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Decision-making about child participation in medical research: a relational approach

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This paper explores the literature on understanding and interpreting parents' motivations for the participation of their child in medical research. The paper analyses how and to what extent ethics of care theory can enhance how we both understand and interpret parents' motivations for research participation. Analysis is focused on the level of attention that needs to be given to a child in the context of his or her caring relationships and the responsibilities that arise within these relationships. This paper seeks to illustrate how it is necessary to move away from an individualistic approach to decision-making to one that refocuses our attention on the web of relationships within which a child is usually placed.

Sufficient acknowledgement and appropriate treatment of the complex interests and responsibility in caring relationships is crucial to determining the suitability of decision-making about child participation in medical research. If care ethics provides an improved understanding and interpretation of parents' motivations for research participation, then it is necessary to consider the extent to which this improved understanding and interpretation of parents' motivations based on care theory can usefully inform principles that underpin existing ethical and legal frameworks for decision-making.

Introduction

Decision-making frameworks that regulate child participation in medical research should strike an appropriate balance between protecting research participants and facilitating sound research.¹ There is increasing focus on a complex debate about children's rights to self-determination and empowerment, focussing largely on issues

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¹ Current ethical and legal frameworks restate principles found in the Nuremberg Code and the 1954 World Medical Association (hereafter 'WMA') Declaration of Helsinki (most recently revised in October 2013). Professional bodies in the United Kingdom (hereafter 'UK') have issued guidance on good practice in research: the Royal College of Paediatrics and Child Health guidance, 'Ethics Advisory Committee guidelines for the ethical conduct of medical research involving children', (2000) 82 *Archives of Disease in Childhood* 177; General Medical Council guidance, for example, GMC (2010), *Good practice in research and consent to research*, and GMC (2007), *0-18 years: guidance for all doctors*; Medical Research Council guidance, for example, MRC (2004), *MRC ethics guide: medical research involving children*. Reference to a 'child' is someone aged 0-18 years.

of procedure and informed consent,² with inadequate attention being given to the more substantive issue of how decisions about research participation are made and the role of parents as decision-makers for their children's participation in the 'activity' of medical research.³ The rights of children and their families continue to demand protection and safeguarding, as one must always remain vigilant of conflicting interests and the pressure of commercial gain in the realm of research. In maintaining vigilance about what is being asked of parents, it is crucial to improve our understanding and interpretation of parents' motivations for the participation of their child in medical research.

There are "two long-standing issues of ethical concern"⁴ that are described as "inherent"⁵ to medical research practice: the first issue being "the tension between the welfare of the individual and the welfare of the group",⁶ and the second issue being "the constantly shifting boundaries between acceptable therapy and research".⁷ Liaschenko and Underwood conclude that:

More than a century of modern medical research has suggested that the ethical concerns arising from said research may be unresolvable. If that is so, research ethics will not provide a final resolution but, rather, will more likely serve as an ongoing cultural attempt to deal with the problems of research. Keeping aware of the actual practices of clinical research must lead to more than monitoring and refining procedural responses to ensure that clinical research is ethical.⁸

² Further detailed analysis of informed consent, child assent and dissent, and 'Gillick Competence' is beyond the scope of this paper, see *Gillick v West Norfolk and Wisbech AHA* [1986] AC 112; Children Act 1989 s 3(1); Family Law Reform Act 1969 s 8(1), which applies only to therapeutic and diagnostic procedures; D Hunter, and BK Pierscionek, 'Children, Gillick Competency and Consent for Involvement in Research' (2007) 33(11) *Journal of Medical Ethics* 659; E Cave, 'Goodbye Gillick? Identifying and resolving problems with the concept of child (2013) competence' *Legal Studies* 1.

³ C Petrini, 'The Ethics of Paediatric Trials: Questions of Procedure and of Substance' (2013) 81(2) *Medico-Legal Journal* 74; G Williams, 'Children as means and ends in large-scale medical research' (2011) *Bioethics* (online) 1; E Cave, 'Seen but not heard? Children in clinical trials' (2010) 18 *Medical Law Review* 1; Nuffield Council on Bioethics, 'Children, Medicines, and Clinical Trials: Background Paper', Nuffield Council on Bioethics, Workshop: 9 December 2011; B Baylis, and J Downie, 'The limits of altruism and arbitrary age limits' (2006) 3(4) *American Journal of Bioethics* 19; TM Burke, R Abramovitch, and S Zlotkin, 'Children's Understanding of the Risks and Benefits Associated with Research' (2005) 31(12) *Journal of Medical Ethics* 715; T John, T Hope, J Savulescu, A Stein, AJ Pollard, 'Children's consent and paediatric research: is it appropriate for healthy children to be the decision-makers in clinical research?' (2008) 93 *Archives of Disease in Childhood* 379; I Singh, 'Capacity and competence in children as research participants' (2007) 8 *European Molecular Biology Association reports* (special issue) S35; L Hagger, *The Child As Vulnerable Patient: Protection and Empowerment*, (Ashgate, 2009), Chapter 7 'Children in Research', pp 175-211.

⁴ J Liaschenko, and SM Underwood, 'Children in Research: Fathers in Cancer Research – Meanings and Reasons for Participation' (2001) 7(1) *Journal of Family Nursing* 71, at 72. RB Levi, R Marsick, D Drotar, E Kodish, 'Diagnosis, Disclosure, and Informed Consent: Learning from Parents of Children with Cancer' (2000) 22(1) *Journal of Pediatric Hematology/Oncology* 3.

⁵ *Ibid.*, at p 71.

⁶ *Ibid.*

⁷ *Ibid.*

⁸ *Ibid.*, at p 88.

There is limited data available that documents how parents experience the research process.⁹ And much of the literature that does consider research participation focuses on informed consent, rather than shedding any ‘new’ light on parental understanding and attitudes towards research.¹⁰ The few studies that have been done so far illustrate important findings about parents’ motivations for research participation and their ‘journey’ of decision-making at a time when they “feel significant responsibility to act in the best interests of their children”.¹¹

Empirical evidence about the context in which decisions about child participation in medical research are made, particularly decisions about research that have the potential to benefit a child directly, will be case specific, or rather medical condition or illness specific. Fisher, McKevitt, and Boaz have explored the experiences of parents, living in different countries, whose children suffered from a range of medical conditions, which varied in severity.¹² I will analyse some of the studies in Fisher, McKevitt, and Boaz’s paper to illustrate that calls for a broader approach “to gather the complexity” of the situation are justified, and that this broader approach “should examine needs, emotions, thoughts and fears of children and their families considering participation or participating already”.¹³ Thus, a broader approach is needed to better appreciate the complexity of the decision-making process and how it is necessary to improve our understanding and interpretation of parents’ motivations regarding child participation in medical research.

A. Empirical studies: the complexity of decision-making

I will now analyse empirical evidence on the decision-making ‘journey’ that parents and their children follow to trace important findings about parents’ motivations for research participation. Evidence from the empirical studies suggests that care ethics is reflective of how families and children actually make decisions. Meanings of care have been explored through an analysis of its economic character in different domains of life and its ethical implications for rights-based discourses.¹⁴ It has been analysed that “care invokes a host of cluster concepts” and these include obligation,

⁹ BJ Stenson, J-C Becher, N McIntosh, ‘Neonatal research: the parental perspective’ (2004) 89 *Archives of Disease in Childhood Fetal and Neonatal Edition* F321; KS Hoehn, et al. ‘What factors are important to parents making decisions about neonatal research?’ (2005) 90 *Archives of Disease in Childhood Fetal and Neonatal Edition* F267; CJ Morley, et al. ‘What do parents think about enrolling their premature babies in several research studies?’ (2005) 90 *Archives of Disease in Childhood Fetal and Neonatal Edition* F225.

¹⁰ H Chappuy, et al. ‘Parental Consent in paediatric clinical research’ (2006) 91 *Archives of Disease in Childhood* 112.

¹¹ HR Fisher, C McKevitt, and A Boaz, ‘Why do parents enroll their children in research: a narrative synthesis’ (2011) 37 *Journal of Medical Ethics* 544, at p 550.

¹² *Ibid*, at p 544.

¹³ F Wulf, M Krasuka, and M Bullinger, ‘Determinants of decision-making and patient participation in paediatric clinical trials: A literature review’ (2012) 2 *Open Journal of Pediatrics* 1, at p 7. M Glogowska, S Roulstone, P Enderby, T Peters, and R Campbell, ‘Who’s afraid of the randomized controlled trial? Parents’ views of an SLT research study’ (2001) 36 *International Journal of Language and Communication Disorders* 499, at p 500.

¹⁴ C Hughes, *Key Concepts in Feminist Theory and Research* (Sage Publications, 2002), at p 8.

dependency, responsibility, friendship, duty, reciprocity and trust.¹⁵ Speculation about decision-making for child participation in medical research has triggered discussion about the following:

1. 'positive obligations';
2. dependency in terms of the wider community of children depending on individual children to participate in research;
3. responsibilities in terms of, (i) the responsibilities of physicians, (ii) the responsibility of children and their families to one another in their caring relationships, and (iii) the responsibility of the child and their family as a unit with respect to their assessment of risk and benefit informing their decision to participate in research or not because their decision will impact the wider community of children;
4. the duty of physicians to child patients and their families; and,
5. the trust that children and their families place in physicians when making any decision about research participation.

Joan Tronto took note of various criticisms that tend to follow from relying heavily on the concept of care, namely that care is a fluid concept and too vague to be of use in transforming values.¹⁶ Tronto highlights that care involves a degree of conflict:¹⁷

Care as a practice involves more than simply good intentions. It requires a deep and thoughtful knowledge of the situation, and of all the actors' situations, needs and competencies. To use the care ethic requires a knowledge of the context of the care process. Those who engage in a care process must make judgements: judgements about needs, conflicting needs, strategies for achieving ends, the responsiveness of care receivers, and so forth... Care rests upon judgements that extend far beyond personal awareness.¹⁸

Tronto's focus on understanding both the nature of care and its place in human life is relevant to understanding decision-making about child participation in medical research. The fact that care must be understood in terms of its ability to invoke a host of cluster concepts, which include obligation, dependency, responsibility, duty, and trust, should be recognised as something positive, a strength of the concept as opposed to a weakness. This complexity reflects the reality of decision-making in difficult situations. Joe Brierly and Vic Larches¹⁹ highlight the issue of family involvement in healthcare decision-making and support the influence of an ethic of care to facilitate decision-making. Brierly and Larches advocate that an ethic of care

¹⁵ Ibid, at pp 118-119; Hughes draws upon the research of Silva and Smart (E Silva, and C Smart, (eds) *The New Family?* (London: Sage, 1999)), and Finch and Mason (J Finch, and J Mason, *Negotiating Family Responsibilities*, (London: Routledge, 1993).

¹⁶ O Flanagan, and J Adler, 'Impartiality and Particularity' (1983) 50(3) *Social Research* 576; A Rudnick, 'A Meta-Ethical Critique of Care Ethics' (2005) 22(6) *Theoretical Medicine and Bioethics* 505; M Drakopoulou, 'The Ethic of Care, Female Subjectivity and Feminist Legal Scholarship' (2000) 8 *Feminist Legal Studies* 199; S Sevenhuijsen, 'Caring in the third way: the relation between obligation, responsibility and care in *Third Way* discourse' (2000) 20(5) *Critical Social Policy* 5.

¹⁷ J Tronto, *Moral Boundaries: A Political Argument for an Ethic of Care* (Routledge, 1993) at p 102.

¹⁸ Ibid, at pp 136-137.

¹⁹ J Brierley, and V Larcher, 'Cui bono? Can feminist ethics show a path in complex decision-making where 'classical' theories cannot?' (2011) 6 *Clinical Ethics* 86.

has the potential to provide “creative solutions to clinical situations not readily soluble by standard ethical norms”, suggesting that “moral thinking outside the restrictions of more traditional current medical ethics may help ease moral dilemmas and lead to a resolution that recognises and supports the humanity of those involved”.²⁰

The following analysis of empirical studies includes studies conducted both within and outside the UK; studies conducted outside the UK are mainly from the United States (US) and Canada. It should be noted that reference to mothers’ perspectives in my discussion of the empirical studies reflects the focus of the studies and the fact that most studies involved interviews with mothers only.²¹

i. Vaccine research

Paediatric vaccine studies in the UK have been subject to the Medicines for Human Use (Clinical Trials Regulations) 2004 (hereafter ‘CTR 2004’).²² Child participation in clinical research studies is essential for vaccine licensure and public health policy, but little is known about parental decision-making in this context and why parents agree to engage in clinical research studies involving their children.²³ It is hoped that studies about parental decision-making can improve understanding of parental perceptions of the trials process and this could enhance recruitment to and conduct of essential paediatric vaccine research.²⁴

²⁰ Ibid.

²¹ PK Pletsch, and PE Stevens, ‘Children in Research: Informed Consent and Critical Factors Affecting Mothers’ (2001) 7(1) *Journal of Family Nursing* 50.

²² The CTR 2004 implemented the Clinical Trials Directive 2001/20/EC in the UK, and is most significant for research involving medicinal products; Council Regulation (EC) 1901/2006 on medicinal products for paediatric use operates together with the CTR 2004 specifically to promote research on the paediatric population. The New Regulation No 536/2014 of the European Parliament and of the Council on clinical trials on medicinal products for human use, adopted on 16 April 2014, updates the rules on clinical trials and repeals Directive 2001/20/EC: http://ec.europa.eu/health/human-use/clinical-trials/developments/index_en.htm (last accessed 9 April 2015). The Mental Capacity Act 2005 (hereafter ‘MCA 2005’) applies to all ‘intrusive research’, which does not fall within the remit of the CTR 2004 in the UK. The common law must be consulted for cases of medical research that do not qualify as a clinical trial under the CTR 2004, and are not a case of ‘intrusive research’ under the MCA 2005.

²³ TEA Chantler, A Lees, ER Moxon, D Mant, AJ Pollard, R Fitzpatrick, ‘The Role Familiarity With Science and Medicine Plays in Parents’ Decision-Making About Enrolling a Child in Vaccine Research’ (2007) 17 *Qualitative Health Research* 311. Note the controversy surrounding the MMR (measles, mumps and rubella) vaccine triggered by Andrew Wakefield’s paper in the *Lancet*; Wakefield was not advising against vaccination completely, but was advising that single vaccinations be given. More recent developments have been in the form of government concession in the US Vaccine Court and a published study that verifies the research of Wakefield’s and others on the link between the MMR vaccine and autism: <http://healthimpactnews.com/2013/new-published-study-verifies-andrew-wakefields-research-on-autism-again/> (last accessed 9 April 2015).

²⁴ TEA Chantler, A Lees, ER Moxon, D Mant, AJ Pollard, R Fitzpatrick, ‘The Role Familiarity With Science and Medicine Plays in Parents’ Decision-Making About Enrolling a Child in Vaccine Research’ (2007) 17 *Qualitative Health Research* 311, at p 311.

The data analysis in one study, in which parents were interviewed about their decision for or against enrolling their child in a vaccine study, suggests that the ability of parents to evaluate a vaccine study depends on “how attuned they are with science and medicine, either professionally or as consumers of health services”,²⁵ and that this familiarity is “a predictor of parents’ confidence in their decision-making”.²⁶ Altruism and trust was found to motivate many parents, but concern is raised that if this altruism and trust is “uninformed”²⁷ parents can be prone to exploitation, and so it is crucial to ensure that parents are confident about both their judgement of a particular study and the potential benefit to their child and society.²⁸

The vaccine research paper looks at a preschool booster study (recruiting children aged 3-3.5 years to the trial), which involved two home visits, and a meningitis vaccine study (recruiting infants aged 1 year), which involved three home visits.²⁹ Interviewees of the vaccine study expressed the view that it was important to continue medical advancement for the benefit of society, however they believed that children should take part in research only where the medical benefits are considered to outweigh any potential risks.³⁰ It is noted that, in taking very seriously their responsibility of deciding on behalf of their child, parents would evaluate the risks and benefits to ensure that “the advantages both for the child and for other children outweighed any disadvantages”.³¹ Thus, child *and* children were factored into the parental decision-making process, whilst acknowledging that they, the parents, are making a decision on the behalf of their child.

The vaccine research study found a combination of reasons cited by parents willing for their child to participate in a vaccine study, however altruism was found to be the most quoted reason for participation.³² It was found that “[p]arents wanted to contribute to medical advancement and, specifically, to help children. Participation was viewed as a social responsibility by some parents, particularly if they or their family had benefited from medicine advancement”.³³ Some parents also appealed to their professional background in the field of medicine or research and how this encouraged their participation, as “they were interested or felt a sense of professional responsibility to take part”.³⁴ Parents’ willingness to take part, in some cases, also depended on the importance they attributed to the study. So, for example, some parents considered that the aim of reducing the pain of post-vaccination reactions was

²⁵ Ibid.

²⁶ Ibid.

²⁷ Ibid.

²⁸ Ibid.

²⁹ More details about the vaccine studies at pp 313-314.

³⁰ TEA Chantler, A Lees, ER Moxon, D Mant, AJ Pollard, R Fitzpatrick, ‘The Role Familiarity With Science and Medicine Plays in Parents’ Decision-Making About Enrolling a Child in Vaccine Research’ (2007) 17 *Qualitative Health Research* 311, at p 315.

³¹ Ibid.

³² Ibid.

³³ Ibid.

³⁴ Ibid.

not worth their child having to undergo a potentially painful blood test, whereas other parents considered anything that helped develop new vaccines was worthwhile.³⁵

Parents who were positive about research participation demanded reassurance that the study would not have a detrimental effect on their child. This assessment of detriment took the form of two main issues being considered by parents: their child's suitability to the study and the safety of the study. Conclusions reached from this vaccine research study focussed on the fact that there is "insufficient understanding of the nature and origins of such altruistic behaviour on the part of participants in health research" and that there "is enormous scope for further improvements in the health of children from public health research but only if we can learn how to work appropriately with the altruism and trust of parents".³⁶

ii. Clinical trials of emerging therapies for diabetes³⁷

Results from a study in the US analysing decision-making for involvement in clinical research of mothers of diabetic children, suggests that "mothers engage in a personal calculus"³⁸ before making their decision. In maintaining treatment of children living with diabetes, diabetic children and their parents are regularly approached by clinical researchers for clinical trials of emerging therapies.³⁹ Mothers' perspectives were the focus of the report. Mothers were considered "advocates for their children"⁴⁰ and the experiences of mothers of children with diabetes were considered to be "sufficiently distinct to merit separate analysis"⁴¹ from other illness populations that participated in a larger study.⁴² The research questions that guided the analysis of this study were: (1) How do mothers of children with diabetes make decisions about giving consent for their children to participate in research? (2) What motivates mothers to keep their children in research once they are enrolled? (3) How do mothers evaluate the clinical studies their children have participated in?⁴³ The important context of this study is the nature of childhood diabetes, with the most common type in the paediatric population

³⁵ Ibid, at p 316; further detail is however not provided to confirm what these parents deemed 'worthwhile' and what the parents meant by doing 'anything' to help develop new vaccines.

³⁶ Ibid, at p 321.

³⁷ PK Pletsch, and PE Stevens, 'Inclusion of Children in Clinical Research: Lessons Learned from Mothers of Diabetic Children', (2001) 10 *Clinical Nursing Research* 140.

³⁸ Ibid, at p 140.

³⁹ Ibid. The US federal guidelines mandating inclusion of children in clinical research meant that more and more children would be sought as participants in clinical trials; while the new policy gave researchers the opportunity to conduct more research to help treat children and not have to rely on research conducted exclusively with adults, concerns were raised about how to ethically enrol, retain, and involve children in research, and it became necessary to investigate such concerns in order to "arrive at a just and adequate research practice that includes children": PK Pletsch, and PE Stevens, 'Inclusion of Children in Clinical Research: Lessons Learned from Mothers of Diabetic Children', (2001) 10 *Clinical Nursing Research* 140, at p 141.

⁴⁰ PK Pletsch, and PE Stevens, 'Inclusion of Children in Clinical Research: Lessons Learned from Mothers of Diabetic Children', (2001) 10 *Clinical Nursing Research* 140, at p 141.

⁴¹ Ibid.

⁴² Ibid; the larger study involved children from four illness populations, diabetes, sickle-cell anemia, oncology, and bone marrow transplant.

⁴³ Ibid.

being insulin-dependent diabetes mellitus (IDDM), so treatment is complex and demanding.⁴⁴ Diabetes in children is described as “a chronic illness that intimately affects the everyday life of the family”.⁴⁵

It was found that, “personal calculus in making research participation choices”⁴⁶ involved a careful calculation of potential consequences for their children, before consenting or declining to participate, focussing on three main ‘calculations’: firstly, judging whether their child’s well-being was likely to suffer disruption, in the form of disturbing the daily metabolic control and stability that had already been achieved; secondly, an analysis of personal benefits that their child could potentially receive through involvement in a clinical study; and thirdly, weighing the opportunities of research participation against the risks that their children might incur.⁴⁷ The reasonableness of participation was measured against any disruption to child *and* family.⁴⁸

In evaluating satisfaction with their children’s research experience, it was found that the issue of benefit was “pivotal to their satisfaction”,⁴⁹ but one key difference was found before and after the study:

Before their child started a study, mothers were focussed on whether study participation would make daily illness-related behaviours easier, more convenient, or less painful. After their child had finished a study, mothers had a wider view of personal benefit, both expected and unexpected, and they recognised social benefit as well. It was as though mothers’ perspectives on benefit broadened through experience over time in the research.⁵⁰

Unanticipated personal benefits included “increased time and connection with health care providers”,⁵¹ “improvement in children’s self-care skills”,⁵² and, perhaps most important of all, “[c]hanges in a child’s self-concept or attitude toward the illness”⁵³ with one mother stating that: “The study built up my kid’s self-esteem. ...If there is something out there, some other study that can get rid of it for him or make it easier for him, he will go for it now”.⁵⁴ Some mothers however, did not have a positive experience of research participation, and were dissatisfied with the personal benefits, instilling caution about affiliation in future studies as opposed to having the effect of

⁴⁴ Ibid, at p 142.

⁴⁵ Ibid.

⁴⁶ Ibid, at p 146.

⁴⁷ Ibid. Recruitment for the clinical studies was usually initiated at clinic visits or educational programs.

⁴⁸ This study also discusses monetary recompense; note the system of health insurance in the US, with families often possessing different levels of health insurance, and how a balancing of opportunity against potential risk is likely to include this factor, as compared to the UK. Further discussion about offering incentives for research participation is beyond the scope of this paper.

⁴⁹ PK Pletsch, and PE Stevens, ‘Inclusion of Children in Clinical Research: Lessons Learned from Mothers of Diabetic Children’, (2001) 10 *Clinical Nursing Research* 140, at p 154.

⁵⁰ Ibid, at pp 154-155.

⁵¹ Ibid, at p 155.

⁵² Ibid.

⁵³ Ibid.

⁵⁴ Ibid, at pp 155-156.

facilitating openness to future studies.⁵⁵ This was primarily because the mothers did not feel that the health and well-being of their child was the primary concern. But one mother admitted that: “Maybe it was naive on my part to think the drug company doing the research would have the children’s best interests at heart”.⁵⁶

Researchers described a finding about the notion of ‘social benefit’ in the following way: “If personal benefit from being in a study was secured, social benefit took on meaning”.⁵⁷ One mother made a distinction between help “on the small scope” to her daughter, and help “on the larger scope” to others, stating that “it would be nice to help everyone who had to deal with diabetes”.⁵⁸ In fact, it was found that most mothers found it “gratifying” to be participating in research, to engage in the effort to “find answers” and to “move forward” to improve treatment for not just their own child, but for *all* diabetic children.⁵⁹ Interviews with parents and families “revealed a solidarity with other families who knew what it was like to live with diabetes, and an obligation to contribute to advancing knowledge of diabetes and diabetes management”.⁶⁰ Parents described their child’s participation in the research as “helping out”, “to help the diabetes effort”, and transferred this intention to their children, with one mother stating that: “It was neat for my son to know that he was part of something. Yes, he has this disease, but he was in something bigger, something positive that was trying to make things a little easier for kids and parents”.⁶¹

It is noted that, missing from this particular study and analysis, is information about those mothers who were unwilling to consent to their diabetic child’s participation in clinical research.⁶² More knowledge about ‘non-consenting’ is likely to provide useful information about the process of decision-making that some parents go through, and to what extent they adopt both an individualistic and relational perspective to child participation in research before refusing consent.

iii. Childhood cancer clinical trials

In a study that looked at the meaning and experience of clinical trial participation for Canadian parents of children with cancer,⁶³ and the conditions and feelings that influenced their decisions, a key theme identified was “helping future families of

⁵⁵ Ibid, at p 156.

⁵⁶ Ibid.

⁵⁷ Ibid.

⁵⁸ Ibid.

⁵⁹ Ibid, at pp 156-157.

⁶⁰ Ibid, at p 157.

⁶¹ Ibid.

⁶² Ibid, at p 158.

⁶³ RL Woodgate, and RA Yanofsky, ‘Parents’ Experiences in Decision-Making with Childhood Cancer Clinical Trials’, (2010) 33(1) *Cancer Nursing* 11. JA Deatrick, DB Angst, and C Moore, ‘Parents’ views of their Children’s Participation in Phase I Oncology Clinical Trials’, (2002) 19 *Journal of Pediatric Oncology Nursing* 114; R Schaffer, et al., ‘Parents’ Online Portrayals of Pediatric Treatment and Research Options’, (2009) 4(3) *Journal of Empirical Research of Human Research Ethics* 73.

children with cancer”.⁶⁴ Being informed of past successes did not necessarily trigger this approach, but rather, parents were “genuinely concerned” about helping future families of children diagnosed with cancer, with one mother stating:

It is relevant to society. It is relevant to future care analysis, of individuals which is why I did want to be a part of it. It is relevant to me as a parent who can prevent some other child getting care that they don't need, or get better care than they could have gotten because my child took part in the trial.⁶⁵

It is useful to learn from this study, through the language adopted, that parents did in fact consider themselves now part of “a unique community”,⁶⁶ or “part of the chain of people”,⁶⁷ and whilst this ‘membership’ encouraged those who consented to participation, it resulted in much guilt for those parents who declined participation.⁶⁸ Thus, to participate or not to participate is a secondary thought in some respect, since parents who declined also accepted membership of a ‘community’ through their feelings of guilt.

It was concluded that the analysis in this study confirmed “the childhood cancer experience is a relational process shaped by evolving intrapersonal, interpersonal, and transpersonal relationships and communication”,⁶⁹ with parents’ suffering made “more bearable”⁷⁰ because of meaningful relationships that parents had with, not only their own children, but other families of children with cancer, with healthcare team members also providing crucial support.⁷¹ Parents were found to associate making the “right” decision with being a “good” parent.⁷² In light of these findings, and “the emphasis parents placed on the relational aspect of their experiences”, conclusions in this study include the importance of “[u]nderstanding the processes that link human relationships and the relief of suffering in the context of childhood cancer trials”.⁷³

⁶⁴ RL Woodgate, and RA Yanofsky, ‘Parents’ Experiences in Decision-Making with Childhood Cancer Clinical Trials’, (2010) 33(1) *Cancer Nursing* 11; this was one of six themes that emerged from the data analysis, with the other five themes being, “living a surreal event”, “wanting the best for my child”, “coming to terms with my decision”, “making one difficult decision among many”, and “experiencing a sense of trust”.

⁶⁵ RL Woodgate, and RA Yanofsky, ‘Parents’ Experiences in Decision-Making with Childhood Cancer Clinical Trials’, (2010) 33(1) *Cancer Nursing* 11, at p 14.

⁶⁶ *Ibid*, at p 15.

⁶⁷ *Ibid*.

⁶⁸ *Ibid*.

⁶⁹ *Ibid*, at p 16.

⁷⁰ *Ibid*.

⁷¹ *Ibid*.

⁷² *Ibid*. Other studies focusing on end-of-life decision-making and enrolment in clinical trials have considered this notion of a “good” parent: P Hinds, et al., ‘End-of-life care preferences of pediatric patients with cancer’, (2005) 23(36) *Journal of Clinical Oncology* 9146; JR Kane, MB Hellsten, A Coldsmith, ‘Human suffering: the need for relationship-based research in pediatric end-of-life care’, (2004) 21(3) *Journal of Pediatric Oncology Nursing* 180. Also, one study revealed that it was important for parents of dying children to know that they had been “good” parents: RL Woodgate, ‘Living in a world without closure: reality for parents who have experienced the death of a child’, (2006) 22(2) *Journal of Palliative Care* 75.

⁷³ RL Woodgate, and RA Yanofsky, ‘Parents’ Experiences in Decision-Making with Childhood Cancer Clinical Trials’, (2010) 33(1) *Cancer Nursing* 11, at p 17.

iv. Neonatal clinical trials

Neonatology is a relatively young discipline and many aspects of care are yet to be investigated. Parents of sick newborn babies are often approached to consider the enrolment of their child into clinical trials.⁷⁴ One particular exploratory study aimed to help address the gap in the literature about the understanding of parents and the process by which they make decisions to enrol their child into trials, exploring the thoughts and feelings of parents in either choosing or declining to participate in neonatal clinical trials.⁷⁵ The study focused particularly on the fact that “there is a dearth of information... as to why some parents decline to participate”,⁷⁶ with more information available about ‘consenting parents’ who often express altruistic views⁷⁷ as the reason for enrolling their infants into research, or consider it a moral obligation to the Neonatal Intensive Care Unit (NICU) and society.⁷⁸

The exploratory study found that parents make their decision “following a typical journey”:⁷⁹ first, parents must overcome the initial shock of having their baby admitted to the NICU, and then parents weigh up the risks and benefits of the trial against the need to protect their baby from perceived harm.⁸⁰ During this study, the NICU was involved in three “non-urgent clinical trials”: a ventilation trial comparing two modes of CPAP ventilation, a blood transfusion trial that was comparing a single infusion to a divided dose twenty-four hours apart, and an immunoglobulin trial comparing this with a placebo.⁸¹ It was found that parents who chose to participate believed that there was no harm to their baby and these parents display altruistic principles stating that they were pleased to be helping future babies.⁸² I think it should however be noted that the altruistic views and “feel good factor” came into ‘the journey’ after harms and benefits had been assessed by these parents and after the parents initial views of confusion and shock about being approached to consider trial participation at such an emotional time. Parents were found to experience “a gradual acceptance of the situation”⁸³ within a few days, during which time they began to

⁷⁴ S Jollye, ‘An exploratory study to determine how parents decide whether to enrol their infants into neonatal clinical trials’, (2009) 15 *Journal of Neonatal Nursing* 18. In N Singhal, K Oberle, E Burgess, J Huber-Okrainec, ‘Parents’ perceptions of research with newborns’, (2002) 22(1) *Journal of Perinatology* 57, it is specifically argued that there is a gap in literature investigating parental attitudes to neonatal research.

⁷⁵ S Jollye, ‘An exploratory study to determine how parents decide whether to enrol their infants into neonatal clinical trials’, (2009) 15 *Journal of Neonatal Nursing* 18, at p 19.

⁷⁶ *Ibid.*

⁷⁷ *Ibid.* KS Hoehn, et al., ‘What factors are important to parents making decisions about neonatal research?’ (2005) 90 *Archives of Disease in Childhood Fetal and Neonatal Edition* F267; A Gammelgaard, et al., ‘Perceptions of parents on the participation of their infants in clinical research’, (2006) 91 *Archives of Disease in Childhood* 977.

⁷⁸ S Jollye, ‘An exploratory study to determine how parents decide whether to enrol their infants into neonatal clinical trials’, (2009) 15 *Journal of Neonatal Nursing* 18, at 19. SA Mason, and PF Allmark, for the EURICON study, ‘Obtaining informed consent to neonatal randomized controlled trials: interviews with parents and clinicians in the EURICON study’, (2000) 356 *Lancet* 2045.

⁷⁹ S Jollye, ‘An exploratory study to determine how parents decide whether to enrol their infants into neonatal clinical trials’, (2009) 15 *Journal of Neonatal Nursing* 18, at p 19.

⁸⁰ *Ibid.*

⁸¹ *Ibid.*

⁸² *Ibid.*, at p 18.

⁸³ *Ibid.*, at p 20.

form relationships with staff and this empowered parents to ask more questions about clinical trial participation. Some parents interpreted ‘research’ as alluding to the possibility that things can “go wrong”,⁸⁴ whilst others expressed uncertainty about follow-up once the trial was completed and whether their child would get “checked up”.⁸⁵ But upon clarification about their baby’s situation and grasping the concept of the clinical trial, parents began to weigh up the risks and benefits to their baby.⁸⁶

The study found that those parents who gave their consent to research “developed”⁸⁷ an altruistic view by seeing themselves as helping babies in the future.⁸⁸ The parents acknowledged those “previous parents” who had been involved in research that had resulted in help to their baby and expressed a desire “to show their appreciation by helping future babies”.⁸⁹ Parents were “upon reflection”⁹⁰ pleased to have participated in the research.⁹¹ When some parents were asked if they would want to be involved in more trials, many parents opined that “they would be happy providing they saw a benefit to the trial and there was no perceived harm to their child”. This approach to decision-making would suggest that first in their assessment of whether to consent to their child participating in a research trial they consider the benefit or value of the trial itself before proceeding to assess any potential harms to their child, and so this indicates that parents engage in a form of assessment for the wider community of children of which their child is a member before they assess whether their child will be involved in the trial. It was in fact found that parents who chose to participate in the clinical trial “displayed an overwhelming sense of satisfaction”⁹² and it gave them “a sense of pride and well being”,⁹³ with one parent stating: “If we’ve helped now for something in the future then you’ve done your bit – you know what I mean?”⁹⁴

On the other hand, it was found that parents who declined participation felt that the perceived risks to their baby were too great, and outweighed the benefits.⁹⁵ These parents feared that their baby might endure, in their view, further suffering, and that if their baby’s condition deteriorated then fault would lay with them for making the decision to enrol their baby in the trial.⁹⁶ However, upon reflection, these ‘declining parents’ experienced feelings of guilt at reaching this decision and not participating in

⁸⁴ Ibid.

⁸⁵ Ibid.

⁸⁶ Ibid.

⁸⁷ Ibid, at p 22.

⁸⁸ Ibid.

⁸⁹ Ibid.

⁹⁰ Ibid.

⁹¹ Ibid.

⁹² Ibid.

⁹³ Ibid.

⁹⁴ Ibid, mother in interview G.

⁹⁵ Ibid.

⁹⁶ Ibid. C Snowdon, D Elbourne, J Garcia, ‘Declining enrolment in a clinical trial and injurious misconceptions: is there a flipside to the therapeutic misconception? (2007) 2(4) *Clinical Ethics* 193; C Snowdon, D Elbourne, J Garcia, “‘It was a snap decision’”: parental and professional perspectives on the speed of decisions about participation in perinatal randomized controlled trials’, (2006) 62 *Social Science and Medicine* 2279.

the trial,⁹⁷ expressing an acknowledgement that “they [clinicians and researchers] have to do these things to develop”.⁹⁸ In explanations for declining participation was the feeling among parents that more time to make the decision with prior knowledge about trial participation, before their baby was unwell, is likely to have better prepared parents to make a decision.⁹⁹

It is emphasised in the study that while parents did not feel any pressure to enrol in a trial, they nevertheless “experienced guilt upon reflection for not participating and in hindsight wondered whether they should have participated”.¹⁰⁰ The study concludes that more research is needed to understand why parents experience such guilt.¹⁰¹ While I agree that more research must be undertaken to confirm why parents experience such guilt, the studies suggest that feelings of guilt also indicate that parents engage in a more relational approach to decision-making that incorporates a sense of responsibility to the ‘class’ or wider community of children, and that parents struggle between assessing the value of a study in their own risk-benefit analysis for their own individual child, and the wider community of children of which their child is a member.

Another neonatal clinical trials study¹⁰² draws particular attention to the fact that, in the US, treatment in the NICU is driven more and more by research protocols, and so family perspectives of being involved in neonatal research is being increasingly considered. However, it is found that few investigations have explored family experiences.¹⁰³ Ward opines that “[t]he traditional way for understanding choice about research enrolment, with its moral thrust on informed consent and autonomous decision-making, needs further development”,¹⁰⁴ with only a small number of studies having actually examined parental beliefs about neonatal research.¹⁰⁵ In this particular study, parents who had enrolled their child in a research study that involved greater than minimal risk with prospect of direct benefit to the neonate were asked about their beliefs and experiences with respect to their neonate’s research participation.¹⁰⁶ Ward advocates that “by examining the entire process of their neonate’s research participation rather than focussing on a specific component (for example, validity of

⁹⁷ S Jollye, ‘An exploratory study to determine how parents decide whether to enrol their infants into neonatal clinical trials’, (2009) 15 *Journal of Neonatal Nursing* 18, at p 22.

⁹⁸ Ibid.

⁹⁹ Ibid.

¹⁰⁰ Ibid.

¹⁰¹ Ibid. BJ Stenson, JC Becher, N McIntosh, ‘Neonatal research: the parental perspective’, (2004) 89 *Archives of Disease in Childhood* F321; SA Mason, PJ Allmark, ‘Obtaining informed consent to neonatal randomised controlled trials: interviews with parents and clinicians in the EURICON study’, (2000) 356 *Lancet* 2045; C Snowdon, J Garcia, D Elbourne, ‘Making sense of randomisation: responses of parents of critically ill babies to random allocation of treatment in a clinical trial’, (1997) 45 *Social Science and Medicine* 1337.

¹⁰² FR Ward, ‘Chaos, vulnerability and control: parental beliefs about neonatal clinical trials’, (2009) 29 *Journal of Perinatology* 156.

¹⁰³ Ibid, at p 156.

¹⁰⁴ Ibid.

¹⁰⁵ Ibid.

¹⁰⁶ Ibid, at pp 156-157.

parental permission or understanding of randomisation), a more nuanced and comprehensive view of parental perception was obtained”.¹⁰⁷

Ward’s analysis found that particular themes surrounding research participation emerged, and chose to organise these in the following three categories: chaos, vulnerability, and control.¹⁰⁸ “Chaos”¹⁰⁹ broadly reflects the feelings of fear and confusion experienced by many parents at the time of making the decision about neonatal research participation.¹¹⁰ “Vulnerability”¹¹¹ covers parents express perceptions of their own vulnerability,¹¹² filtering into the issue of risk-benefit analysis and parents speaking about how important it is to weigh the risks and benefits of the research.¹¹³ Parents felt that the responsibility to make a decision about research participation was “a parental duty”,¹¹⁴ despite many finding it very difficult, with parents expressing fears of making the wrong decision about neonatal research involvement.¹¹⁵ “Situational vulnerability” is a term used by Ward, stating that “[s]ituational vulnerability for parents resulted from the circumstances of their child’s critical illness”, with parents feeling “vulnerable because of the unfamiliar and frightening conditions in which they found themselves”, and part of this vulnerability mentioned by some parents “was their roles as parents in the NICU”.¹¹⁶ The third theme of “control”¹¹⁷ that emerged from the data reflects the control over decision-making, and so reflects parents’ understanding of their right to permit or decline the enrolment of their child in research.¹¹⁸ It was confirmed in this study that knowledge of potential risks and benefits of research participation is “not only a requirement of ethical research, but also a necessity for parents’ satisfaction in the process of decision-making”.¹¹⁹

Ward applies care ethics to decision-making frameworks that regulate child participation in medical research by including the work of Carol Gilligan in her analysis, albeit to compare it to a different theoretical framework of naturalistic decision-making (NDM).¹²⁰ Ward considers that parents’ descriptions of enrolling their neonates in research are consistent with the theoretical framework of naturalistic decision-making, according to which decisions are influenced by personal

¹⁰⁷ Ibid; in this study the following were excluded: families who were unable to speak or understand English, and families whose neonate had not been discharged home or had died.

¹⁰⁸ FR Ward, ‘Chaos, vulnerability and control: parental beliefs about neonatal clinical trials’, (2009) 29 *Journal of Perinatology* 156, at p 157.

¹⁰⁹ Ibid.

¹¹⁰ Ibid, at pp 157-158.

¹¹¹ Ibid, at p 158.

¹¹² Ibid.

¹¹³ Ibid, at p 159.

¹¹⁴ Ibid.

¹¹⁵ Ibid.

¹¹⁶ Ibid.

¹¹⁷ Ibid.

¹¹⁸ Ibid.

¹¹⁹ Ibid, at p 160.

¹²⁰ Relevant works include C Gilligan, *In a Different Voice* (Harvard University Press, 1982); *In a Different Voice – Psychological Theory and Women’s Development* (Harvard University Press, 1993). I will analyse care ethics in more detail in the following section of this paper.

circumstances and are made in changing contexts.¹²¹ Ward opines that parental decision-making to enrol their neonates in research trials “typify NDM” because the decisions are distinguished by various complexities that are characteristic of decision-making in actual real world situations, such as time pressure, uncertainty, and the high personal stakes at play.¹²² Ward compares naturalistic decision-making to the work of Gilligan, stating that emphasis is needed on how “moral decisions are made by individuals within an intricate network of interdependent relationships”, and that “[c]ontext and responsibility to specific others are crucial to decision-making”.¹²³ Ward notes that it has been demonstrated by decision-making researchers that “decisions based on emotion, affective features and hypervigilance, which are contextual elements present when parents are making decisions about clinical research, are not necessarily dysfunctional”.¹²⁴

v. Concluding observations

The empirical evidence reflects a necessity to focus on the ‘experience’ of the child and family in the context of their caring relationships, and the responsibilities that flow from these relationships. It is also necessary to consider the connection and sense of responsibility found with *other* children and the families of other children. Therefore, the empirical evidence confirms that some distinction should be made between (i) clinical research on children with life threatening conditions, such as cancer, (ii) clinical research on children who have chronic illnesses that pose no

¹²¹ FR Ward, ‘Chaos, vulnerability and control: parental beliefs about neonatal clinical trials’, (2009) 29 *Journal of Perinatology* 156, at 160; J Noone, ‘Concept analysis of decision-making’, (2002) 37(3) *Nursing Forum* 21.

¹²² FR Ward, ‘Chaos, vulnerability and control: parental beliefs about neonatal clinical trials’, (2009) 29 *Journal of Perinatology* 156, at 160; R Lipshitz, G Klein, J Orasanu, E Salas, ‘Focus article: taking stock of naturalistic decision-making’, (2001) 14 *Journal of Behavioral Decision Making* 331; R Lipshitz, ‘Converging themes in the study of decision making in realistic settings’, in GA Klein, J Orasanu, R Calderwood, C Zsombok, (eds) *Decision Making in Action: Models and Methods*, (Ablex Publishing: Norwood, NJ, 1993), pp 103-137.

¹²³ FR Ward, ‘Chaos, vulnerability and control: parental beliefs about neonatal clinical trials’, (2009) 29 *Journal of Perinatology* 156, at p 160. E Burgess, N Singhal, H Amin, DD McMillan, H Devrome, ‘Consent for clinical research in the neonatal intensive care unit: a retrospective survey and a prospective study’, (2003) 88 *Archives of Disease in Childhood Fetal and Neonatal Edition* F280, discussion F285-F286; N Singhal, K Oberle, E Burgess, J Huber-Okraïneç, ‘Parents’ perceptions of research with newborns’, (2002) 22(1) *Journal of Perinatology* 57; JA Zupancic, P Gillie, DL Streiner, JL Watts, B Schmidt, ‘Determinants of parental authorization for involvement of newborn infants in clinical trials’, (1997) 99 *Pediatrics* 1.

¹²⁴ FR Ward, ‘Chaos, vulnerability and control: parental beliefs about neonatal clinical trials’, (2009) 29 *Journal of Perinatology* 156, at p 160; for more detail see, for example, TD Wilson, and JW Schooler, ‘Thinking too much – introspection can reduce the quality of preferences and decisions’, (1991) 60 *Journal of Personality and Social Psychology* 181; TD Wilson, DJ Lisle, JW Schooler, SD Hodges, KJ Klaaren, SJ Lafleur, ‘Introspecting about reasons can reduce post-choice satisfaction’, (1993) 19 *Personality and Social Psychology Bulletin* 331; A Bechara, ‘The role of emotion in decision-making: evidence from neurological patients with orbitofrontal damage’, (2004) 55 *Brain Cognition* 30; SC Chuang, ‘Sadder but wiser or happier and smarter? A demonstration of judgment and decision-making’, (2007) 141 *Journal of Psychology* 63; JH Johnston, JE Driskell, E Salas, ‘Vigilant and hypervigilant decision making’, (1997) 82 *Journal of Applied Psychology* 614.

immediate danger of death, and (iii) clinical research on children who are not suffering from any illness.¹²⁵

In looking at the different studies of decision-making about participation in research and clinical trials, the aim that one must in all cases strike an appropriate balance between facilitating research and protecting research participants is clear. What is less clear is how and to what extent we understand and interpret parents' motivations for research participation, which represent a significant factor in striking the appropriate balance. Fisher, McKeivitt and Boaz conclude that a "tailored approach... sensitive to the differing experiences of parents is needed when discussing potential research participation"¹²⁶, and evidence from the empirical studies suggests that care ethics is reflective of how families and children actually make decisions.

B. Understanding and interpreting parents' motivations: ethics of care theory

In striking an appropriate balance between facilitating medical research and protecting research participants, it is necessary to look beyond the 'individual interests' of the individual child participant and consider the interests of those in caring relationships with the individual child participant and the interests of the 'ill community' of which the individual child participant is a member. An appeal to context and the situation or experience of an individual child must take due account of the child in the context of his or her relationships and the responsibilities that can arise within these relationships, with the expectation that this is not likely to be the same for any two children. Thus, sufficient acknowledgement and appropriate treatment of the complex interests and responsibility in caring relationships is crucial to determining the suitability of decision-making about child participation in medical research.

In the next section, I focus on specific principles of research ethics that currently underpin ethical and legal frameworks for decision-making about child participation in medical research. In doing so, I seek to highlight how the application of care ethics can help to develop these principles so that they more accurately reflect the decision-making process for child participants, their parents, and healthcare professionals. My analysis of care theory will follow Robert Leckey's distinction between "relational theory" and communitarianism, and the claim that relational theory can be distinguished "in its commitment to the capacity of individuals".¹²⁷ In challenging allegations that care ethics is merely a form of virtue ethics, I follow Virginia Held's argument; Held argues that a sharp distinction should be drawn between the ethics of

¹²⁵ PE Stevens, and PK Pletsch, 'Ethical issues of informed consent: mothers' experiences enrolling their children in bone marrow transplantation research', (2002) 25(2) *Cancer Nursing* 81, at p 84. PK Pletsch, and PE Stevens, 'Children in Research: Informed Consent and Critical Factors Affecting Mothers', (2001) 7(1) *Journal of Family Nursing* 50, at p 68.

¹²⁶ HR Fisher, C McKeivitt, and A Boaz, 'Why do parents enroll their children in research: a narrative synthesis', (2011) 37 *Journal of Medical Ethics* 544, at p 550.

¹²⁷ R Leckey, *Contextual Subjects*, (Toronto: University of Toronto Press, 2008), at p 10. Further discussion about communitarianism is beyond the scope of this paper.

care and virtue ethics because the ethics of care focuses on relationships, whereas virtue ethics focuses on the individuals' dispositions.¹²⁸

An ethic of care in decision-making about child participation in research

Evidence from empirical studies suggests that a starting point which focuses on interdependent relationships rather than the isolated individual research participant more accurately reflects the decision-making of parents and families for research participation. Evidence of this can be seen in the empirical studies analysed in the previous section of this paper. This starting point and approach focused on interdependent relationships facilitates a necessary shift from the historical motivation of research ethics and law (protection from exploitation and what one minimally owes another human being), to embrace a 'new focus' on what one can positively give another human being¹²⁹ to meet the dependency needs of individuals in networks of relationships and the responsibilities that arise in these relationships.¹³⁰

I have suggested that care ethics provides an improved understanding and interpretation of parents' motivations for research participation. To what extent can this improved understanding and interpretation of parents' motivations based on care theory usefully inform principles that underpin existing ethical and legal frameworks for decision-making?

In examining existing principles of research ethics, it is important to consider the principle of human primacy,¹³¹ which is, that the interests of the individual should prevail over those of science and society. So how can principles of care theory usefully inform the principle of human primacy? Should the principle of human primacy be informed by "the primacy of human interconnectedness"¹³² to focus on the important contribution of families and carers, and the network of relationships that link the wider community of children and their families, which is currently sidelined?

¹²⁸ V Held, *The Ethics of Care: Personal Political and Global* (New York: Oxford University Press, 2006). Cf. TL Beauchamp and JF Childress, *Principles of Biomedical Ethics*, (Oxford University Press, 7th edn, 2013). Further discussion about care ethics and virtue ethics is beyond the scope of this paper; see M Sander-Staudt, 'The Unhappy Marriage of Care Ethics and Virtue Ethics', (2006) 21(4) *Hypatia* 21, and R Halwani, 'Care Ethics and Virtue Ethics', (2003) 18(3) *Hypatia* 161.

¹²⁹ R Graaf, and JJM Deldon, 'A Paradigm Change in Research Ethics', in J Schildmann, et al. (eds) *Human Medical Research*, (Springer Basel, 2012), pp 155-162, especially p 157; I do not concur with Graaf and Deldon's assertion about what one 'owes' to another human being, but find it more appropriate to talk about what one can 'give' to another human being based on an ethic of care that recognises the practice of 'give and take' in networks of relationships.

¹³⁰ Many of the arguments and suggestions I make could also be applied to adults, those over the age of 18, being invited to participate in medical research, but further analysis is beyond the scope of this paper. My discussion continues to focus on those aged 0-18, unless stated otherwise in specific examples or cases cited.

¹³¹ See for example S Simonsen, *Acceptable Risk in Biomedical Research: European Perspectives*, (Springer: 2012), at p 53, and G Helgesson, and S Eriksson, 'Against the principle that the individual shall have priority over science', (2008) 34 *Journal of Medical Ethics* 54, at p 56.

¹³² M Drakopoulou, 'The Ethic of Care, Female Subjectivity and Feminist Legal Scholarship', (2000) 8 *Feminist Legal Studies* 199.

Maria Drakopoulou described Gilligan's work as: "a vision of human relationships and of society grounded upon the primacy of human connectedness, wherein care and compassion are seen as fundamental and where emotions, peaceful co-operation, empathy, friendship and responsibility are aspired to rather than universal, abstract, rational principles (autonomy, freedom, justice, equality and rights)".¹³³ Public health ethics frameworks have also been criticised for being individualistic and thus inadequate, and this has led to calls for a more relational perspective to public health ethics.¹³⁴ Daniel Engster¹³⁵ provides a compelling outlook of how care must expand beyond those closest to us. Engster emphasises that, "our desire for survival and functioning along with our inevitable dependency makes caring for others in need a moral goal written into the very fabric of our existence".¹³⁶ Engster states:

It is only by expanding our caring beyond our circle of family and friends and extending it to all others in need that we ultimately come to recognise our universal human self and experience our interdependency with all other human beings. We then come to know ourselves as dependent creatures who share with all other human beings a common need for the care of other human beings, and discover the morality that lies at the heart of human existence: caring.¹³⁷

Jonathan Herring's analysis of 'caring relationships', can be applied to the situation of research participation, and not just for individual child participants, but also with respect to the wider community of children. Herring's analysis reflects many of the observations noted in the empirical studies above, as he argues:

First, in a caring relationship the interests and identities of the two people become intermingled. Their interests become interdependent. It becomes impossible to consider the welfare or rights of the one in isolation. Hence the focus must be on the relationship, rather than the individuals. Second, the language of 'carers' is generally taken to refer to those who are caring for older people or disabled adults. The unfortunate consequence of this is that it sidelines the many other forms of caring that take place, be that of children, friends or partners. While the appropriate legal response to different caring relationships may vary, it is important to recognise the broader range of care work that takes place. Third, and flowing from the previous point, the language of 'carer' and 'carer for' ignores the fact that we all need care. We are all vulnerable and rely on others to provide for our needs. To divide society up into those providing care and those needing care disguises the vulnerability that we all face. Further, for many people in the course of a relationship they will at some point be regarded as a 'carer' and at another point a 'cared for'; and often both at the same time. To separate the parties in a

¹³³ Ibid.

¹³⁴ NP Kenny, SB Sherwin, and FE Baylis, 'Re-visioning Public Health Ethics: A Relational Perspective', (2010) 101(1) *Canadian Journal of Public Health* 9, and MJ Roberts, and MR Reich, 'Ethical analysis in public health', (2002) 359 *The Lancet* 1055; LM Lee, 'Public Health Ethics Theory: Review and Path to Convergence', (2012) *Journal of Law, Medicine and Ethics* 85.

¹³⁵ D Engster, *The Heart of Justice: Care Ethics and Political Theory* (Oxford Scholarship Online: May 2007).

¹³⁶ Ibid, at p 65.

¹³⁷ Ibid, at p 244.

relationship into carers and recipients of care oversimplifies the complexities of many relationships.¹³⁸

The first and second features of Herring's analysis can inform the particular situation of a child participating in research, and the attention that needs to be given to those in caring relationships with the child in terms of how decision-making about research participation is likely to impact relationships and give rise to responsibilities within those relationships. The third feature of Herring's analysis can take us beyond the particular relationships between child and family or child and carers, to a network of relationships between a child and the wider community of children of which he or she is a member, and in turn, the families and/or carers of other children in the wider community of children. Any assessment of the rights or medical needs of an individual must be made "in a situational context", and never "a matter of assessing a person in isolation".¹³⁹ Thus, it can be argued that the needs and rights of each person should be considered "in the context of their relationships".¹⁴⁰ Herring draws attention to Susan Dodds' argument that an adequate legal and social system must accept human vulnerability and the need for care,¹⁴¹ as Dodds states:

A vulnerability-centred view of the self and of persons is better able to capture many of our moral motivations and intuitions than can be captured by an autonomy-focused approach. We are all vulnerable to the exigencies of our embodied, social and relational existence and, in recognizing this inherent human vulnerability, we can see the ways in which a range of social institutions and structures protect us against some vulnerabilities, while others expose us to risk.¹⁴²

Dodds' analysis can be applied to particular concerns in the context of decision-making about child participation in medical research in terms of justifying the altruism of children to participate in research and how it will be someone else, a parent or carer, who is likely to make this 'altruistic decision' about research participation that will benefit present and future children. Using the language of "human vulnerability" and "risk" and making a connection between them, reflects the practice, or rather, the 'institution', of medical research.

For cases of research that are expected to fall within the MCA 2005, it is useful to note Herring's analysis about individuals who lack capacity under the MCA 2005 and those with whom they are in caring relationships. Herring argues that it is not possible to consider the well-being of an individual who lacks capacity without considering the well-being of those in caring relationships with him or her because their interests are "intertwined".¹⁴³ Herring opines that "it is extremely difficult, if not impossible to

¹³⁸ J Herring, *Caring and the law*, (Hart Publishing, 2013), at pp 4-5. For more discussion on themes of 'vulnerability' and 'care' in the context of family law see J Wallbank, and J Herring, (eds), *Vulnerabilities, Care and Family Law* (Routledge, 2014).

¹³⁹ J Herring, *Caring and the law*, (Hart Publishing, 2013), at p 86.

¹⁴⁰ Ibid.

¹⁴¹ Ibid.

¹⁴² S Dodds, 'Depending on Care: Recognition of Vulnerability and the Social Contribution of Care Provision', (2007) 21 *Bioethics* 500, at p 510, cited in J Herring, *Caring and the law*, (Hart Publishing, 2013), at p 86.

¹⁴³ J Herring, *Caring and the law*, (Hart Publishing, 2013), at p 166.

imagine that a decision which severely harms either the carer or the dependent could be seen as justified in the context of a relationship”.¹⁴⁴ Herring considers how a court must bear in mind the Human Rights Act 1998 (hereafter ‘HRA 1998’) when interpreting the meaning of best interests under the MCA 2005; namely Article 8 of the ECHR, the right to respect for private and family life, which in this context would translate to the right to respect for the private and family life of the person who lacks capacity and their carer.¹⁴⁵ Herring suggests that, although these would not be arguments made from an ethic of care perspective, they “could be used to support a result that would be consistent with it”,¹⁴⁶ presenting the analysis that Article 8 rights¹⁴⁷ of a carer will be engaged if a decision is deemed to severely impact the personal life of the carer.

To justify child participation in clinical trials that are regulated by the CTR 2004, the trial must either relate to a condition from which the minor suffers or must be one which can only be carried out on minors; it is further specified that ‘some direct benefit for the group of patients involved in the clinical trials is to be obtained from that trial’.¹⁴⁸ This requirement that ‘some direct benefit is to be obtained’ makes it very difficult to justify any research on children because clinical trials involve some level of uncertainty about whether the participants will benefit.¹⁴⁹ After all, if the investigator had sufficient evidence to know that the child participants will benefit from taking a new drug, there could be no significant justification for carrying out a clinical trial.¹⁵⁰ In practice this criteria is not interpreted literally, and what seems to be required is that there generally be a realistic possibility that participants may benefit from participation.¹⁵¹ If we reflect on empirical data in the previous section of this paper, regarding how families make decisions about child participation in clinical trials, this provision should be interpreted to take account of *all* relevant interests at play in the decision-making process, thus the interests of the wider community of children of which the individual child participant is a member. It is perhaps arguable that the New Regulation No 536/2014 of the European Parliament and of the Council on clinical trials on medicinal products for human use, which updates the rules on clinical trials, better reflects all relevant interests at play in decision-making about child participation in medical research. One of the conditions that must be met under Regulation No 536/2014 is that,

(g) there are scientific grounds for expecting that participation in the clinical trial will produce:

- (i) a direct benefit for the minor concerned outweighing the risks and burdens involved; or
- (ii) some benefit for the population represented by the minor concerned and such a clinical trial will pose only minimal risk to, and

¹⁴⁴ Ibid, at p 167.

¹⁴⁵ Ibid, at p 166.

¹⁴⁶ Ibid.

¹⁴⁷ Ibid. Under Article 8(2) the interests of a person lacking capacity can only justify interference in the rights of the carer if the interests are deemed sufficiently strong to make the interference necessary and proportionate.

¹⁴⁸ CTR 2004, Sch 1, Pt 4, para 9.

¹⁴⁹ Jackson, E., *Law and the Regulation of Medicines*, (Hart Publishing, 2012), at p 41.

¹⁵⁰ Ibid.

¹⁵¹ Ibid.

will impose minimal burden on, the minor concerned in comparison with the standard treatment of the minor's condition.¹⁵²

To what extent is the insertion of 'population represented' a useful amendment? Does 'population represented' better reflect decision-making about research participation and how decision-making invokes a conception of responsibility for a medical illness or condition? Will this serve to facilitate and support the decision-making process for child participants, their parents, and healthcare professionals?

The standard of 'best interests' will apply to cases of research that will fall within the remit of the common law. In such cases it will be appropriate to consider Jo Bridgeman's assertion that, even if one agrees that decisions about the healthcare of children and treatment for serious conditions are rightly determined by a 'best interests' assessment, "as the central question, it makes a difference whether best interests are determined according to assumptions of individualism, abstraction or according to responsibilities established in relationships".¹⁵³ Bridgeman argues that "[t]he latter requires a different set of questions to be asked to determine the best interests of the child".¹⁵⁴ These "different" sets of questions pertain to: how parents' concerns for the well-being of their children "directs consideration to the needs of the individual child",¹⁵⁵ how the responsibilities of parents arising from the parent-child relationship "directs consideration to the expertise of parents, their knowledge of the child, gained as they care for them",¹⁵⁶ and how medical evidence is only "partial evidence about the best interests of the child",¹⁵⁷ being focussed on medical prognosis and treatment options. Furthermore, the court is required "to confront, and examine, limits to caring",¹⁵⁸ which may involve personal choices, but which may also arise within the context of external factors, in terms of the support and resources available to parents.¹⁵⁹ If one follows Bridgeman's assertion, that 'best interests' are determined according to responsibilities established in relationships, then does decision-making about research participation invoke a conception of responsibility for a medical illness or condition that unites children, families, and physicians? For a physician the responsibility will take shape through their professional responsibility and specialisation. For children and families, will responsibility be acquired through the impact of diagnosis and managing a medical illness or condition? Where the child is not suffering from any illness or condition, and the case is vaccination for example, will the responsibility be triggered upon acquiring knowledge about the risk of disease or illness to child and children if the child is not vaccinated?

¹⁵² Article 32

¹⁵³ J Bridgeman, *Parental Responsibility, Young Children, and Healthcare Law*, (Cambridge University Press, 2007), at p 108; J Bridgeman, 'Accountability, Support or Relationship? Conceptions of Parental Responsibility', (2007) 58(3) *Northern Ireland Legal Quarterly* 307, and J Bridgeman, 'Parental Responsibility, Responsible Parenting and Legal Regulation', pp 233-249, in J Bridgeman, H Keating, C Lind, (eds) *Responsibility, Law and the Family*, (Ashgate, 2008).

¹⁵⁴ J Bridgeman, *Parental Responsibility, Young Children, and Healthcare Law*, (Cambridge University Press, 2007), at p 108.

¹⁵⁵ *Ibid.*

¹⁵⁶ *Ibid.*

¹⁵⁷ *Ibid.*

¹⁵⁸ *Ibid.*

¹⁵⁹ *Ibid.* A Wade, 'Being Responsible: 'Good' Parents and Children's Autonomy', pp 211-229, and, C Lind, 'Conclusion: Regulating for Responsibility in an Age of Complex Families', pp 269-275, in J Bridgeman, H Keating, C Lind, (eds) *Responsibility, Law and the Family*, (Ashgate, 2008).

The discussion and analysis in this paper poses more questions than it answers. But if one accepts that ‘best interests’ are determined according to responsibilities established in relationships, and decision-making about research participation invokes a conception of responsibility for a medical illness or condition, then it is necessary to consider whether this conception of responsibility should be more appropriately reflected in ethical and legal decision-making frameworks to facilitate and support the decision-making process for child participants, their parents, and healthcare professionals.

An analysis of case law reveals that judges, in their application of the best interests test, acknowledge the context in which decisions are made about those who cannot decide for themselves, and how a more relational approach to decision-making is needed, realising an ethic of care. I will now analyse how ‘best interests’ was defined and interpreted in the case of *Simms v Simms and another; A v A and another*.¹⁶⁰ In my analysis of *Simms*, I will consider the cases of *Re T (A Minor) (Wardship: Medical Treatment)*¹⁶¹ and *Re Y (Adult Patient) (Transplant: Bone Marrow)*,¹⁶² which, although cases about medical treatment and not research, inform my understanding of the role of care reasoning in *Simms*. An analysis of these ‘treatment cases’ together with *Simms* will be relevant for any future cases about experimental or innovative treatment as well as any cases of medical research that fall within the remit of the common law.

The court took a relational view of best interests in the case of *Simms*, “whereby the practical attitude and wishes of the incompetent patient’s relatives set the parameters of decision-making concerning their future treatment”.¹⁶³ But what exactly makes the approach to best interests in this case ‘relational’? In *Simms* the court ruled that an experimental treatment would be in the best interests of two patients suffering from probable variant Creutzfeldt-Jacob Disease¹⁶⁴ who were incompetent to consent to any treatment,¹⁶⁵ a male patient aged 18 and a female patient aged 16.¹⁶⁶ There was no guarantee that the treatment would in fact be beneficial, having never been tested on humans before, but without intervention they would both die. The mere possibility of the treatment being beneficial to the patients proved to be enough to tip the scales of

¹⁶⁰ [2002] EWHC 2734 (Fam.), [2003] Fam. 83, [2003] 2 WLR 1465, [2003] 1 All ER 669, [2003] 1 FLR 879, [2003] 1 FCR 361, (2004) 7 CCL Rep. 407, [2004] Lloyd’s Rep. Med. 236, (2003) 71 BMLR 61, [2003] Fam. Law 317, (2003) 153 NLJ 21.

¹⁶¹ *Re T (A Minor) (Wardship: Medical Treatment)* (1996) 35 BMLR 63, [1997] 1 WLR 242.

¹⁶² *Re Y (Adult Patient) (Transplant: Bone Marrow)* (1996) 35 BMLR 111, [1996] 2 FLR 787, [1997] Fam. 110.

¹⁶³ J Harrington, ‘Deciding best interests: medical progress, clinical judgment and the “good family”’, (2003) 3 *Web Journal of Current Legal Issues* 1, at p 7.

¹⁶⁴ vCJD, referred to as the human form of ‘mad cow disease’, or Bovine Spongiform Encephalopathy (BSE).

¹⁶⁵ This was a result of the disease, which involves the progressive impairment of neurological functioning.

¹⁶⁶ *Simms* was decided before the MCA 2005 came into force, and so one might consider that the process of decision-making and outcome of *Simms* might have been different if the case was decided post-MCA 2005, given the age of the patients and circumstances of the case.

best interests. It was held that treatment would be in their best interests in light of both the poor prognosis without treatment and the lack of viable alternatives.¹⁶⁷

The case of *Simms* is described as having taken “a broad view of best interests”.¹⁶⁸ In her discussion of best interests, Butler-Sloss P began by stating that she had to “assess the best interests in the widest possible way to include the medical and non-medical benefits and disadvantages, the broader welfare issues of the two patients, their abilities, their future with or without treatment, the views of the families, and the impact of refusal of the applications” and that all such matters had to be “weighed up and balanced in order for the court to come to a decision in the exercise of its discretion”.¹⁶⁹ She concluded discussion with greatest focus on the views of the parents and the impact of refusal of the application on the parents: “In a finely balanced case I should give the views of the parents and the effect upon them of refusal great weight in the wider considerations of the best interests test which the court has to apply to each patient”.¹⁷⁰ If such wider considerations result in a relational view of best interests, then it can be considered that, similarly, Butler – Sloss P took a relational view of best interests in the cases of *Re T (A Minor) (Wardship: Medical Treatment)*¹⁷¹ and *Re Y (Adult Patient) (Transplant: Bone Marrow)*¹⁷² by giving a certain level of importance to the views and wishes of family members with respect to what the family considered to be best for the individual patient, and the family’s determination of what was best for the individual patient was influenced by their mutually dependent relationships. In the former case, a mother opposed that her one-year old child be given a liver transplant and in the latter case, the removal of bone marrow from an incompetent patient was authorised for donation to her sister.¹⁷³ *Simms*, *Re T* and *Re Y* represent an elision of interests.¹⁷⁴ Harrington notes that this elision of interests can in fact be seen as realising the ethic of care as articulated by scholars like Gilligan.¹⁷⁵ This elision of interests might not be so clear for a court to take account of in a situation where the patient’s family is “indifferent

¹⁶⁷ A presentation about the treatment decision: D Body, Irwin Mitchell, ‘Re: Jonathan Simms (Treatment Decision) 2002 EWHC 2734 (Fam)’, 11 March 2009. A follow up study of the treatment established by the MRC in 2004 and finished in 2006: (2008) 15(5) *European Journal of Neurology* 458.

¹⁶⁸ J Harrington, ‘Deciding best interests: medical progress, clinical judgment and the “good family”’, (2003) 3 *Web Journal of Current Legal Issues* 1, at p 6. ‘Incompetent Patients, experimental Treatment and the ‘Bolam Test’: *J.S. v. An N.H.S. Trust*; *J.A. v. An N.H.S. Trust*, (2003) 11 *Medical Law Review* 237. Whilst not a case involving a child, *An NHS Trust v J* [2006] EWHC 3152 (Fam.), [2006] All ER (D) 73 (Dec.), a case in which the patient’s family opposed the administration of innovative therapy, raises difficult questions about how ‘best interests’ is interpreted: P Lewis, ‘Withdrawal of treatment from a patient in permanent vegetative state: judicial involvement and innovative “treatment”’, (2007) 15(3) *Medical Law Review* 392; L Skene, D Wilkinson, G Kahane, J Savulescu, ‘Neuroimaging and the withdrawal of life-sustaining treatment from patients in vegetative state’, (2009) 17(2) *Medical Law Review* 245.

¹⁶⁹ [2003] 1 All ER 669, at [60].

¹⁷⁰ *Ibid.*, at [64].

¹⁷¹ *Re T (A Minor) (Wardship: Medical Treatment)* (1996) 35 BMLR 63, [1997] 1 WLR 242.

¹⁷² *Re Y (Adult Patient) (Transplant: Bone Marrow)* (1996) 35 BMLR 111, [1996] 2 FLR 787, [1997] Fam. 110.

¹⁷³ S Elliston, *The Best Interests of the Child in Healthcare*. (Routledge-Cavendish, 2007) provides more detailed analysis of these cases and discussion about the best interests test.

¹⁷⁴ J Harrington, ‘Deciding best interests: medical progress, clinical judgment and the “good family”’, (2003) 3 *Web Journal of Current Legal Issues* 1, at p 7.

¹⁷⁵ *Ibid.*

or downright abusive” or where the patient is “more or less alone in the world” or “is enmeshed in a web of ‘non-standard’ relationships”,¹⁷⁶ but this should not take attention away from situations that do clearly merit a more relational approach to decision-making.

Case law demonstrates that caring networks and responsibilities cannot be disentangled from the central question of a child’s own interests. If we view decision-making about children through the lens of care theory, is there greater potential to effectively accommodate both sets of interests involved and strike a more appropriate balance between these sets of interests: (i) the interests of the individual child participant with the interests of the community of children, and (ii) the interests of the individual child participant with those in caring relationships with the child? I propose that a dual “interests” test would provide the basis for justification for cases of child participation in medical research and cases of experimental or innovative treatment: is the research or experimental and innovative treatment “not against the interests” of the individual child participant *and* “in the interests” of the community of children? If the answer to both is in the affirmative then the research or experimental and innovative treatment should be administered. The test would not enable the recruitment of children into medical research against their wishes. The test would provide the much-needed clarity of justification that is not found in the current best interest approach.

Conclusion

Many of the empirical studies that focus on motivations for paediatric research participation have been conducted in the US, and therefore more empirical studies should be conducted in the UK to inform and develop existing findings. Much more needs to be *said* and *learnt* about the institution of research and the responsibilities that individuals can have towards an institution of research because “[w]e must treat children with respect by bringing them up as members of families, of communities and of a society which values and upholds the rights and obligations of everyone, with the interests of children held in the highest esteem”.¹⁷⁷

A broader approach to decision-making, informed by theoretical principles grounded in care ethics, is needed to better appreciate the complexity of the decision-making process for research participation. If care ethics can help enhance our understanding and interpretation of parents’ motivations for their child’s participation in medical research, then it is important to consider how care ethics can inform and develop principles that underpin existing ethical and legal decision-making frameworks to facilitate and support the decision-making process for child participants, their parents, and healthcare professionals.

¹⁷⁶ Ibid.

¹⁷⁷ J Herring, ‘The Human Rights Act and the welfare principle in family law – conflicting or complementary?’ (1999) 11 *Child and Family Law Quarterly* 223, at p 234.

In looking at the ethical and legal guidance that regulates decision-making about child participation in medical research, all guidance essentially looks beyond the interests of the individual child participant in one way or another. The guidance *either* gives importance to the parents role in decision-making by requiring their consent (and so acknowledging that one must take account of the interests of those in caring relationships with the child who will be affected by any decision to participate in research in terms of caring for the child), *or* approves research which is not in the best interests of the child participant but is “not against the interests” of the child participant and will be “interests” of the community of children. Before reform to existing law can be considered, it is necessary to achieve greater consistency in the ethical and professional guidance that will inform the law, and to appropriately identify the conception of responsibility found in decision-making. If a dual interests test (“not against the interests” of the individual child participant *and* “in the interests” of the community of children) can provide the basis for justification for cases of medical research participation and the administration of experimental or innovative treatment then such a test should be incorporated in ethical and professional guidance. Whilst difficult cases about research participation will no doubt continue to pose distinctive, challenging and complex questions for decision-makers, the suitable incorporation of a dual interests test can provide the much-needed clarity of justification that is lacking in decision-making frameworks.