1 Medical Law as Applied to Neonatal Surgery

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Abstract

Medical law as applied to neonatal surgery, when considered in terms of the number of requests for legal or ethical opinions, is mainly concerned with the withdrawal or withholding of treatment. However, this must be placed into the context of the chronological opportunities for law to intervene in clinical care. For that reason alone, this chapter commences with the unborn child, passing through the stage of birth, initial decisions on viability (and acquiring a legal parent); before progressing to the 'baby cases', and subsequent guidance when considering the withdrawal of care in neonatal surgery.

Keywords

Ethics • Medical law • Neonatal surgery • Paediatric surgery

Medical law as applied to neonatal surgery, when considered in terms of the number of requests for legal or ethical opinions, is mainly concerned with the withdrawal or withholding of treatment. However, this must be placed into the context of the chronological opportunities for law to intervene in clinical care. For that reason alone, this chapter commences with the unborn child, passing through the stage of birth, initial decisions on viability (and acquiring a legal parent); before progressing to the 'baby cases', and subsequent guidance when considering the withdrawal of care in neonatal surgery.

Contained within a book emerging from one of the founding centres of neonatal surgery in the British Isles, it is unsurprising that this chapter rests squarely on the common law in England and Wales. However the judges creating that law constantly survey the decisions of their colleagues in North America, Canada and Australasia which in turn influences the English decisions. Since the commencement of the Human Rights Act 1998, our courts are also constrained by the European Convention of Human

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Rights, so that the law pertaining to neonatal surgery described in this book is derived from broad international experience.

1.1 Wrongful Birth

International experience is nowhere better reflected than in wrongful birth. This is a topic which mainly relates to foetal medicine, rather than to neonatal surgery. Applicable only to the precursor of the newborn child, it is included for completeness. But many of us provide antenatal counselling to prospective parents, and it is instructive to reflect on the consequences that could, in principle, flow from this.

Parents of children born with an affliction that could and should have been detected in utero have been suing their clinicians for some years. An early case [1] in the New York Court of Appeals found that parents could claim the costs of institutional care of their child who was born with Down's syndrome, following their doctor's failure to recommend amniocentesis to the 37 year old mother. Courts immediately found such cases difficult due to conflicts of interest. There was public policy to consider; of favouring life over abortion; to be weighed against a woman's prerogative of control over her own body. What emerged was a rule accepted in at least 30 US states that valid claims for wrongful birth will succeed [2].

In the United Kingdom, the action is also allowed, with evidence that many are settled without recourse to the courts [3]. Nevertheless, litigation over failure to diagnose a wide field of diseases that are identifiable antenatally, including congenital rubella syndrome, Duchenne muscular dystrophy and Down's syndrome have been reported.

In addition, in a Scottish case [4], a father was been awarded damages for the shock and distress he has suffered as a result of the birth of an affected child. This was unusual, since such damages have usually been limited to the mother, and evidence of psychiatric harm has previously been required. Neither of these applied in McLelland.

1.2 Proposed Guidelines for Instituting Intensive Care at Birth

In a report [5] commissioned by the Nuffield Council on Bioethics, guidelines were proposed for deciding as to whether babies of certain gestational age should have limitations placed on their resuscitation and intensive care. These proposals were based solely on judgement of the best interests of a premature child, irrespective of the wider issue of whether clinical resources were available to support this aspect of neonatal medicine. The working party concluded that below 22 weeks of gestation, no baby should be resuscitated, unless this was taking place within all the safeguards of a clinical research study. For babies between 22 weeks and 22 weeks 6 days of gestation, "…standard practice should be not to resuscitate a baby, (and that) … resuscitation would normally *not* be considered or proposed". In this group, parents' views might lead to a reversal of this approach, after a thorough discussion of the risks and prognosis with an experienced clinician. In babies between 23 weeks 0 days and 23 weeks 6 days, precedence should be given to the views of the babies parents, but there is no clinical obligation to embark on treatment that is 'wholly contrary' to clinical judgment.

This brief description does not do justice to a 250 page report of great quality. However, it is cited as an illustration of the national efforts being made to define some limits to treatment at the commencement of extra-uterine life, based on a balance between the importance of preserving life, whilst at the same time acting a in a child's best interest.

1.3 Parental Responsibility

Parental responsibility is conferred by statute [6] and is defined as 'all the rights, duties, powers, responsibilities and authority which by law, a parent of a child has in relation to the child …. ' Included is the right to provide consent for treatment where necessary. The child's mother (the woman who gave birth to the baby, rather than the person who provided the egg from which he was conceived, if different) automatically gains parental responsibility. The child's father gains parental responsibility automatically if married at the time of the birth registration. Since 2003, unmarried fathers also get parental responsibility automatically, when they register the birth.

If the father subsequently marries the mother, he acquires parental responsibility, an acquisition described as 'legitimation' [7].

Alternatively, parental responsibility can be acquired by the unmarried father either with the agreement of the child's mother, or by application to a court.

Parental responsibility is passed to adoptive parents on legal adoption. It may be shared with guardians appointed by parents; with local authorities; and is linked to various legal orders [8].

The person with parental responsibility who provides consent for a child's surgery must act in the child's best interests in so doing. These are usually self evident, and the agreement between parents and surgeon is reached after full disclosure of the relevant information.

1.4 The 'Baby Cases'

Medical law is a relatively modern discipline. In some respects, it has been built upon cases considering whether a child with congenital malformations should be treated, or allowed to die without operation. It should be remembered that these 'withdrawal' cases only get to court if there is dissent; between surgeons, physicians, nurses or parents. Provided all agree that withdrawal (or continuation of treatment) is in a baby's best interest, the effects of their joint decision attract no public attention. It is only where one or other group powerfully disagree over the management plan that litigation occurs, and it is helpful to begin with the English cases, in chronological order.

1.4.1 Baby Alexandra, and the Question of Life's Sanctity

In a case known as Re B,[1] the parents of a newborn with Down's syndrome and duodenal atresia wished to allow their child to die, rather than undergo surgery. Her doctors disagreed, and the local authority was given care and control of the baby. The court authorised surgery, but when the child was transferred for operation, the surgeons were unwilling to operate, in view of the parents' objections. The local authority returned to court, but the judge, after hearing the parents' views, withdrew authorisation for the surgery.

The case was then considered by the Court of Appeal, which was told that other surgeons would be prepared to operate. This court found that the judge had placed too much emphasis on the wishes of the parents, and that it was the *best interests* of the child that should prevail. To determine these best interests, the appeal court created a test: Was Alexandra's life "…. demonstrably going to be so awful that in effect she should be condemned to die, or whether the life of this child is still so imponderable that it would be wrong for her to be condemned to die?"

Concluding that the surgery would give her the chance to live the normal life expectancy of a child with Down's syndrome, the court allowed the appeal, and Alexandra's surgery was performed. However, in his leading judgment, Templeman LJ acknowledged that "… there may be cases … of severe proved damage where the future is so certain and where the life of the child is so bound to be full of pain and suffering that the court might be driven to a different conclusion". The court thus established two cornerstones of modern jurisprudence. That there was no absolute parental right to control the fate of a child in these circumstances; and that there was no absolute right to life for a child.

Thus the foundations were laid for the *quality of life* to be used as a yardstick of the success of

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[1] Re B (A Minor) (Wardship: Medical Treatment) (1982) FLR 117.

therapy, rather than merely the preservation of life, irrespective of its quality.

Furthermore, the case provided an early example of a balancing exercise that must be employed when determining the best interests of children. Such an exercise is as applicable to surgical decision-making as it is to judicial deliberation.

1.4.2 Dr. Arthur

No account of neonatal law can ignore the case of Dr. Leonard Arthur [9], who was charged (initially) with the murder of a child with Down's syndrome.

It must be understood that this famous case is a legal anomaly. It is a solitary criminal case nestling amongst a group of private civil medical law cases, and the outcome was unexpected.

Dr. Arthur's patient was a baby boy with uncomplicated Down's syndrome who had been rejected by his mother. On the basis that neither parent wished the child to survive, Dr. Arthur prescribed 'nursing care only', together with dihydrocodeine as required, 5 mg four hourly. The child died 2 days after birth; the cause of death being attributed to bronchopneumonia resulting from Down's syndrome.

The prosecution alleged that Dr. Arthur decided to cause the death of the child. The jury disagreed, and acquitted him after 2 h deliberation. A successful conviction had been anticipated. The case caused a furore, commentators roundly criticising [10] the judge's presentation of the legal issues to the jury. In particular, the judge failed to apprise the jury of Dr. Arthur's homicidal intent.

It could be inferred from the facts of the case that Dr. Arthur administered dihydrocodeine in order to end his patient's life. This element of intention to kill is crucial in obtaining a conviction for murder. How Dr. Arthur escaped this remains a matter of speculation amongst lawyers, who almost invariably point out [11] that the case holds no value as a precedent for future decisions.

Dr. Arthur was represented at trial by George Carman QC, the foremost defence counsel of his generation. Controversially, he advised his client *not* to give live evidence at the trial. Carman's biographer [12] reveals that in the barrister's view, "if Leonard Arthur had been asked 'When you decided on the way to treat this baby, what did you intend to happen?', Arthur would have replied 'I intended it to die'. End of story".

The case was therefore highlighted as an anomalous criminal judgement, but together with a reported case a few weeks preceding it [13], (that no action being taken against a doctor who had allegedly refused to sustain a baby with spina bifida), it brought non-treatment of newborns to the public attention. It also caused consternation amongst doctors, (some of whom) failing to appreciate the distinction that was being made between withholding treatment from a dying patient, as opposed to depriving hydration and nutrition from a child who was otherwise healthy. This error was encapsulated in a statement from the President of the Royal College of Physicians: "… I say that with a child suffering from Down's and with a parental wish that it should not survive, it is ethical to terminate life … [14]".

In reality, Dr. Arthur's mistake, in retrospect, was to conflate 'futility' with an obligation to accede to the parents' wishes that their child should not be treated. One of the legal mistakes was to allow the jury to believe that the doctor's duty to a child with Down's syndrome could be different from, and lower than, that owed to a child without the syndrome. That was and is quite wrong. The doctor's obligation is to do what is reasonable in all the circumstances of his or her patient.

1.4.3 Re C, and the Emergence of the Best Interests of the Child

Baby C was born prematurely in 1988 with hydrocephalus; at birth, her doctors considered her to be terminally ill, due to associated cerebral structural damage. However, a shunt was inserted at 2 weeks to prevent enlargement of her head. The question arose as to whether and how she should be treated in the event of shunt blockage, or infection. It was the disparity of the advice between the local authority's social and legal services that lead to a review of the case in the Court of Appeal [15]. The child's social worker concluded that the doctors should treat C in a way "appropriate to a non-handicapped child". The legal department concluded differently, that C should "… receive treatment as is appropriate to her condition". The leading judge in the Court of Appeal was firmly in agreement with the latter view:

"You do not treat a blind child as if she were sighted, or one with a diseased heart as if she was wholly fit" [16].

The Court of Appeal was careful to issue directions that were not explicit, authorising the hospital "… to treat the minor to allow her life to come to an end peacefully and with dignity".

Re C is the case that Lord Templeman had anticipated during his judgement in Baby Alexandra. Baby C was dying, untreatable, with a quality of life far removed from that which a child with Down's syndrome could reasonably expect. Baby C's physical limitations could be predicted to lead to the demonstrably awful and intolerable life of suffering that Alexandra would hope to avoid.

The decision confirmed that there is no absolute right to life; and the full judgement provides powerful reassurance [17] that English law refuses to countenance killing patients.

1.4.4 Re J, and 'Substituted Judgements'

In the case of a 27 week premature baby [18] with severe brain damage, the question for the court was how the child should be managed in the event of a further collapse. J was born at 1.1 kg, and required ventilation for 4 weeks. Oxygen-dependent for a further 6 weeks, he was discharged home at 3 months of age, but had a cyanotic collapse at home a few days later. This acute illness, which necessitated 3 more weeks of ventilation, caused parenchymal brain damage; the prognosis was of severe spastic quadriplegia.

In an initial approach to the court, following the diagnosis of the brain damage, an order was made that it would not be in J's best interests to reintubate him "unless to do so seemed appropriate given the prevailing situation. If he developed a chest infection treatment with antibiotics and maintenance of hydration was recommended, but not prolonged ventilation" [19].

Representing the public interest, the Official Solicitor appealed this decision, on the grounds that a court was never justified in withholding consent to life-saving treatment to a child, irrespective of the quality of life which it would afterwards experience. The Court of Appeal held that a medical course of action which failed to prevent death could still be in a child's best interests. Furthermore, that there was no absolute rule that, (except when a child was already dying), neither the court nor any responsible parent could approve the withholding of life-saving treatment on the basis of the quality of the child's life". This judgement, and those that preceded it, established a precedent in English law for the withdrawal of treatment on the basis of a poor quality of life.

The court in Re J also reviewed the 'demonstrably so awful' test that had emerged in baby Alexandra's case. There was concern that this test allowed courts to determine the patient's quality of life by their own standards, whilst having no understanding of the situation from the patient's own perspective. Thus, the restrictions that severely disabled people face in their daily activities might not be as incompatible with a rewarding and fulfilling life as many judges might assume.

From this idea flowed the proposal that the anticipated quality of life that the child might have to endure should be judged *from the viewpoint of the child*; as to whether it would be intolerable *for him*.

This is described as the 'substituted judgement' test. The Court thus emphasised that any assessment of the forthcoming quality of life should be made from the assumed view of the child patient, rather than that of the adult decision-maker.

This was a radical view from a legal system based upon judges arriving at their own view of a child's best interests, and drew wide criticism [20]. Not least, because it involves the creation of a legal fiction: Baby J had no capacity to create a 'viewpoint', so there was no way in which his supposed views could be predicted. Any assumed view would thus be entirely a creature of the judge's imagination. Nevertheless, the substituted judgement was an important milestone in the jurisprudence of withdrawal, and its effects remain visible today.

1.4.5 Re C, and the Reassertion of Parental Rights?

This case from 1996 concerns a baby with biliary atresia [21]. C underwent a Kasai procedure at three and a half weeks, but biliary drainage was not achieved. His parents were influenced by the pain and distress their son experienced in preparation for, and subsequent to, the surgery and resolved that if the Kasai was unsuccessful, they did not wish him to undergo a liver transplant. The clinicians looking after C provided a unanimous prognosis that without transplant, he would die; and thus it was in his best interests to receive a new liver when one became available.

After the failure of the portoenterostomy was recognised, C's parents left the jurisdiction, taking jobs in a distant Commonwealth country. The clinicians, via the local authority, applied to the courts seeking three decisions; (i) whether it was in C's best interests to undergo liver transplantation; (ii) permission to perform transplantation notwithstanding his mothers refusal to consent; (iii) for the child to be returned to England for this purpose. When C was 17 months old, the High Court granted all three requests, ordering his return to this country within 21 days.

C's parents appealed, and the Court of Appeal handed down the judgement 5 weeks later.

This court distinguished C from previous cases, which it asserted had been decided largely upon the *medical* best interests of the children concerned. Butler-Sloss LJ, a judge in the appeal, considered that insufficient emphasis had been given to "the enormous significance of the close attachment between the mother and baby [and whether it was]. .in the best interests of C … to direct the mother to take on this total commitment where she [did] not agree with the course proposed".

The court thus expanded the concept of 'best interests' to incorporate non-medical considerations, such as how a decision might have impact upon the relationship between a child and his parents; and arguably, on the interests of the mother.

The ruling was mainly criticised on this basis; that there was a failure sufficiently to differentiate the interests of the child and his mother … which arguably, could be in conflict. For instance, cases may occur when parents wish to move to a distant country only for reasons of employment … irrespective of the harm to their child, now unable to get access to necessary therapy. Commentators [22] suggest that the emphasis this case gives to (enhanced) parental rights is reminiscent of the situation in England in the nineteenth century. Nevertheless, the case does emphasise the need to consider the wider aspects of a child's best interests when deciding cases of treatment withdrawal.

1.4.6 Re A; Conjoined Twins, and the Impact on the Influence of Parents

In a case [23] from September 2000, the Court of Appeal was faced with the onerous task of balancing the opposing interests of two babies. Born conjoined, these ischiopagus twins shared a common aorta. The court heard that Mary, the weaker child, would die during the proposed separation from Jodie, who was given a good prognosis if separated. The court was also told that if separation was not performed, death of both twins would be inevitable in a matter of months, due to heart failure.

The reason for the approach to court was that the parents of the twins, who were Maltese, were devout Roman Catholics; they were unwilling to provide consent to allow one twin to be sacrificed in order that the other might live.

In this unusual situation, the court had to decide the correct principle to apply when there was an overt conflict between the rights of the two girls; and between their rights, and those of their parents. Furthermore, the criminal law problem; that Mary's inevitable death would raise the inescapable inference that the surgeons had intended her death.

In respect of the conflicting rights between the babies, the majority of the judges held that their interests should be balanced, and the least detrimental alternative should be chosen. Since surgery would offer Jodie the chance of a relatively normal life, whilst not affecting Mary's fate, the court sanctioned the operation.

Considering the conflict between the interests of the girls and their parents, the court reiterated the principle that the parents' views were not determinative. In doing so, the court rejected the approach in Re C, above. In finding that the parents' religious views were not of decisive importance when considering the jeopardy a child's life, the court reaffirmed the general principle that it is the *child's* welfare that is of paramount importance. Crucially, what the Court of Appeal *did not do* was reject the wider principle in Re C; that evaluation of the child's best interests should not be confined to medical best interests.

In terms of the criminal law, the difficulty of the situation before the court was reflected in the variety of the solutions found to assert that separation, resulting in Mary's death, would be lawful. The judges were searching for a defence to what would otherwise be murder. One judge construed this as a form of self-defence; seeing "… no difference between … resort to legitimate self defence and removing the threat of fatal harm to [Jodie] presented by Mary's draining her life blood".

The court, agonising, concluded that the surgery could lawfully be performed.

In Bainham's words [24], the case:

> "[Is] one rather stark demonstration of the lack of a shared morality about these life and death decisions. For the Roman Catholic parents it was morally wrong to kill Mary. For others it was morally wrong not to bring about her death since there was a moral duty to save Jodie".

This series of cases provides the common law background for our current handling of withdrawal of care in neonatal surgical cases. These, together with statutory and professional influences have provided the principles by which we are guided in clinical practice.

1.5 Statutory Guidance

The Children Act 1989 is the cornerstone of modern children's legislation in England and Wales, and was intent on placing the child's interests, rather than those of the parents, at the centre of decision making. At the opening line of the Children Act 1989 [25] is the *paramountcy* principle:

"When a court determines any question with respect to:

(a) the upbringing of a child … the child's welfare shall be the court's paramount importance"

The Act provides, in addition, for a welfare 'checklist', by which a court must evaluate the effect of any proposed decision that will affect the child. These include:

(a) the ascertainable wishes and feelings of the child concerned (considered in the light of his age and understanding);
(b) his physical, emotional and educational needs;
(c) the likely effect on him of any change in his circumstances;
(d) his age, sex, background and any characteristics of his which the court considers relevant;
(e) any harm which he has suffered, or is at risk of suffering;
(f) how capable each of his parents, and any other person in relation to whom the court considers the question is relevant, is of meeting his needs;
(g) the range of powers available to the court under this Act in the proceedings in question.

It can immediately be seen that not every heading on the checklist is applicable to surgical babies. But some headings from this checklist form an aide memoire for reminding us all of the matters that we should be considering when we decide whether the clinical management we propose is in the child's best interest; reminiscent of the expansion from solely medical best interests that the court in *Re C* alluded to. It should be emphasised that although the welfare checklist is applicable to withdrawal of treatment (as a "decision that will affect the child"), in the vast majority of cases, the checklist will be employed in lesser decisions.

As an example, faced with the decision as to whether stoma formation is the correct approach in a baby with NEC, the main consideration will undoubtedly be on 'surgical' grounds of safety and efficacy. However, if the result of that initial determination still leaves you in equipoise, the ability of the nurses (or the parents) to manage the stoma; the cultural implications of exteriorised bowel; and the potential problem this may cause with bonding with his parents may also require some thought. In considering these influences, you have adhered to the principles behind the creation of the welfare checklist.

1.6 Practical Application

As neonatal surgeons, we are sometimes faced with a neonate who has lost all the small bowel. It may be instructive to consider how we deal with the next steps, upon this discovery.

It is self evident that it is far better to anticipate such findings, and discuss the ramifications of total gut loss before you start the surgery on their child. Nevertheless, once the diagnosis is made at operation, it is likely that you will need to return to the parents, further to discuss the clinical situation, before making a final decision on treatment. The correct surgical decision will depend on the circumstances, but options such as central venous catheter insertion and long term parental nutrition, or prompt withdrawal of treatment are likely to be discussed.

In reality, if the clinicians (surgeons, neonatologists and nurses) and the parents are all in complete agreement as to the correct next step, the opportunity to embark upon a discussion of ethical or legal principles does not arise. However, any decision to withdraw treatment should be made only after consideration of the relevant guidelines from the Royal College of Paediatrics & Child Health [26].

These are currently undergoing revision, but provide various categories of clinical situations where it may be legal and ethical to consider withholding or withdrawing life sustaining treatment. Included in theses categories is the "No Chance" situation, where treatment will only delay death, and will not alleviate suffering; and the "No purpose" situation, where the degree of mental or physical impairment would be so great that it would be unreasonable to expect the patient to bear it.

Originally designed to assist clinicians' categorise and thus better understand the wide variety of case they face, these guidelines now begin to feel outdated, hence their revision.

It is to be expected that any unanimous decision will coincide with the best interests of the child, her welfare being paramount, and this will be enacted.

It is only when there is disagreement, with any one of these four parties failing to support the clinical decision, that further exploration of ethics and law may have to begin. In some circumstances, the disagreement is based upon an incorrect belief; and a full discussion between clinical staff and the parents may resolve this.

If the disagreement is based on fundamental differences over the child's prognosis, or over which treatment most closely corresponds with the patient's best interests, it is prudent to obtain an early second clinical opinion. This may be from within the unit, or from an adjacent hospital. If the second opinion does not resolve the disagreement, an opinion from the local clinical ethics committee (CEC) may be helpful, if only to clarify precisely the grounds of conflict.

A member of the CEC may be able to identify options that the clinicians, or parents, regard as sufficiently common ground to allow resolution of the conflict. Even if this is not achieved, a formal review by the CEC will be construed as an important and necessary step, should review by a court later become necessary. Further consideration by experts within speciality organisations or Royal Colleges may also aid resolution. However, experience indicates that in situations where the CEC review fails to resolve the disagreement, the intervention of a court is likely to become necessary.

This is surprisingly easy to arrange, using the Trust solicitor as a starting point, to clarify the question(s) that the court is asked to decide. Referral to a court should not be seen as a failure. The court is simply another form of second opinion, and its decision will usually be welcomed by those on both sides of the disagreement, since this will bring certainty to the next clinical step, both for clinicians and parents. It should be noted that courts in England and Wales will not usually insist that any identified clinician follows a particular course of treatment. The court merely identifies the child's best interests, and clarifies what further steps would be lawful. If the judgement prescribes treatment that doctors are unwilling to provide on clinical grounds, their obligation will be to refer the patient to a centre that may be prepared to embark on the proposed treatment, and maintain the patient's condition until a transfer can be achieved.

It should be noted that referral to the medical defence organisations is not advocated in this process, since these bodies exist to promote the interests of the doctors, rather than those of the patients. It is submitted that the mechanism described will cater thoroughly for the needs of the neonatal surgical patient; if you feel that recourse to your defence body is prudent, that is clearly a matter for you.

In summary, the common law has provided us with clear guidance in resolving some of the dilemmas in caring for neonatal surgical patients, and this is strongly reinforced by statutory guidance, identifying the child's best interests as paramount.

It will rarely be possible (or proper) to solve dilemmas of treatment limitation without first establishing a broad consensus of opinion that includes those of the baby's parents. In the absence of such unanimity, recourse to the courts for a 'second opinion' will usually be of great assistance, and should be viewed as a positive step.

Conclude … the courts may have an increasing role in resolving these uncertainties.

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