not a relevant consideration in determining the child's welfare. As McFarlane LJ acknowledged: 'It goes without saying that in many cases, all other things being equal, the views of the parents will be respected and are likely to be determinative.'[38] But McFarlane LJ also set out compelling reasons for caution:

> [I]t is well recognised that parents in the appalling position that these and other parents can find themselves may lose their objectivity and be willing to "try anything", even if, when viewed objectively, their preferred option is not in a child's best interests. As the authorities … underline again and again, the sole principle is that the best interests of the child must prevail and that must apply even to cases where parents, for the best of motives, hold on to some alternative view.[39]

VIABILITY OF UNPROVEN TREATMENT

So far, we have considered and commended the court's application of the best interest test in preference to a test of significant harm. This section considers the relevance of the untested nature of nucleoside therapy and the impact this had on the perceived futility of treatment. The emphasis on the viability of nucleoside therapy flowed from the parental acknowledgement that Charlie's current quality of life was not worth extending,[40] and the fact that this was the only available alternative.[41] Francis J considered that treatment was not viable. One reason was the perceived irreversibility of

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[33] *ibid* [105].
[34] See J Bridgeman, 'Misunderstanding, threats, and fear, of the law in conflicts over children's healthcare: In the Matter of Ashya King' [2014] EWHC 2964' (2015) 23(3) Med Law Rev 477.
[35] M Brazier, E Cave, *Medicine, Patients and the Law* (Manchester University Press, Manchester, 6th edn, 2016), 448.
[36] [2017] EWCA Civ 410, (n 3) [74].
[37] *ibid,* [95].
[38] *ibid*, [112].
[39] *ibid*, [112]. And see *Gillick v West Norfolk and Wisbech Area Health Authority and Department of Health and Social Security* [1986] AC 112 page 170, per Lord Fraser; page 184 per Lord Scarman; and page 200 per Lord Templeman.
[40] [2017] EWHC 972 (Fam), (n 1) [14].
[41] [2017] EWCA Civ 410, (n 3) [19].

Charlie's condition. A second, related reason was the negligible chance of improvement if treatment were successful. As Charlie deteriorated, his parents came to share this view but argued that: 'Had Charlie been given the treatment sooner he would have had the potential to be a normal healthy little boy'.[42] GOSH on the other hand, asserted that the therapy 'cannot and could not have assisted Charlie'.[43] A third reason was the possibility that Charlie was in pain[44] and that this pain might be significant.[45] Such was Charlie's quality of life, the courts found that it should not be sustained without the prospect of improvement: this prospect was not offered by nucleoside therapy which was considered 'futile'.[46]

Clinicians were no doubt guided by the Royal College of Paediatricians and Child Health's[47] 2014 guidance, which was also cited by the Court of Appeal in *Gard*.[48] It identifies three sets of circumstances when withdrawal of life-sustaining treatment might be considered:

- If treatment is unable or unlikely to result in the child living much longer
- Where treatment may prolong life but will cause the child unacceptable pain and suffering
- If an older child with a life limiting illness repeatedly makes it clear they do not want treatment and this decision is supported by their parents and doctors.

More specifically, it advises that some children may be unable to derive benefit from treatment:

> [T]he nature and severity of the child's underlying condition may make it difficult or impossible for them to enjoy the benefits that continued life brings. … Even in the absence of demonstrable pain or suffering, continuation of life sustaining treatment (LST) may not be in their best interests because it cannot provide overall benefit to them.

In the previous section, we argued that the parental view on the value of treatment is not determinative. Nor does science provide a definitive answer. As we shall see, best interests are widely construed and are not limited to clinical factors. Furthermore, the clinical factors themselves are often uncertain, changeable and challengeable. In the *Gard* decisions, the emphasis changes subtly from Professor Hirano's evidence that the chance of improvement offered by nucleoside therapy would be 'low but not zero';[49] to Francis J's conclusion that the potential benefit would be 'as close to zero as makes no difference. In other words, as I have already said, it is futile';[50] and then to McFarlane LJ's finding that the evidence of potential improvement is purely theoretical.[51] The issue was complicated

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[42] 'Charlie Gard: Mother's full statement – 'we are so sorry that we couldn't save you'' The Telegraph 24 July 2017.
[43] GOSH, Latest statement on GOSH patient Charlie Gard' 24 July 2017, para 10 <http://www.gosh.nhs.uk/news/latest-press-releases/gosh-position-statement-issued-high-court-24-july-2017> accessed 30 October 2017.
[44] [2017] EWHC 972 (Fam), (n 1) [22], [49], [113]-[115], [121], [128].
[45] *ibid*, [114].
[46] *ibid*, [126].
[47] V Larcher et al on behalf of the Royal College of Paediatrics and Child Health, 'Making Decisions to Limit Treatment in Life-limiting and Life-threatening Conditions in Children: A Framework for Practice' (2014).
[48] [2017] EWCA Civ 410, (n 3) at [75] and [93]. Also referred to in *Kings College Hospital NHS Foundation Trust v Y and MH* [2015] EWHC 1966 (Fam), [28] per MacDonald J. And see [51].
[49] [2017] EWCA Civ 410, (n 3) [24].
[50] [2017] EWHC 972 (Fam), (n 1) [119].
[51] [2017] EWCA Civ 410, (n 3) [24]-[25].

by the unproven nature of the only available treatment. Three precedents provide guidance on the compatibility of unproven treatment with the best interests of an incompetent patient.

In *Simms v Simms and An NHS Trust,*[52] a new and untested intracerebral infusion was proposed by the parents of two young people who lacked competence to decide for themselves. The young people were suffering from variant Creutzfeldt-Jakob disease, which is progressive and fatal. A Japanese Neuropathologist, Dr Doh-ura, had conducted research on animals that indicated the drug Pentosan Polysulphate might extend life expectancy, even if applied in the late stages of the disease. Two legal questions were raised. The first was whether a reasonable body of medical opinion would support administration of the therapy, as per the *Bolam* test. Dame Butler-Sloss acknowledged the difficulty of fulfilling this obligation when the therapy was untested and concluded that: 'The '*Bolam* test' ought not to be allowed to inhibit medical progress.'[53] So long as treatment was not clearly futile, it was *Bolam*-compliant. The second legal issue was whether the surgical procedure was in the young people's best interests. As in *Gard*, there was uncertainty around the benefits of therapy:

> None of the medical witnesses entirely ruled out the possibility of some benefit. … Where there is no alternative treatment available and the disease is progressive and fatal, it seems to me to be reasonable to consider experimental treatment with unknown benefits and risks, but without significant risks of increased suffering to the patient, in cases where there is some chance of benefit to the patient.[54]

The treatment would not lead to recovery, but Dame Butler-Sloss was satisfied that their lives were worth preserving and that 'any treatment that might be beneficial would be of value to them'.[55] The views of the family were accorded great weight.[56]

In *An NHS Trust v J,*[57] doctors proposed the administration of an innovative therapy to a patient, J, in a persistent vegetative state. Research papers had indicated that the drug Zolpidem, used to treat insomnia, might enhance J's awareness. The family opposed the treatment and sought withdrawal of artificial hydration and nutrition. If J's awareness was heightened, they felt, this would only enhance J's distress. Sir Mark Potter P accepted the expert opinion that a three-day course of treatment was in J's best interests and ordered it to proceed. Was *Bolam* tacitly relevant here too? If a reasonable doctor would consider the treatment to be clinically viable, this offsets at least one potential constraint on compassionate use of unlicensed treatment. Another potential constraint is the best interests test and here the views of the family were considered but were not determinative.

Finally, in *An NHS Trust v SR*[58] a mother refused consent to standard post-operative treatment of medulloblastoma, arguing that alternative, non-conventional treatment was in her son, seven-year-old Neon Roberts', best interests. Declaring the conventional treatment proposed by the NHS trust lawful, Bodey J responded that:

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[52] [2002] EWHC 2734 (Fam).
[53] *ibid*, [48].
[54] *ibid*, [57].
[55] *ibid*, [60].
[56] *ibid*, [64].
[57] [2006] EWHC 3152.
[58] *An NHS Trust v SR* [2012] EWHC 3842.

> The treatment proposed … would have to be (or should preferably be) properly studied, tested, reported on and peer-reviewed…. [T]he proposed plan would have to have a prognosis as to probable survival rate not much less than (and preferably equal to) the sort of survival rate achievable through the use of the orthodox treatment.[59]

Thus, before unproven therapy can be sanctioned to treat a patient unable to provide consent, two hurdles must be overcome: the *Bolam* test and the best interests test. In the High Court *Gard* decision, Francis J considered and distinguished *Simms*.[60] The futility and untested nature of the treatment could not be considered compatible with Charlie's best interests. The chance of improvement was not zero, but by the time the case reached the courts, nor was it seen as sufficient to justify prolonged treatment. Add to this the difficulties in establishing the reasonableness of treatment under the *Bolam* test and the decision, whilst heart-breaking for Charlie's family, was not only justifiable in law, but on the evidence, it was the *only* decision justifiable in law.

Since the *Gard* decision, another case sheds light on the compatibility of unproven treatment with a patient's best interests. *B v D*[61] involved a twenty-seven-year-old soldier who had suffered traumatic brain injury. The case was brought by his mother who sought stem cell treatment for D in Serbia, funded by a compensation pay-out. The treatment was unproven and not without risk, the chance of benefit was slim.[62]

D's understanding of the treatment and its prospect of success was limited and he was found to lack capacity. Section 4 of the Mental Capacity Act 2005 requires a decision to be taken in D's best interests. Welfare must be considered 'in the widest sense'[63] and this will often involve eliciting the views of family,[64] as well as the person's past and present wishes.[65] D's mother's view was therefore relevant, but crucially, Mr Justice Baker was able to discuss the matter with D and establish that D wanted the treatment which he hoped would make him 'normal'. The Ministry of Defence and the Official Solicitor opposed the treatment, in part because they saw D's optimism regarding the unproven and unlicensed treatment's efficacy as evidence of a lack of understanding. Baker J, on the other hand, saw it 'more as an expression of the strength of his wish to have the treatment'.[66] Not having the treatment would adversely affect D's emotional welfare. Baker J recounted the words of Munby J: 'What good is it making someone safer if it merely makes them miserable?'[67] and asserted that: 'All life is an experiment'. The balance was fine, but subject to a number of conditions, the Court of Protection sanctioned the unproven treatment.

Notwithstanding our appreciation of the respect for the rights, will and preferences of people lacking capacity, as required by Article 12 of the UN Convention on the Rights of Persons with Disabilities 2006, *B v D* is concerning. The cost to D's emotional welfare of not having the treatment might be as

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[59] *ibid*, [25].
[60] [2017] EWHC 972 (Fam), (n 1) [126].
[61] [2017] EWCOP 15.
[62] *Ibid*, [58] per Baker J: 'the evidence that it is, or might be, an effective treatment for traumatic brain injury is almost entirely anecdotal'.
[63] [2014] AC 591 (n 6), [33] per Lady Hale.
[64] Mental Capacity Act 2005, s. 4(7)(b). And see *M v A Hospital* [2017] EWCOP 19, [27].
[65] Mental Capacity Act 2005, s. 4(6)(a).
[66] [2017] EWCOP 15, (n 61) [57].
[67] *Ibid*, [60] citing *Re MM (an adult)* [2007] EWHC 2003 (Fam), [120].

great if the treatment confirms expectations and proves inefficacious.[68] Moreover, it is difficult to align clinical evidence suggesting that the treatment lacks viability[69] and that the proposed treating clinic 'does not adhere to the international regulations that should be followed in these matters',[70] with practice that accords with a responsible body of medical opinion. The judgment makes reference to neither *Simms* nor *Bolam.*

The case of *B v D*[71] deserves a commentary of its own. What is pertinent to the *Gard* decision is the distinction that can be drawn between cases where best interests can be determined in light of the patient's views and those where that is impossible. The legal regimes applying to adults and children lacking capacity have in common the requirement to view best interests from the patient's perspective.[72] *B v D* makes clear the potential weight of the patient's views.[73] Parents of very young children often know their child best and are therefore in an optimal position to speak to the child's emotional and sensory interests. To extend their relevance beyond this would take us ever closer to a substituted judgement test. A child-centred approach accommodates the views of parents, but does not substitute them for a best interest determination.

TEMPORAL BEST INTERESTS

Our preliminary conclusion that the court's decisions were in Charlie's best interests does not determine the question of whether or not an alternative decision might have been made by the *hospital* in accordance with both the *Bolam* test and the best interest principle. We submit that bringing a case to court subtly alters the way the best interests test is applied.[74]

The hospital deals with a dynamic situation which alters with the fluctuating health of the patient, views of relevant parties and treatment options. Doctors serve as gatekeepers of best interests and the threshold for involving the court is high. In part, this flows from the resource implications of going to court and the stresses of having professional opinion held up to intense public scrutiny. It is also a result of the relevance to the wide best interest assessment of the patient's emotional and sensory interests,[75] which have potential to be adversely affected by legal dispute.

In court, on the other hand, the ambits of the decision are framed by the declarations sought and the evidence available.[76] The court is not free to choose any decision it considers to be in the best interests of the patient. As we have argued, the role of judge is not one of mediator but protector of the child's best interests. Parental views do not hold just because they are reasonable or will not cause significant

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[68] *Ibid*, [45].
[69] *Ibid*, [45], [46].
[70] *Ibid*, [54].
[71] [2017] EWCOP 15 (n 61).
[72] [2014] AC 591, (n 6) [45] per Lady Hale.
[73] See also *Wye Valley NHS Trust v Mr B* [2015] EWCOP 60, [10] per Peter Jackson J: '[O]nce incapacity is established so that a best interests decision must be made, there is no theoretical limit to the weight or lack of weight that should be given to the person's wishes and feelings, beliefs and values.'
[74] See for example *M (Withdrawal of treatment: Need for proceedings)* [2017] EWCOP 19.
[75] [2006] EWHC 507 (Fam) (n 26).
[76] See M Brazier, 'An Intractable Dispute: When Parents and Professionals Disagree' (2005) 13 Med Law Rev 412, 417.

harm to the child. The result is that whilst the best interests test governs both the clinical and court setting, there are differences in its scope and application. This is not explicitly acknowledged in professional guidance. The General Medical Council exhorts doctors to 'always act in the best interests of children', but also acknowledges that 'identifying their best interests is not always easy. This is particularly the case in relation to treatment that does not have proven health benefits …'[77] Vaccination policy provides an illustration of the different operation of best interests criteria in healthcare and judicial settings. Provided those with parental responsibility agree, they can decline to have their children vaccinated. And yet, vaccination disputes between those with parental responsibility have been resolved in favour of vaccination on the basis that it was in the best interests of the children concerned.[78]

It is arguable then that GOSH had greater scope than the court in determining best interests in a manner that was compatible with parental views. We would argue however that in this case the scope was not sufficient to justify acceding to the parents' wishes. Three arguments warrant consideration. First, with the benefit of hindsight, a trial of nucleoside therapy would arguably have been less detrimental to Charlie's interests than the months of delay that resulted from the legal dispute. But GOSH could only act on the available facts. Second, there is the argument that GOSH failed in its attempts at mediation. However, this was not a case offering a range of compromise positions, but a stark choice between two options: allow the unproven therapy or withdraw treatment and allow Charlie to die.[79] Third, there is professional guidance suggesting that unproven treatment might have been considered in Charlie's case. Department of Health guidance[80] says this is appropriate when no alternatives exist, the disease is progressive and fatal, the risks minimal and there is some chance of benefit. This is questionable, however, in light of GMC guidance.[81] Good Medical Practice guidance states that doctors must 'be satisfied that the drugs or treatment serve the patient's needs' and must 'provide effective treatments based on the best available evidence'.[82] The Declaration of Helsinki too goes further than the Department of Health guidance:

> In the treatment of an individual patient, where proven interventions do not exist or other known interventions have been ineffective, the physician, after seeking expert advice, with informed consent from the patient or a legally authorised representative, may use an unproven intervention if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering. This intervention should subsequently be made the

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[77] General Medical Council, *0-18 Guidance for all Doctors* (2007), p 8. <http://www.gmc-uk.org/guidance/ethical_guidance/children_guidance_contents.asp> accessed 30 October 2017.

[78] *Re C (welfare of children: immunisation)* [2003] 2 FLR 1095; *LCC v A, B, C and D* [2011] EWHC 4033; *F (mother) v F (father)* [2013] EWHC 2683 (Fam); *Re SL (permission to vaccinate)* [2017] EWHC 125 (Fam). And see E Cave, 'Voluntary vaccination: the pandemic effect' (2017) 37(2) Legal Studies 279.

[79] See I Brassington, 'Charlie Gard: an ethical analysis of a legal non-problem' J Med Ethics Blog, 11 August 2017 <http://blogs.bmj.com/medical-ethics/2017/08/11/charlie-gard-an-ethical-analysis-of-a-legal-non-problem/?utm_source=TrendMD&utm_medium=cpc&utm_campaign=JME_blog_TrendMD-0> accessed 30 October 2017.

[80] Department of Health, *Reference Guide to Consent for Examination of Treatment* (2nd edn, 2009), para 41.

[81] See General Medical Council, 'GMC response to proposed legislation to encourage medical innovation' (April 2014), p 8. <http://www.gmc.uk.org/GMC_s_response_to_the_consultation_on_the_Medical_innovation_Bill.pdf_59860303.pdf> accessed 30 October 2017.

[82] GMC, *Good Medical Practice* 2013, para 16.

> object of research, designed to evaluate its safety and efficacy. In all cases, new information must be recorded and, where appropriate, made publicly available.[83]

In Charlie's case, the evidence was that therapy did not offer 'hope of saving life, re-establishing health or alleviating suffering'. The hospital had strong grounds for supposing that the treatment would be unethical and contrary to established legal principle. Given the strain on relations between the parents and GOSH, one option would be to seek the advice of an ethics committee. The 2002 version of the Council for International Organisations of Medical Sciences guidance recognised that some states require submission of cases for compassionate use to an ethics committee.[84] GOSH has an ethics committee but the Gard case was withdrawn when it became apparent that Charlie's health had deteriorated. Having ruled out this option, it was eminently appropriate that GOSH approached the court.

CONCLUSION

In decisions about life-sustaining treatment of a young child, best interests are determined neither by parents nor clinicians, but either through a hospital-based process of compromise and mediation, or a court-based judicial decision. In a hospital setting, the views of parents will often carry the day. Hospitals are keen to avoid court because their prioritisation of the child's best interests includes the emotional, sensory and physical interests that legal dispute might compromise. Clinicians must be convinced that any harms to the child associated with contravening the wishes of parents are less impactful than the harms associated with accommodating their viewpoint. Once the case proceeds to court, the relevance of the parental view dwindles. It is relevant in determining the child's quality of life and insofar as the decision will impact on the engagement of the parent with the child and the effect this will have on the child's welfare, but because welfare cannot be determined by reference to the child's values, views and wishes, clinical factors play a dominant role.[85]

In many cases, particularly where parents are united, the progression of the case to court is indicative of an intractable dispute. Even then, as Mr Justice Francis was at pains to point out, mediation should be encouraged so that each fully understands the alternative viewpoint.[86] The costs associated with a breakdown in the relationship between clinicians and parents can be financial, emotional and physical. Clinicians are, in a very real sense, mediators. Treatment is an enterprise that is dependent upon cooperation and this necessitates a relational approach. Whilst the duty to communicate with and

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[83] World Medical Association, *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects* (64th WMA General Assembly, Fortaleza, Brazil, October 2013), [37].

[84] See Council for International Organizations of Medical Sciences*, International Ethical Guidelines for Biomedical Research Involving Human Subjects* (Geneva, 2002), Commentary on guideline 2. Note there is no equivalent guidance in the 2016 version.

[85] See for example *In the Matter of D (A child)* [2017] EWCA Civ 1695, [62] per Sir Munby.

[86] [2017] EWHC 972 (Fam), (n 1) [130]; [2017] EWHC 1909 (Fam), (n 7) [20].

consult parents is clear in both law[87] and ethics,[88] the waters are muddied by inconsistent ethical guidance on unproven, innovative treatment and latterly by inconsistencies in the legal approach.[89]

In the *Gard* case, professional guidance from the GMC and RCPCH raised doubts as to the ethics of sanctioning the unproven therapy and in law it was questionable on existing legal precedent that it would satisfy either the best interests test or the *Bolam* standard of reasonable care. In light of this, mediation could not have focussed on finding a compromise, for there was no such middle path. Parents may know their children best, and their decision may be motivated by love, hope and compassion, but that decision may still conflict with the best interests of the child. When dialogue failed, it was right and proper to ask the court to determine the issue. We have outlined discrepancies in professional guidelines on access to innovative treatment, resolution of which might assist parties in articulating and applying risk benefit analysis. We have also argued that clinical ethics committees are well served to balance the ethical tensions between parental autonomy, harm prevention and beneficence and that their independence and distance from the issue are relevant mediation credentials.

The decision fell to the courts to resolve and at this point the framing and application of best interests was constrained by the available evidence and the declarations sought by GOSH. Judges are not mediators, but are instead constrained by the dominant principle of best interests and the requirement to consider the test from the child's point of view. *Gard* was a test case for a new recognition of parental rights, albeit in the limited situation where parents pose a treatment alternative unlikely to cause the child significant harm. The rejection of this argument was an unmitigated blow to Chris Gard and Connie Yates, but we have argued that the principle it upholds - namely the elevation of the child's interests above the parents'- gives some cause for optimism. It is a very muted victory given its desperately sad outcome.

[87] *Glass v United Kingdom* (Application No 61827/00).

[88] V Larcher et al on behalf of the Royal College of Paediatrics and Child Health, 'Making Decisions to Limit Treatment in Life-limiting and Life-threatening Conditions in Children: A Framework for Practice' (2015) BMJ 1, 14. See also M Brazier, (n70) and R Heywood, 'Parents and medical professionals: Conflict, cooperation, and best interests' (2012) 21(1) Med Law Rev 29.

[89] See discussion above of *B v D* [2017] EWCOP 15.