Institution: University of Manchester

Unit of Assessment: 20 (Law)

Title of case study:
Ethical and Legal Guidelines on the Care of Extremely Premature and/or Sick Neonates

1. Summary of the impact

Research undertaken at the University of Manchester (UoM) considers legal guidelines as they relate to the Care of Extremely Premature and/or Sick Neonates and has sought to identify deficiencies in the law, clarify the issues at stake in policy debates and make proposals for constructive responses. Impact has occurred through the utilisation of research in an influential Nuffield Council on Bioethics (NCOB) report. This has led to uptake within guidance provided to health professionals and parents, and ultimately the implementation of report recommendations – most notably the timetable that correlates the decision process on resuscitation to set stages in gestational age, alongside a more holistic approach to best interests – by the British Association of Perinatal Medicine (BAPM) in 2008. The BAPM guidance continues to have a significant impact on clinical practice.

2. Underpinning research

The impact is based on ongoing research conducted at UoM (1993-date) and forms part of a wider study of the law as it relates to the relationships between doctors, vulnerable patients and families. The role of the law relating to the care of infants, and who should speak on their behalf, cannot be divorced from this wider context unless the neonate is not to be regarded as a legal person at birth.

Ongoing developments in neonatal medicine enable doctors to resuscitate babies born at ever earlier stages in gestation, and to keep alive babies with very severe impairments. Such developments generate legal and ethical questions relating to the status of the fetus/neonate and the rights of parents to make decisions about the treatment of their infant. This research strongly endorses the granting of a legal personality at birth, rejecting ethical arguments on moral personhood as basis for law [D][E]. The initial research was conducted by Professor Margot Brazier (currently Professor, and former director of the Centre for Social Ethics and Policy), joined from the 4th (2007) edition of her seminal work *Medicine Patients and the Law* by Dr Emma Cave (Reader, Durham University), with ongoing work developed in tandem; recognising that it is crucial legal and ethical analysis keeps apace with medical developments [A].

Taken as a whole, the research sought to identify and assess:

- How **critical care decisions** relating to the resuscitation of extremely premature and /or sick neonates might best be made in conformity to key legal and ethical principles.
- How far parents or doctors should be regarded as the **principal decision makers**.
- How **communication between parents and professionals** can be improved, and the risk of legal conflict minimised [B].
- The difficult dilemmas posed in the context of **debates of fetal viability** and late abortions (see point 2, below).

Overall, the research focused upon how far conflict can be minimised and how parents and doctors might effectively work in partnership, whilst ensuring that the practical and 'real life' factors inherent within such human tragedies are fully taken into account. The principal results of the research are:

1. The neonate (unlike the fetus) once 'born alive' does and should enjoy **full legal personality**.
2. The lack of clarity about the legal test of 'born alive' may need **Parliamentary intervention** as the case law is in many cases of great antiquity, and unfit to address the challenges posed by modern medicine.
3. The **legal test of best interests** is in need of further clarification and expansion, and the thorny problems of parental and sibling interests should not be avoided.
4. Decisions about **resuscitation** should be made where possible by parents and doctors together.

5. Decisions about withholding or **withdrawing intensive neonatal care** should be made where possible by parents and doctors together.
6. **Parental views** should carry great weight, as it is the parents who will have to care for the child should s/he survive with significant disabilities.
7. Much greater emphasis should be placed on **communication between professionals and parents** as many conflicts that end up in the courts derive from communication failures.
8. Simple and **accessible guidelines** were needed to assist decision making and these might well be best drawn from professional guidance drafted with substantial lay input.

3. References to the research (all references available upon request - AUR)

[E] has been reprinted several times and continues to be a major reference point for debates on the ethics and law relating to perinatal medicine. [C] is now in its 5th edition (w/ Emma Cave) and is a leading critical text on medical law that embodies Brazier's own original research.

[A] (2006) Nuffield Council on Bioethics 'Critical Care decisions in Fetal and Neonatal Medicine: Ethical Issues' (November) (report chaired and drafted by Brazier) (AUR)
[B] (2005) Brazier, M. "An Intractable Dispute: When Parents and Professionals Disagree" Medical Law Review 13(3) 412-418 doi:10.1093/medlaw/fwi029
[C] (2003) Brazier, M. *Medicine, Patients and the Law* (Third Edition) (London: Penguin) (See: Chapters. 14 & 15) (AUR)
[D] (1999) Brazier, M. "Liberty, Responsibility, Maternity" Current Legal Problems 52(1): 359-391 (AUR)
[E] (1995) Brazier, M. "Government regulations in the UK" in Goldworth, A. & Silverman, W. *et al* (eds.) *Ethics and Perinatology* (Oxford: OUP) (AUR)

4. Details of the impact

Pathway to Impact: The research has resulted in significant developments relating to the care and treatment of extremely premature babies and to an enhanced role for parental decision making. It has been deliberated upon, and adapted through the applied policy recommendations contained within a ground-breaking NCOB report [A]; overseen by Professor Brazier, who was invited to chair the NCOB working party, and co-opted as a member of the council to facilitate communication between the two, a task achieved with *"considerable skill…* [that] *made a significant contribution to other discussions and debates within the council".* As the Director of the NCOB goes on to attest, the invitation was originally offered, in 2004, on the basis of Professor Brazier's *"considerable academic record and experience in chairing other major committees which gave her a knowledge of the wider policy environment"* [1].

Under her leadership the NCOB conducted further multi-disciplinary research. As the (then) Chair of the NCOB confirms, "*Professor Brazier played a key role in the drafting of the Report, and it was her own research which moulded the contents of the Report and the important recommendations made by the Working Party and endorsed by the Council"* [2]. An extensive programme of consultation was initiated, including European debate, which sought the view of parents, professionals and NHS managers. The report played a major role in the amendment and development of professional guidelines and good practice, and was subsequently summarised via an editorial piece in the *Journal of Medical Ethics* [3].

Impact of NCOB Report: As the co-author of the JME piece attests Professor Brazier's role was *"pivotal in the success of the report… a report that integrated a wealth of findings into a coherent and compelling narrative with a set of clear suggestions for policy… its success led to its having a huge influence across the relevant domains of medical practice and policy regulation. No organisation or individual concerned with the matters under review ignores it, and most cite it as a canonical statement of what can be and what ought to be done"* [3]. More specifically, Professor Brazier contributed to the chapter on ethics, and researched and drafted chapter eight on law, as well as supervising the overall production of the final report. Although, as a member of the working party (and former President of BAPM) testifies, whilst Professor Brazier's *"contribution was formally*

in the section on Legal issues, which was one of the cornerstones of the final document… her perceptive inputs to the remainder of the document and her ability to steer a big multidisciplinary group to consensus were most impressive. She was a highly active contributor and challenger throughout the process" [4].

The report resulted in a high level of media interest which promoted vigorous public and professional debate, and kept the subject on the public and professional agenda. Professor Brazier gave a number of public lectures, took part in the BBC radio programmes 'Today' and 'The Moral Maze' and was interviewed by several newspapers, including The Telegraph, and The Independent [5]. More recently, the report featured in the BBC2 documentary '23 Week Babies: The Price of Life' (2010) watched by 2.02 million viewers [1][6].

Within the NCOB report, detailed guidance was offered to assist in the definition of 'best interests', and amongst the **report's main recommendations** were that:

- Guidance should reflect the current medical understanding of the prospects for survival and the incidence of disability for babies born extremely prematurely.
- From 24 weeks gestation the presumption should be that intensive neonatal support should be instituted for the baby.
- From 23-24 weeks precedence should be given to parental wishes.
- From 22-23 weeks intensive neonatal support should not be instituted unless the parents make a fully informed and re-iterated request.
- Below 22 weeks no baby should be resuscitated save with the fully informed consent of both parents and within an approved clinical trial.
- To minimise recourse to traumatic legal proceedings, the parties should have readier access to clinical ethics committees.
- Bioethics mediation, now utilised in parts of the USA, should be introduced in the UK.

Reach and Significance: The NCOB Report is now cited in virtually all accounts and debates relating to the care of extremely premature babies – 176 articles and 10 legal documents since 2006 [2] – and has been downloaded at least 2,212 times (with 23,274 page views) since September 2010 (no download data is available prior to this time) [1][7].

As the NCOB director confirms: "*The British Association of Perinatal Medicine (BAPM) and several other organisations took up the Council's recommendations and worked together to draw up new medical guidance in 2008 on the management of extremely premature babies, closely following the recommendations made in the Council's report"* [1]. This is recognised by BAPM in their palliative care framework:

> *Recent guidance from the Nuffield Council of Bioethics (Nuffield 2006) and the British Association of Perinatal Medicine working group on the clinical care of extremely preterm infants supports the decisions of clinical staff and parents not to resuscitate or institute intensive care when this would not be in the baby's best interests. The Department of Health is developing guidance on end-of-life care for adults but not yet for the fetus, neonate, or infant.* [8]

As the BAPM secretary noted at the time: *"the Nuffield Council for Bioethics advised us to develop an update to our previous document (2001). We were able to discuss the draft with members of the NCoB Working Group in December and are delighted that they were very supportive of the progress and direction of the framework"* (BAPM Newsletter). This led to the BAPM promulgating guidance on 'The Management of Babies Born Extremely Preterm…' in August 2008, which remains in place to this day [8]. As noted, it closely follows NCOB guidance, and thus represents the translation of research into practical impact in neonatal care. Crucially, the BAPM framework mirrors the NCOB timeline and the criteria to be utilised in the assessment of 'best interests'. The former President of BAPM confirms that the NCOB report significantly influenced BAPM, and that the ensuing guidelines have had an impact on practice in neonatal care:

> *"This document remains the reference document in a range of settings and is very*

> *frequently quoted in talks and publications as the benchmark in the field. No lecture on perinatal ethics in this country or abroad fails to refer to it, even if it is just as a starting point. The document formed the basis of the professional document prepared under the aegis of BAPM, RCPCH, RCOG, RCM, and RCN, entitled Management of babies born extremely preterm at less than 26 weeks of gestation: a framework for clinical practice at the time of birth, published in Archives of Disease in Childhood, which is still the mainstay of UK policy today… The document from this working group remains one of the most influential documents in perinatal care since it was published and required reading for all trainees in the area."* [3]

The report has also been considered in detail by the Royal College of Obstetricians and Gynaecologists (RCOG) – with a recognition that the Nuffield *"recommendations have recently been considered and adopted in the development of a professional framework for care"* [9] –and welcomed by the Royal College of Paediatrics and Child Health (RCPCH), who noted that the *"advice is consistent with the current RCPCH framework for 'Withholding or Withdrawing Life Sustaining Treatment' (2004)"* [10].

In conclusion, the NCOB Guidelines draw heavily on Professor Brazier's prior work and her individual and steering contribution to the NCOB report. Furthermore, impacts are clearly on-going as a recent article (2012) in the Telegraph attests; "*with no legal definition of 'viable' when it comes to premature babies"*, an experienced neonatal consultant observes that:

> *"…most decisions he and the unit take are based on guidelines from the Nuffield Council on Bioethics, revised by the British Association of Perinatal Medicine. The guide states that before 22 weeks 'any intervention is experimental', and should only happen within a 'clinical research study that has been assessed and approved by a research ethics committee and with informed parental consent.'"* [5]

The research continues to influence debate, with particular respect to: firstly, criteria that should guide decisions on resuscitation; secondly, how to give more concrete guidance on best interests; and thirdly, how to promote partnership between parents and professionals, noting how communication breakdown could trigger legal conflict.

5. Sources to corroborate the impact (all claims referenced in the text)

[1] Testimonial from Director, Nuffield Council on Bioethics (22nd May 2013)
[2] Testimonial from former Chair, Nuffield Council on Bioethics (7th May 2013)
[3] Testimonial from Member of the NCOB Working Party (17th July 2013) & (2007) Brazier, M. & Archard, D. "Letting Babies Die" *Journal of Medical Ethics* 33(3)
[4] Testimonial from former President, BAPM (20th June 2012)
[5] Press Coverage: (2006) The Telegraph "Ethics body sets limit for baby treatment" (16th November); (2006) The Independent 'The Big Question: Should doctors try to save extremely premature babies?' (16th November); (2012) Daily Telegraph 'Premature birth: the fight for survival' (29th April)
[6] (2010) '23 Weeks: The Price of Life' (aired on BBC2: 9th March 2011)
[7] Webpage – NCOB Media coverage of Report
[8] BAPM Documents: (2010) 'Palliative Care (Supportive and End of Life Care) A Framework for Clinical Practice in Perinatal Medicine: Report of the Working Group' (August); (2008) BAPM News 19 (April); (2008) 'The Management of Babies Born Extremely Preterm at Less than 26 Weeks of Gestation: A Framework for Clinical Practice at the time of Birth (August)
[9] (2010) ROCG 'Termination of Pregnancy for Fetal Abnormality in England, Scotland and Wales' (May) p.6
[10] (2006) RCPCH 'Response to the Nuffield Council on Bioethics proposed guidelines on treating premature babies' (15th November)